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

FOOD SAFETY ACTION PLAN

REPORT

2012-2014
TARGETED SURVEYS - CHEMISTRY

Deoxynivalenol in Selected Foods

RDIMS 5854831
Data tables RDIMS 5874628

Special Surveys
Chemical Evaluation
Food Safety Division
Canadian Food Inspection Agency
1400 Merivale Road
Ottawa Ontario Canada
K1A 0Y9

Table of Contents

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 examine various foods for specific hazards.

This targeted survey focused on a natural toxin, deoxynivalenol (DON), which can contaminate grains in the field. DON is not carcinogenic, but exposure to very high levels may cause gastrointestinal, immunosuppressive and developmental effects in various animal species. As DON is resistant to heat, finished foods may still contain detectable levels of DON despite being substantially processed.

The main objectives of this survey were to:

- establish baseline surveillance data for DON levels in infant formula, dried fruit, soy products, and grain-based products (wheat products, corn products, oat products, milled products of less commonly consumed grains, infant cereals, breakfast cereals, breads, baked goods and crackers); and
- compare the prevalence of DON in infant formula, dried fruit, and grain products found in 2012-2014 with the prevalence found in the previous CFIA DON targetded surveys, where possible.

A total of 3630 samples were analyzed for the presence of DON. These samples included 386 assorted foods (dried fruit and soy products), 543 infant foods (cereal and formula), 1284 milled grain products and 1417 processed grain-based products. Twenty-three percent of the samples tested for DON did not contain detectable levels. The samples with detectable levels of DON were from all types of products sampled in this survey. DON levels ranged from the method reporting limit of 1 part-per-billion (ppb) to a maximum of 4380 ppb. There are no Canadian maximum levels established for DON in finished products, so compliance to a numeric standard could not be evaluated.

All the data generated were shared with Health Canada's Bureau of Chemical Safety for use in performing human health risk assessments. Health Canada's Bureau of Chemical Safety concluded that, overall, the levels of DON found in the foods included in this survey were low and that short-term exposure to elevated levels of DON in the limited number of samples that were identified in this survey are not expected to pose a safety concern. No product recalls were warranted given the lack of 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 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 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 examine the presence and level of a particular hazard in specific foods.

Within the current regulatory framework, some commodities (such as meat products) traded internationally and interprovincially are regulated by 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 that 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.

In the most recent FSSC meeting, mycotoxins (including deoxynivalenol (DON)) were ranked as a high priority due to their potential to adversely affect human health. The

Canadian Grain Commission (CGC), which regulates grain handling in Canada, monitors domestically grown raw grains for DON. Health Canada, which has purview over foods sold in Canada, along with Agriculture and Agri-Food Canada, have conducted surveys of DON that generally focus on finished foods (such as breakfast cereals and beer). [1,2,3,4]. The monitoring of domestically produced or imported finished grain-based products (e.g. flour, bread, cookies) available at the Canadian retail level is limited. The current targeted survey was designed by the CFIA in consultation with federal and provincial partners to continue to build a baseline dataset to assess the exposure of Canadians to deoxynivalenol.

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 food products as outlined in the *Food and Drugs Act* and its associated regulations, including the *Food and Drug Regulations*.

Health Canada's Bureau of Chemical Safety (BCS) establishes the health-based maximum levels for chemical residues, contaminants, and toxins 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. There are also a number of maximum levels that do not appear in the regulations and are referred to as standards, which are available on Health Canada's website[5]. There are Canadian standards for DON in uncleaned soft wheat. However, these standards are considered to be outdated and no longer applicable, and are presently under review by Health Canada's BCS. There are no established Canadian maximum levels for DON in finished grain products (e.g. flour, bran, pasta, baked goods). In the absence of tolerances or MLs, all food products sold in Canada are still subject to Part 1, Section 4 of the *Food and Drugs Act*, which states, in part, that "no person shall sell an article of food that has in or on it any poisonous or harmful substance, is unfit for human consumption, or is adulterated."

In the absence of applicable regulations, elevated levels of DON (relative to previously observed levels) in specific foods are assessed by Health Canada's BCS on a case-by-case basis using the most current scientific data available. If the BCS identifies a potential safety concern, the Canadian Food Inspection Agency can undertake 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. DON

The global food supply has been naturally contaminated with various mycotoxins, toxic secondary metabolites of fungi, for centuries. These toxins are released by moulds which can grow on agricultural products, such as on cereals (e.g. wheat, oats, and corn), legumes, nuts and fruit. The type of agricultural product, insect damage, and the climatic conditions (temperature, humidity) during growth, processing, and storage are some factors that can influence the types and levels of mycotoxins present in the foods available at retail[6].

Research has shown that of the hundreds of mycotoxins associated with food, a small fraction has the potential to adversely affect human health and these are a global health concern. The Codex Alimentarius Commission[*] has published a Code of Practice to reduce and prevent mycotoxin contamination in cereals (e.g., wheat, corn, oats, and barley)[6]. This Code of Practice acknowledges that the complete elimination of mycotoxins from foods is not possible but provides guidance on ways to control and manage the mycotoxin levels at the farm level and after harvest (e.g. during processing, storage, and transport).

DON is a mycotoxin produced by various species of *Fusarium* mould in some crops prior to harvest. It is most commonly found in cereal grains (notably wheat, barley, and corn), and has been detected in their derived products (flours, meals, bran, grits (hominy), cereals, and beer)[7]. It is typically the result of grains suffering from Fusarium head blight (FHB) in the field. Wet, warm weather conditions in the field will favour the development of FHB, and subsequently the production of DON[5]. DON is heat-stable and is only partially destroyed under normal cooking or processing conditions[8].

DON is not known to be carcinogenic, but it has been shown to have acute and chronic effects. Outbreaks in Asia of acute human disease, involving nausea, vomiting, abdominal pain, headache and dizziness, have been attributed to the consumption of grains with high levels of DON[9]. In animal studies, long-term exposures to low levels of DON are associated with decreased food intake, weight loss, developmental effects and effects on the immune system[8,10].

2.2. Rationale

The CFIA does not routinely monitor for the presence of DON in finished foods. The CGC tests raw, domestically-grown cereal grains intended for export and those intended

[*] The Codex Alimentarius Commission is an international body established by the United Nations' Food and Agriculture Organization and the World Health Organization to develop harmonized international food standards, guidelines, and codes of practice to protect the health of the consumers and to ensure fair practices in the food trade.

for domestic use, for mycotoxins, pesticides, and certain metals, but does not have jurisdiction over finished or imported grain products. Mycotoxins, including DON, in grains and grain products have been periodically examined by Health Canada's BCS and through other CFIA activities. Health Canada's BCS and Agriculture and Agri-Food Canada have conducted surveys of DON in some ingredients (raw corn, wheat, barley, and oats) and finished food s (e.g. infant and breakfast cereal,s[1,2,3]. It was deemed appropriate to conduct a larger survey of finished foods (e.g. milled grain/flour/bran/meal of wheat, corn and oats, cookies, pasta) available in Canada over multiple years through the CFIA's FSAP project. The CFIA has previously performed FSAP targeted surveys (2009-2012) to investigate the levels of DON in a variety of food products[11,12,13]. This survey adds to baseline data on the levels of DON in domestic and imported soy products, dried fruit, infant formulas and cereal, milled grain products and processed grain products.

2.3. Sample Overview

A wide variety of foods available on the Canadian retail market were selected and tested. Both the types of products selected and the number of samples per product type depended on the availability of these products on the store shelves.

A total of 3630 samples were tested for DON. The 3630 samples were separated into four product categories; assorted foods, infant foods, milled grain products, and processed grain products. Assorted foods (386 samples) included dried fruits (e.g. figs, dates, raisins) and soy products (e.g. soy beverages, tofu, soybeans). Infant foods (543 samples) included infant formulas (dairy- and soy-based) and infant cereals. Milled grain products (1284 samples) included products derived from wheat, corn, oats, and "other" grains (e.g. quinoa, buckwheat). Specifically, milled grain products included products such as flour, bran, baking mixes, grains, germ, oatmeal, cornmeal etc. Processed grain products (1417 samples) included processed corn products (e.g. tortilla chips and taco shells), baked goods (e.g. cookies, donuts, cake), crackers, pasta (fresh, frozen, dry), bread products (e.g. loaves, bagels, English muffins) and breakfast foods (adult/children's breakfast cereals and breakfast baked goods such as waffles).

All foods were sampled between April 2012 and March 2014 at grocery and specialty stores in 11 Canadian cities. Of the 3630 samples tested for DON, 906 were domestic samples, 1590 were imported products, and 1134 samples were of unspecified origin. Unspecified refers to those samples for which the country of origin could not be assigned from the product label or available sample information. The samples originated in at least 44 countries, including Canada, with approximately 68% of the samples originating in either Canada or the United States. It is important to note that products often contained the statement "imported for Company A in Country Y" or "manufactured for Company B in Country Z". Although the labelling meets the intent of the regulatory standard, it does not specify the true origin of the product. Only those products labelled with a clear statement of "Product of Country A" were considered as being from a specific country of origin. See Table 1 for more details on the sample product types.

Table 1. Distribution of samples by product type and origin

Category	Product Type	Number of Domestic	Number of Imported	Number of Unspecified Origin	Total
Assorted Foods	Dried Fruit	5	75	18	98
	Soy Products	106	113	69	288
Infant Foods	Infant Formula	0	140	5	145
	Infant Cereal	136	257	5	398
Milled Grain Products	Milled Corn Products	5	114	32	151
	Baking Mixes	29	125	92	246
	Other Grain Products	84	127	62	273
	Wheat Products	152	73	75	300
	Oat Products	186	85	43	314
Processed Grain Products	Processed Corn Products	25	41	40	106
	Baked Goods	33	23	81	137
	Crackers	10	47	90	147
	Pasta	46	61	53	160
	Bread Products	57	18	193	268
	Breakfast Foods	32	291	276	599
Grand Total		**906**	**1590**	**1134**	**3630**

2.4. Analytical Methods

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

Samples were tested as sold, meaning that the product was not prepared as per the package instructions (if applicable). The analytical method used for DON is a single-analyte liquid chromatography-tandem mass spectrometry (LC-MS-MS) based on the method used by CFIA. The method reporting limit for DON was 1 ppb for all matrices.

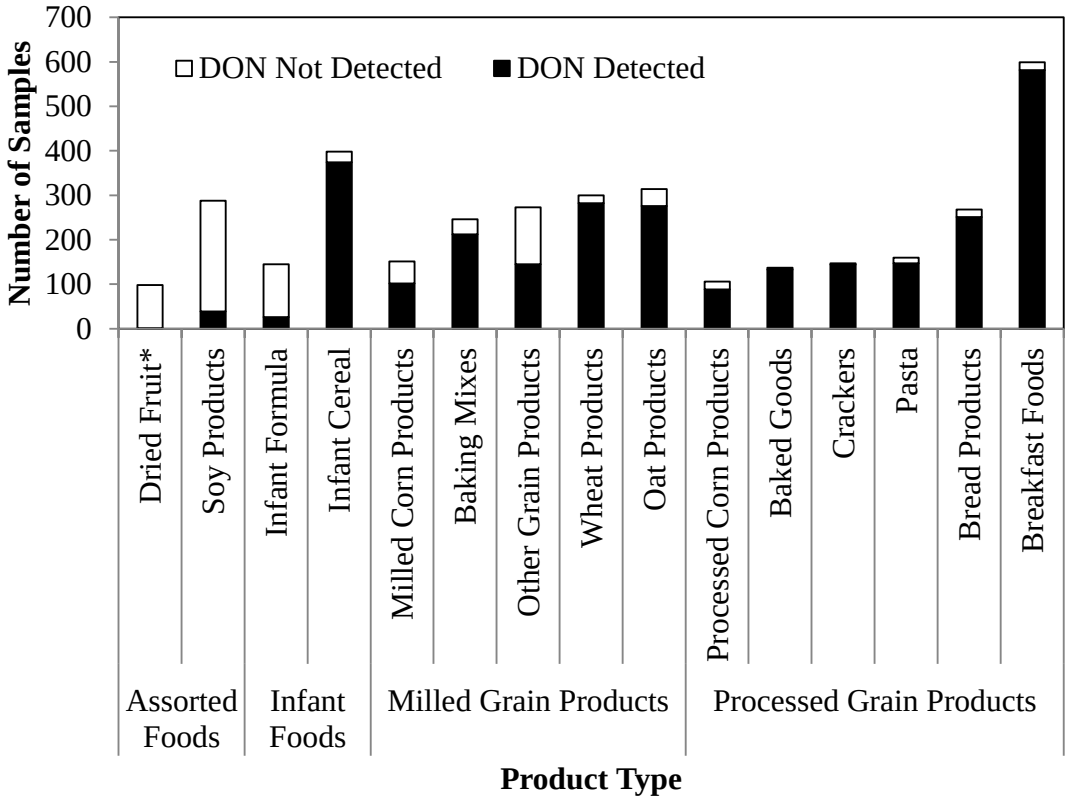
2.5. Limitations

This survey was designed to provide a snapshot of the prevalence and levels of 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 3630 is small. Therefore, care should be taken in the interpretation or extrapolation of the results. Given that the product label may not clearly identify the actual origin of the products or their ingredients, no distinct comparison or conclusions could be made regarding the country of origin and the levels of DON in products.

3. Results and Discussion

3.1 Overview of DON Results

All product categories and product types had samples with a detectable level of DON. The percentage of samples with detectable levels of DON per product type ranged from 1% in dried fruit to 98% in crackers. Figure 1 shows the number of samples analyzed for DON by product type. Of the 3630 samples surveyed, 2801 (77%) had detectable levels of DON. The prevalence of samples with detectable levels of DON varied by product type; assorted foods had the lowest prevalence (10% of samples had detectable levels) and processed grain products had the highest prevalence (95% of samples had detectable levels).



Dried Fruit* = one sample contained a detectable level of DON

Figure 1: Number of samples analyzed for DON by product type (in order of increasing number of samples per category)

For the samples which contained a detectable concentration, the levels of DON ranged from the method reporting limit of 1 ppb to a maximum of 4380 ppb. Assorted foods and infant foods were associated with the lowest average DON levels whereas milled grain products and processed grain products had higher average levels. Figure 2 shows the

average levels of DON by product type. Note that the average DON levels discussed throughout this report were calculated as the mean of the positive detects only.

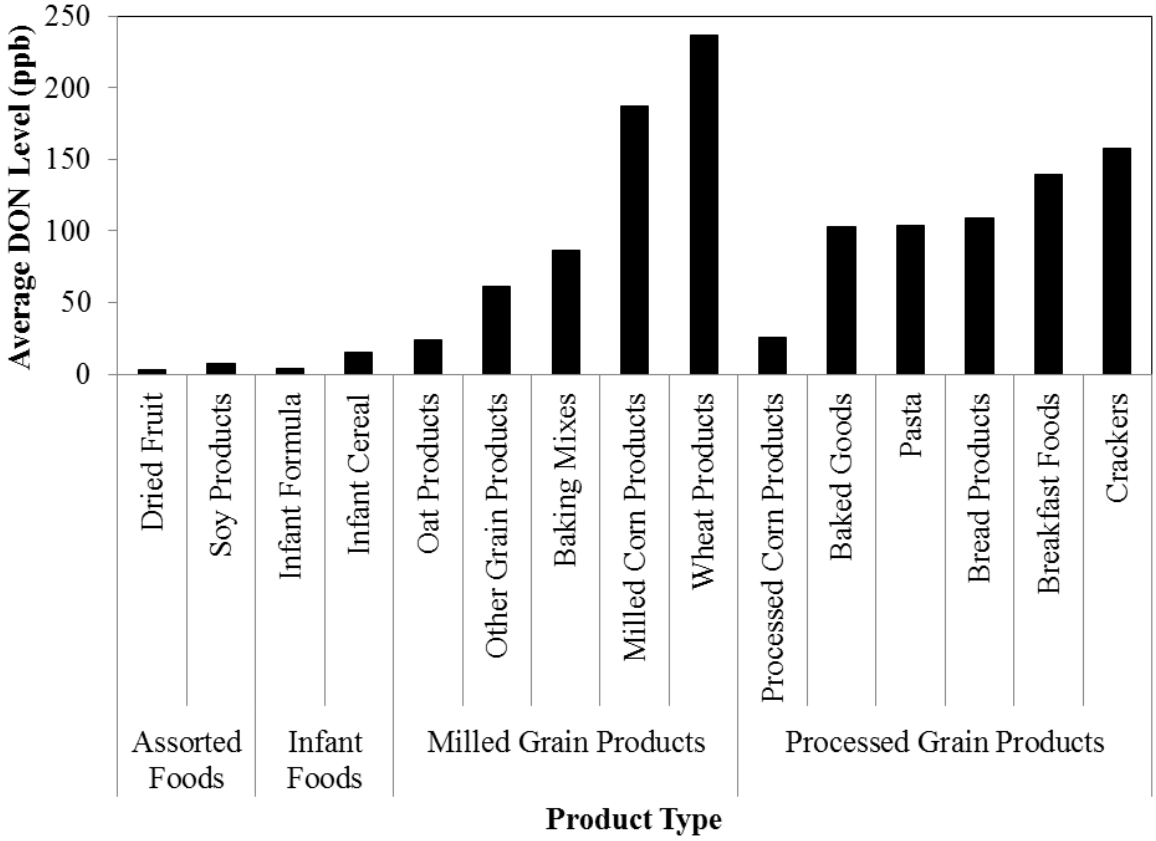
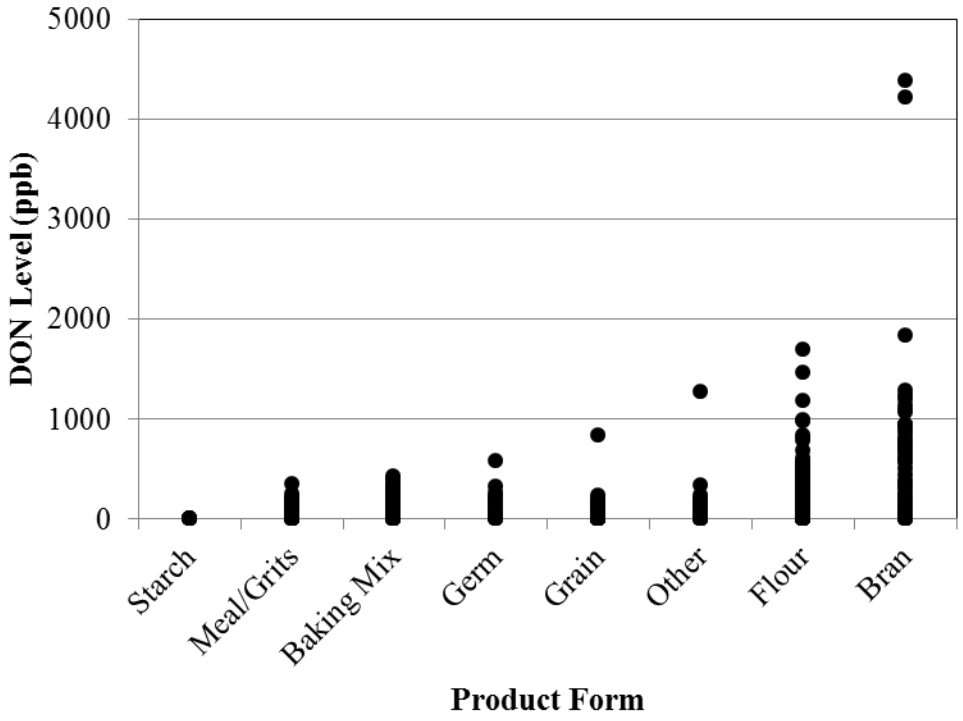


Figure 2: Average DON levels by product type

The levels of DON detected in milled grain products and processed grain products varied by grain type. In general, wheat-based products had the highest average levels of DON whereas oat and other grain products (e.g. rice, millet, quinoa) were associated with the lowest average DON levels. Furthermore, milled grain products had higher average levels of DON in comparison to processed grain products. This is expected, as processed grain products typically consisted of many ingredients, where the primary grain ingredient is diluted, therefore leading to decreased levels of DON in the product.

Milled grain products were associated with the highest average DON levels for the current survey. The detected levels of DON in milled grain products varied by the product form (e.g. bran, flour, starch). Figure 3 illustrates the distribution of DON levels in milled grain products by product form. Products of bran and flour (e.g. corn bran) had the highest detected levels of DON whereas starches (e.g. corn starch) had the lowest levels.



Note: only values above the limit of detection are shown. "Other" refers to cream of wheat, buckwheat, millet, spelt and couscous products.

Figure 3: Distribution of DON levels in milled grain products by product from (in order of increasing maximum DON level)

There are currently no Canadian maximum levels for DON in finished products so comparison to a numeric standard could not be evaluated. The results of the entire dataset were forwarded to Health Canada's Bureau of Chemical Safety for evaluation. Health Canada's Bureau of Chemical Safety concluded that the levels of DON reported in this survey were low overall and not expected to pose a health concern.

The following sections present the analytical results for DON by product type, with the current survey data bolded and italicized in tables. Where possible, the results of the current survey are compared to the previous targeted surveys on DON[11,12,13], to Health Canada (HC) surveys of infant cereal[1] and breakfast cereal[2], to a CFIA and Agriculture and Agri-Food Canada (AAFC) survey of cereal grain[3], and to a European Food Safety Authority (EFSA) scientific report on DON in food[7].

The averages reported in this targeted survey were calculated as the mean of positive detects only (i.e. values less than the reporting limit were excluded). This is also the case for the HC and CFIA/AAFC reference data[1,2,3]. For the European Food Safety Authority (EFSA) survey, sample results less than the limit of quantitation (LOQ) were set to the LOQ and included in the calculation of the average[7]. Additionally, the EFSA data was collected over approximately a 5 year span, with varying LODs and LOQs by region and

year (median LOQ ranged from 30-50 ppb). For these reasons, care must be taken when extrapolating the comparisons between FSAP and EFSA average DON levels.

3.2 DON Results by Product Type

3.2.1 DON in Assorted Foods

The assorted foods category consisted of samples of dried fruit and soy products. In general, the positive rates and concentrations of DON in assorted foods were very low for all product types.

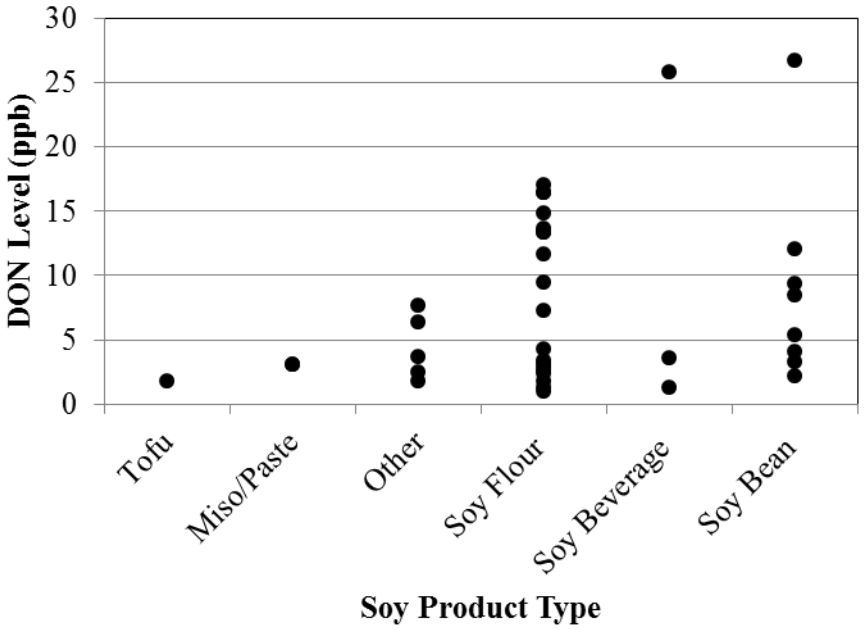
Dried Fruit

A total of 98 dried fruit samples were tested, including apricots, currant, dates, figs and raisins. A single sample of dried fruit (a candied date sample) contained a detectable level (2.8 ppb) of DON.

Dried fruit samples were included in previous DON Surveys (105 samples in 2011-2012 and 97 samples in 2010-2011), with no samples having detectable levels of DON[12,13]. The low prevalence and concentrations of DON in dried fruit products are consistent across all years of targeted surveys. The percentage of samples with detectable DON and the observed DON level is lower in this targeted survey than in a 2013 EFSA survey of DON which included 25 samples of dried fruit, with an average DON concentration of 24 ppb[7].

Soy Products

Soy products (288 samples) consisted of soy beverages, soy beans (fresh, canned, frozen, dried), soy flour, tofu and miso and 86% (249 samples) of the samples did not contain detectable levels of DON. Of the 39 samples (14%) which contained measurable levels of DON, the concentrations ranged from 1.0 ppb to 26.7 ppb. As illustrated in Figure 4, the levels of DON in soy products varied by product type. Here, "Other" includes tempeh, bacon and protein. The lowest levels of DON were detected in paste and tofu whereas beverages and beans had the highest levels.



Note: Only values above the limit of detection are shown

Figure 4: Distribution of DON levels in soy products by product type (in order of increasing maximum)

Table 2 summarizes the current and previous targeted survey data for DON in soy products. In comparison to the previous 2011-2012 targeted survey, soy products have a maximum DON concentration in the current year is 1.5 times higher than the previous year but a very comparable average.

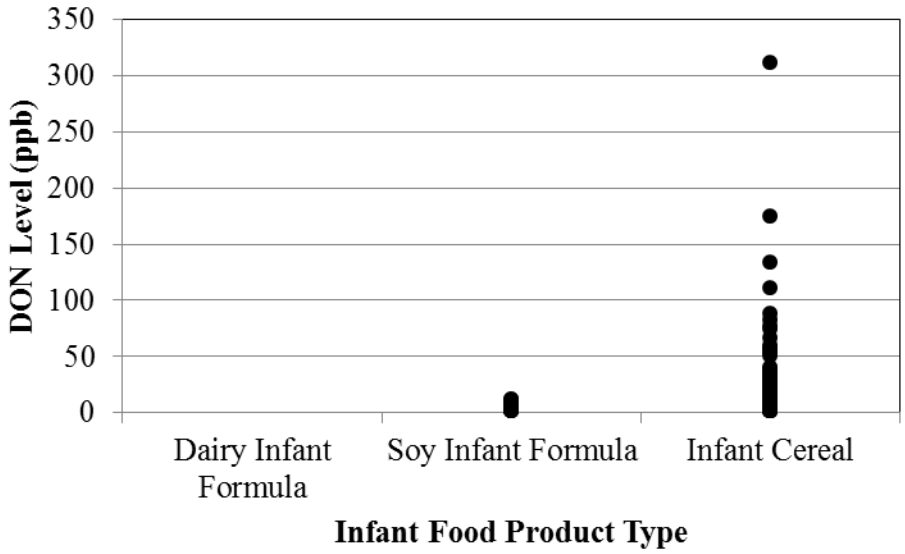
Table 2: Summary of targeted survey data on DON levels in soy products

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum (ppb)	Maximum (ppb)	Average* (ppb)
Soy Products						
CFIA[13]	***2012-2014***	***288***	***39 (14)***	***1.0***	***26.7***	***7.7***
	2011-2012	198	32 (16)	1.1	18.2	8.0

*Average of positive results only

3.2.2 DON in Infant Foods

The infant food category included samples of infant formula (both dairy- and soy-based) and infant cereal. Infant formula products were in the form of powders, concentrated liquids and ready-to-serve liquids. The distribution of DON levels in infant foods is shown in Figure 5.



Note: Only values above the limit of detection are shown

Figure 5: Distribution of DON levels in infant foods by product type (in order of increasing maximum)

Infant Formula

A total of 50 dairy- and 95 soy-based infant formula samples were tested for DON in the current survey. No samples of dairy based infant formula contained detectable levels of DON. This is consistent with the low positive rates and concentrations of DON witnessed in dairy based formulas in previous targeted survey years (see Table 3).

Table 3: Summary of targeted survey data on DON levels in infant formula

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum (ppb)	Maximum (ppb)	Average* (ppb)
Infant Formula - Dairy						
CFIA[12,13]	***2012-2014***	***50***	***0 (0)***	-	-	-
	2011-2012	93	2 (2)	1.0	1.4	1.2
	2010-2011	91	3 (3)	1.1	2.5	1.8
Infant Formula - Soy						
CFIA[12,13]	***2012-2014***	***95***	***26 (27)***	***1.1***	***11.9***	***4.3***
	2011-2012	5	2 (40)	1.3	1.4	1.4
	2010-2011	7	1 (14)	1.5	1.5	-

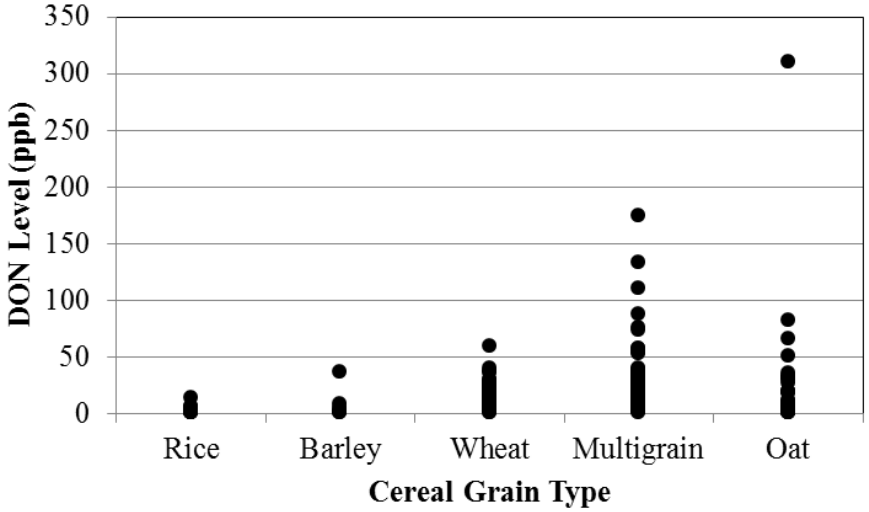
*Average of positive results only

Of the 95 soy-based infant formulas tested, detectable levels were found in 26 samples (27%) which were all powdered products. These samples require the addition of water before consumption (as per the manufacturer's instructions). After accounting for dilution of powdered soy-based infant formulas, the levels of DON in the reconstituted formulas

would be approximately seven to eight times lower. In comparison to the 2011-2012 survey, the current survey has higher maximum and average concentrations of DON but a lower positive rate. A 2013 EFSA survey which included infant formula (only powdered samples) had an average DON concentration of 25.3 ppb, which is higher than the averages observed in the current and previous surveys[7].

Infant Cereal

Infant cereals included single and multigrain varieties (e.g. oat, wheat, barely) as well as products containing dried fruit. Of the 398 samples, 374 (94%) tested positive for DON, with levels ranging from 1.1 ppb to 311 ppb. As illustrated in Figure 6, the concentrations of DON in infant cereals varied by grain type. The lowest average levels of DON were detected in rice cereals whereas multigrain and oat cereals had the highest average levels.



Note: Only values above the limit of detection are shown

Figure 6: Distribution of DON levels in infant cereals by grain type (in order of increasing maximum)

Table 4 summarizes the current and previous survey data for DON in infant cereal. The current survey year has a higher maximum detected value than the previous surveys but with a very comparable average DON level.

Table 4: Summary of FSAP data on DON levels in infant cereal

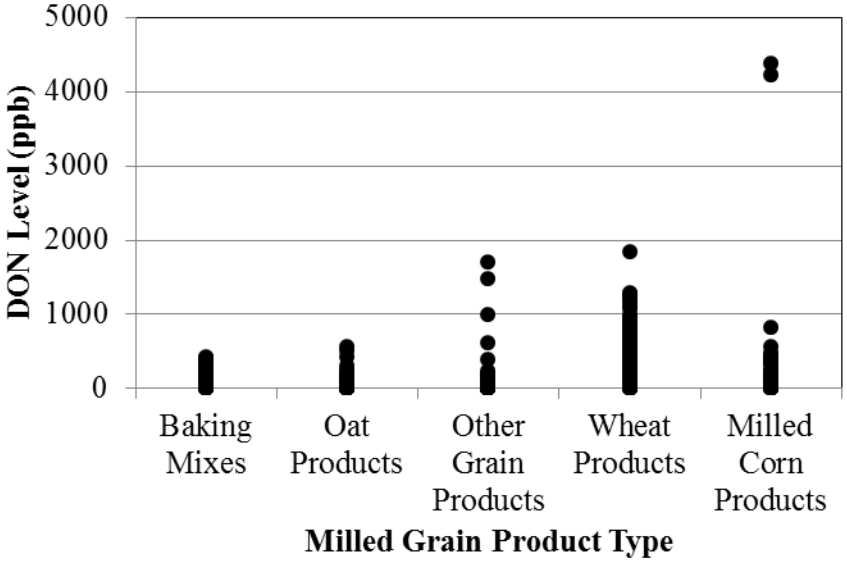
Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum (ppb)	Maximum (ppb)	Average* (ppb)
Infant Cereal						
CFIA[12,13]	***2012-2014***	***398***	***374 (94)***	***1.1***	***311***	***15.7***
	2011-2012	59	49 (83)	1.3	255	21.9
	2010-2011	93	76 (82)	1.1	128	12.1

*Average of positive results only

Health Canada has also investigated the levels of DON in infant cereal over the course of a three year survey[1]. The HC survey included 124 samples of oat, barley and multigrain cereals, with an average DON level of 132 ppb. All years of CFIA targeted surveys have average DON levels considerably lower than the HC value. Note that the LOQ for the HC study was 20 ppb, potentially accounting for the higher average DON level in comparison to the targeted survey data. Additionally, a 2013 EFSA survey sampled 532 infant cereals with an average DON concentration of 39.2 ppb, higher than both the current and previous surveys[7]. The reason(s) for the higher reported DON concentrations in the EFSA survey are not currently known.

3.2.3 DON in Milled Grain Products

The milled grain products category included dry baking mixes as well as a variety of products (e.g. bran, flour, whole grain, starch) of corn, oat, other grains (e.g. buckwheat, quinoa) and wheat. The lowest average concentration of DON was found in oat products (23.8 ppb) and the highest average concentration was in wheat products (237 ppb). The distribution of DON levels in milled grain products is shown in Figure 7.



Note: Only values above the limit of detection are shown

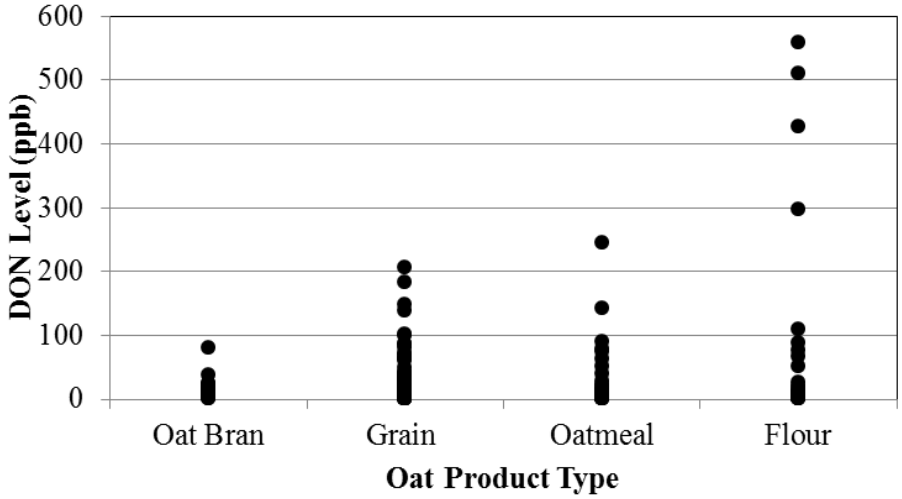
Figure 7: Distribution of DON levels in milled grain products by product type (in order of increasing maximum DON concentration)

Baking Mixes

The baking mixes category included packaged mixes for a variety of baked goods such as cakes, pancakes, brownies and pastries. Of the 246 samples, 212 (86%) tested positive for DON, with concentrations ranging from 1.3 ppb to 426 ppb. The average DON concentration in baking mixes was 86.9 ppb. No baking mixes were sampled in previous surveys for DON.

Oat Products

The oat products category included oat bran, oat flour, oat grain and oatmeal. Of the 314 samples, 276 (88%) found to contain DON, and levels ranged from 1.0 ppb to 558 ppb. The levels of DON in oat products varied by product type; with oat bran having the lowest concentrations and oat flour having the highest (see Figure 8).



Note: Only values above the limit of detection are shown

Figure 8: Distribution of DON levels in oat products by product type (in order of increasing maximum)

Table 5 summarizes the current and previous targeted survey data regarding DON levels in oat products. In comparison to previous survey years, the current data has a higher maximum concentration of DON but the lowest overall average (23.8 ppb). Note that the 2009-2010 survey reporting limit was 10 ppb, influencing the rate of detection, and minimum and average DON levels.

The EFSA also investigated DON levels in oat grain and oat products (e.g. bran, flour), reporting average concentrations of 214.6 ppb in oat grain and 73.4 ppb in oat products[7]. For comparison purposes, the average DON levels in oat grain and oat products (oat bran, oatmeal, flour) for the current survey were 17.2 ppb and 32.9 ppb, respectively. The EFSA average DON concentrations are higher than the targeted survey data for milled oat products. Note that the EFSA mean LOQ was 30-50 ppb

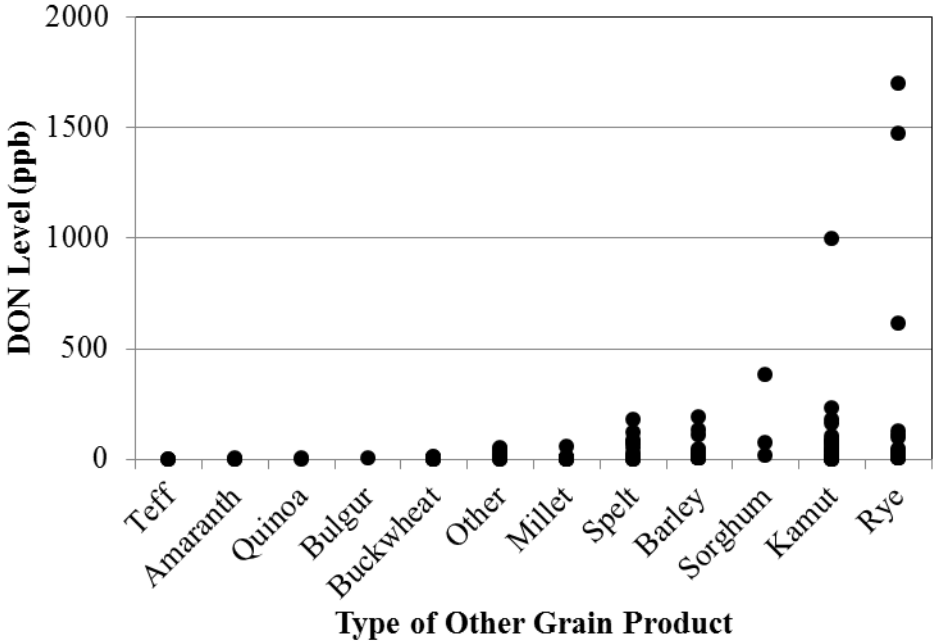
Table 5: Summary of targeted survey data on DON levels in oat products

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum (ppb)	Maximum (ppb)	Average* (ppb)
Oat Products						
CFIA[11,12,13]	***2012-2014***	***314***	***276 (88)***	***1.0***	***558***	***23.8***
	2011-2012	31	30 (97)	1.0	244	33.3
	2010-2011	17	16 (94)	1.8	192	41.0
	2009-2010**	25	7 (28)	20	130	50.0

*Average of positive results only
** The 2009-2010 reporting limit was 10 ppb

Other Grain Products

The other grain products category included products made from rye, kamut, sorghum, millet, quinoa, buckwheat, barley etc. Of the 273 samples, 145 (53%) were found to contain levels of DON, between 1.0 ppb to 1700 ppb. Figure 9 illustrates the distribution of DON levels by product type. Rye products, specifically rye flour, had the highest levels of DON with an average concentration of 317 ppb.



Note: Only values above the limit of detection are shown. "Other" includes rice, graham and triticale products

Figure 9: Distribution of DON levels in other grain products by product type (in order of increasing maximum)

Table 6 summarizes the current and previous targeted data on DON levels in other grain products. In comparison to the previous survey, the current data for DON in other grain products has a higher positive rate and maximum concentration but with a very similar average.

The EFSA also investigated DON levels in other grain products, reporting an average DON concentration of 62.4 ppb[7]. The EFSA "other grain" category included buckwheat, millet, rice, spelt, amaranth and barley products. The EFSA average for other grain products agrees well with the current and previous targeted survey data.

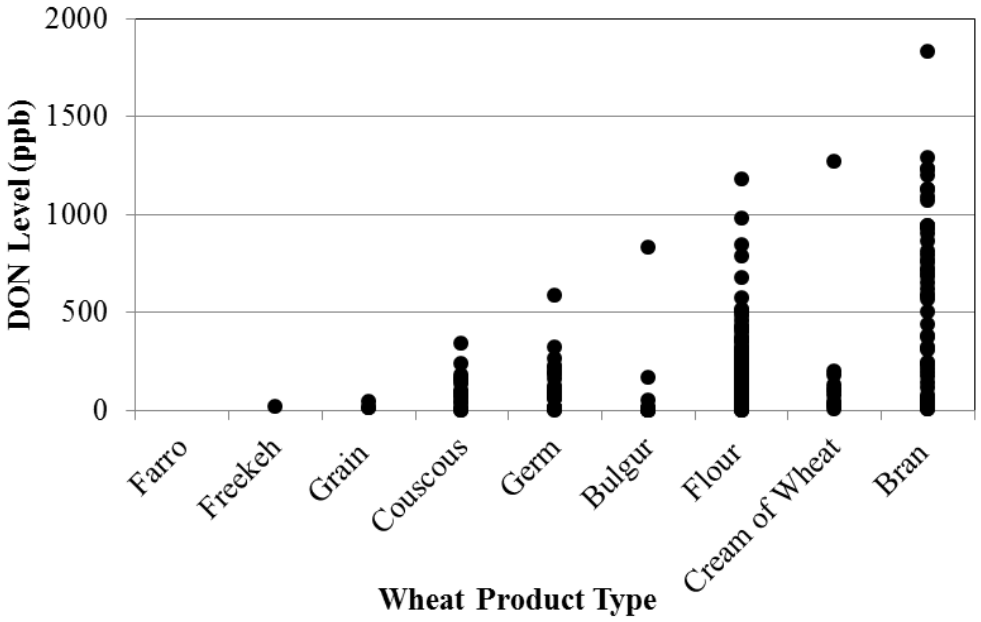
Table 6: Summary of targeted survey data on DON levels in other grain products

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum (ppb)	Maximum (ppb)	Average* (ppb)
Other Grain Products						
CFIA[13]	***2012-2014***	***273***	***145 (53)***	***1.0***	***1700***	***61.2***
	2011-2012	128	62 (48)	1.2	484	60.6

*Average of positive results only

Wheat Products

Wheat products included farro, freekeh (green wheat), wheat grain, couscous, wheat germ, bulgur, wheat flour, cream of wheat and wheat bran. In this survey, 282 of the 300 samples (94%) contained detectable levels of DON. The distribution of DON in wheat products is shown in Figure 10. No samples of farro products tested positive for DON. Wheat bran samples had the highest maximum (1830 ppb) and average (237 ppb) DON levels of the milled wheat products.



Note: Only values above the limit of detection are shown

Figure 10: Distribution of DON levels in milled wheat products by product type (in order of increasing maximum)

Table 7 summarizes the current and previous targeted survey data on DON levels in wheat products. The maximum and average DON concentrations for wheat products for the current survey fit well within the range of values from the previous three survey years. Note that the reporting limit for the 2009-2010 survey was 10 ppb, influencing the positive rate, minimum and average DON levels for that year.

Table 7: Summary of targeted survey data on DON levels in wheat products

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum (ppb)	Maximum (ppb)	Average* (ppb)
Wheat Products						
CFIA[11,12,13]	***2012-2014***	***300***	***282 (94)***	***1.1***	***1830***	***237.0***
	2011-2012	102	100 (98)	1.3	1380	210.4
	2010-2011	96	96 (100)	1.2	1500	165.0
	2009-2010**	75	46 (61)	10	6010	300

*Average of positive results only
** The 2009-2010 reporting limit was 10 ppb

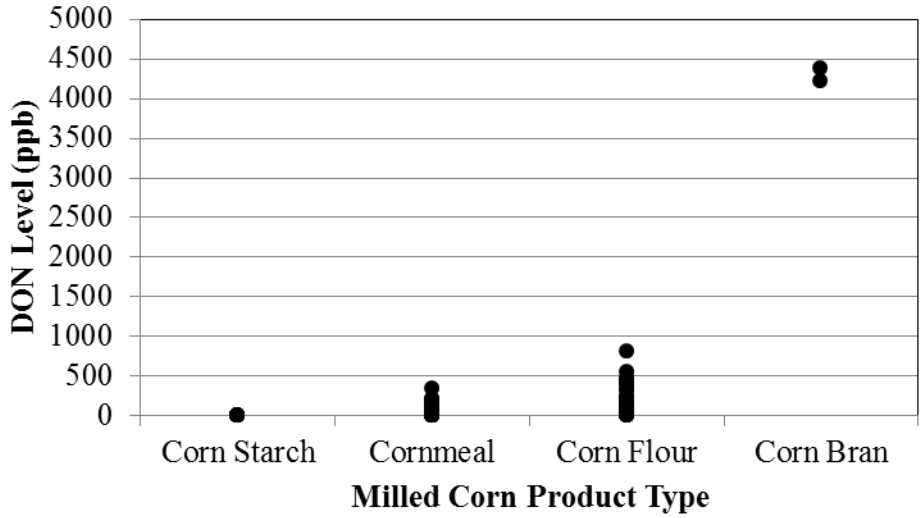
The CFIA, along with Agriculture and Agri-Food Canada, have investigated the levels of DON in wheat grain as part of a multi-year survey, with samples collected from Eastern Canada between 1991-1998[3]. The average DON level in wheat grain from this survey was 1500 ppb, considerably higher than the current survey average for DON in wheat grain (23 ppb for wheat grain only). Note that the CFIA/AAFC survey LOQ was 100

ppb, therefore a higher average DON level is expected in comparison to the targeted survey data. Also, the wheat samples in question were collected from a variety of locations, including directly from farms, feed mills and grain elevators, which would have likely included uncleaned and/or unsorted samples of wheat.

The EFSA has also investigated the levels of DON in wheat, with average DON concentrations in wheat grain of 164.8 ppb and 128 ppb in milled wheat products[7]. The EFSA average for wheat grain is higher than the current survey average (23 ppb); however, the EFSA average for milled wheat products is lower than the current survey average (239 ppb for wheat products other than wheat grain).

Milled Corn Products

Milled corn products included corn starch, cornmeal, corn flour and corn bran. Levels of DON ranged from 1.1 ppb to 4380 ppb in 102 of the 151 samples (68%) tested as part of this survey. The distribution of DON levels in milled corn products varied significantly by product type (see Figure 11). Corn bran samples had considerably higher levels of DON in comparison to starch, cornmeal and flour products.



Note: Only values above the limit of detection are shown

Figure 11: Distribution of DON levels in milled corn products by product type (in order of increasing maximum)

Table 8 summarizes the current and previous targeted survey data on DON levels in milled corn products. In comparison to the previous survey, the current data for DON in corn products has higher maximum levels. Note that the previous targeted survey did not include samples of corn bran. For comparison purposes, exclusion of the two corn bran samples from the current data would lead to an average DON concentration of 105 ppb.

A 2013 EFSA survey included 382 samples of milled corn products (e.g. flour, meal, starch) with a reported average of 149.3 ppb[7]. This average is lower than both the current

and previous targeted surveys. Note that the EFSA survey did not include corn bran samples.

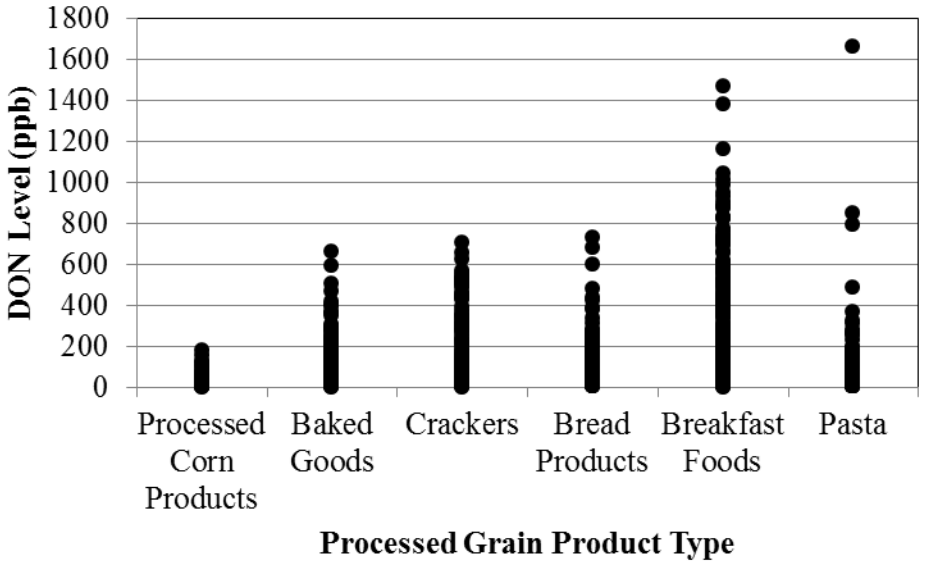
Table 8: Summary of targeted survey data on DON levels in milled corn products

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum (ppb)	Maximum (ppb)	Average* (ppb)
Milled Corn Products						
CFIA[13]	***2012-2014***	***151***	***102 (68)***	***1.1***	***4380***	***187.2***
	2011-2012	73	63 (86)	1.5	2460	175.2

*Average of positive results only

3.2.4 DON in Processed Grain Products

The processed grain products category included samples of processed corn products (corn chips/tortilla chips and taco shells), baked goods (e.g. pastries, muffins), crackers, bread products (e.g. loaves, bagels, English muffins), breakfast foods (cereal and baked goods), and pasta (fresh, frozen, dry). The lowest average concentration of DON was found in processed corn products (26.0 ppb) and the highest average concentration was in crackers (158 ppb). The distribution of DON levels in processed grain products is shown in Figure 12.

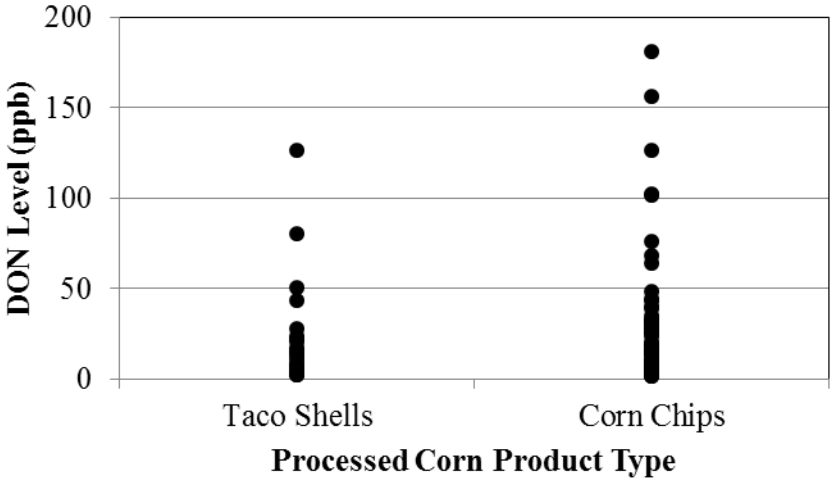


Note: Only values above the limit of detection are shown

Figure 12: Distribution of DON levels in processed grain products by product type (in order of increasing maximum)

Processed Corn Products

This category included 84 samples of corn chips/tortilla chips and 22 taco shell samples. Of the 106 samples, 88 (83%) were found to contain DON, with levels ranging from 1.0 ppb to 181 ppb. Corn chips and taco shells had very similar distributions of DON, with corn chips having slightly higher levels (see Figure 13).



Note: Only values above the limit of detection are shown

Figure 13: Distribution of DON levels in processed corn products (in order of increasing maximum)

Table 9 summarizes the current and previous targeted survey data on DON levels in processed corn products. In comparison to the previous survey, the current data for DON in processed corn products has much lower maximum and average concentrations, the reason for which is unknown.

The 2013 EFSA survey included 37 samples of processed corn products (e.g. corn chips, tortillas) with a reported average of 207.3 ppb[7]. This average is higher than the average determined from the data obtained in both CFIA surveys for DON in processed corn products.

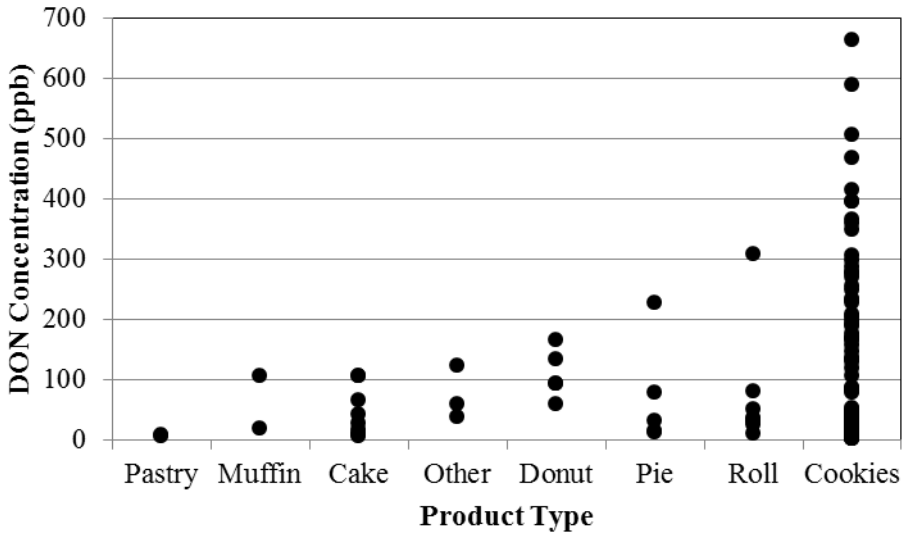
Table 9: Summary of targeted survey data on DON levels in processed corn products

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum (ppb)	Maximum (ppb)	Average* (ppb)
Processed Corn Products						
CFIA[12]	***2012-2014***	***106***	***88 (83)***	***1.0***	***181***	26.1
	2010-2011	59	55 (93)	1.0	1440	116.5

*Average of positive results only

Baked Goods

The baked goods category included samples of pastry, muffins, cake, other (brownies, tarts), donuts, pies, rolls and cookies. DON was detected at levels of 1.2 ppb to 662 ppb in 133 of the 137 samples (97%). The levels of DON in baked goods varied considerably by product type, with cookies having the highest concentrations of DON (see Figure 14).



Note: Only values above the limit of detection are shown

Figure 14: Distribution of DON levels in baked goods (in order of increasing maximum)

Table 10 summarizes the current and previous targeted survey data on DON levels in baked goods. In comparison to the previous survey data on DON in baked goods, the current year has a higher maximum detected value and a higher average. Note that the current survey year had a larger sample size and sampled more cookie samples than the previous 2011-2012 survey.

A 2013 EFSA survey included 214 samples of baked goods (e.g. pastries, cakes) with a reported average of 97.2 ppb[7]. This value falls within the range of averages reported in the current and previous surveys.

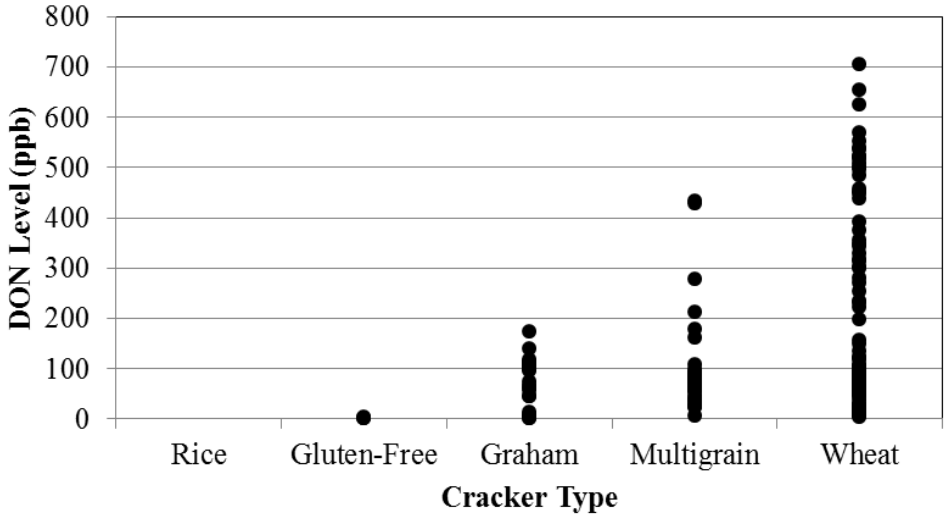
Table 10: Summary of targeted survey data on DON levels in baked goods

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum (ppb)	Maximum (ppb)	Average* (ppb)
Baked Goods						
CFIA[13]	***2012-2014***	***137***	***133 (97)***	***1.2***	***662***	***103.0***
	2011-2012	19	17 (89)	3.3	205	52.8

*Average of positive results only

Crackers

In this survey, 147 samples crackers (including rice, gluten-free, graham, multigrain, and wheat crackers) were analysed for DON. Levels of DON between 1.2 ppb to 705 ppb were found in 144 (98%) of the samples. The distribution of DON in crackers by product type is shown in Figure 15. Wheat crackers had the highest DON levels, with an average of 211 ppb.



Note: Only values above the limit of detection are shown

Figure 15: Distribution of DON levels in crackers by product type (in order of increasing maximum)

Table 11 summarizes the current and previous targeted survey data in crackers. In comparison to the previous survey data, the current year has a higher maximum value but a lower average DON level. Crackers had high positive rates for DON in both the current and previous surveys.

Table 11: Summary of targeted survey data on DON levels in baked goods

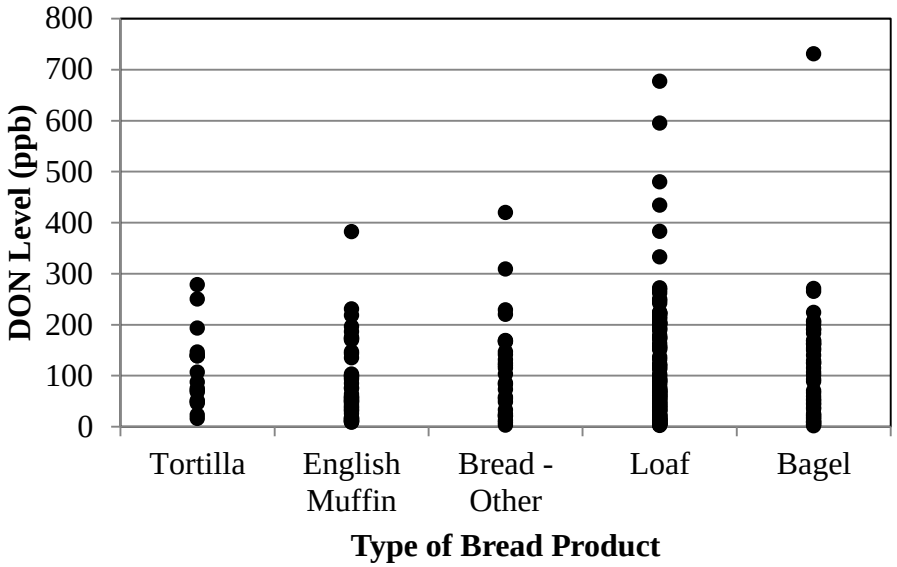
Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum (ppb)	Maximum (ppb)	Average* (ppb)
Crackers						
CFIA[13]	***2012-2014***	***147***	***144 (98)***	***1.2***	***705***	***157.7***
	2011-2012	10	10 (100)	6.3	542	173.7

*Average of positive results only

Bread Products

The bread products category included samples of tortilla wraps, English muffins, other bread products (e.g. naan bread, hot dog buns, pita bread), loaves of bread, and bagels. Of the 267 samples, 251 (94%) had detectable concentrations of DON, with levels that

ranged from 1.6 ppb to 731 ppb. Overall, DON levels in different bread types were fairly consistent. Figure 16 shows the distribution of DON levels in bread products by product type.



Note: Only values above the limit of detection are shown

Figure 16: Distribution of DON levels in bread products (in order of increasing maximum)

Table 12 summarizes the current and previous targeted survey data on DON levels in bread products. In comparison to the previous survey data, the current year has a higher maximum value but a lower average DON level. The positive rates for DON are very consistent between survey years.

A 2013 EFSA survey included 3238 samples of bread products and rolls, including all grain types (e.g. multigrain, whole wheat, white, rye), with an average DON level of 79.8 ppb[7]. Note that the EFSA survey included many samples of "unspecified" bread product type. The EFSA value is comparable to the targeted survey data when considering disparity in product types, sample size, and calculation parameters.

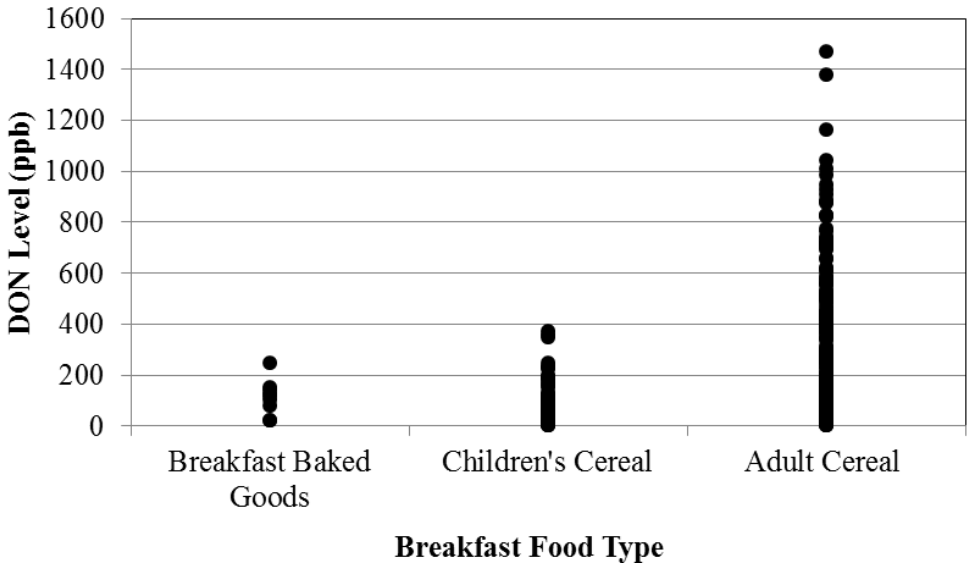
Table 12: Summary of targeted survey data on DON levels in bread products

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum (ppb)	Maximum (ppb)	Average* (ppb)
Bread Products						
CFIA[13]	***2012-2014***	***267***	***251 (94)***	***1.6***	***731***	***109.1***
	2011-2012	164	153 (93)	1.3	473	138.3

*Average of positive results only

Breakfast Foods

Breakfast foods included 387 samples of adult cereal, 201 children's cereal and 11 breakfast baked goods (e.g. waffles, pastries). Ninety-seven percent of cereal samples and 91% of baked goods were found to contain DON. The distribution of DON levels in breakfast foods is shown in Figure 17. Of the breakfast foods tested, samples of adult cereal were associated with the highest maximum and average levels of DON.



Note: Only values above the limit of detection are shown

Figure 17: Distribution of DON levels in breakfast foods (in order of increasing maximum)

The prevalence, minimum, maximum and average levels of DON in breakfast foods are summarized in Table 13. The prevalence of DON in breakfast cereals is consistent across the three targeted surveys. The maximum and average DON levels in breakfast cereals for the current year fit well within the range of previously reported values.

Table 13: Summary of targeted survey data on DON levels in baked goods

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum (ppb)	Maximum (ppb)	Average* (ppb)
Breakfast Baked Goods						
CFIA	***2012-2014***	***11***	***10 (90)***	***18.1***	***244***	***114.5***
Breakfast Cereal						
CFIA[12,13]	***2012-2014***	***588***	***571 (97)***	***1.0***	***1470***	***139.6***
	2011-2012	255	240 (94)	1.0	397	87.7
	2010-2011	197	190 (96)	1.2	2060	156.4

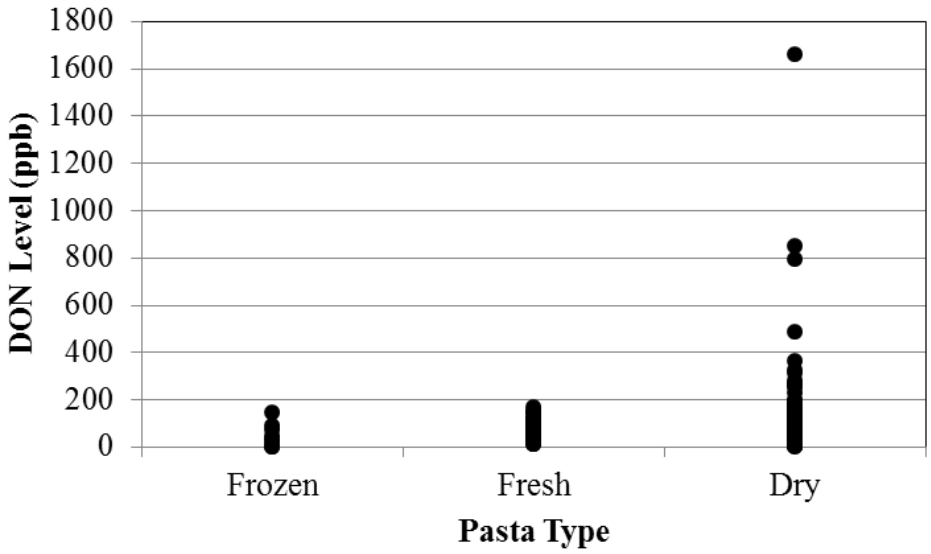
*Average of positive results only

Health Canada has investigated the levels of DON in breakfast cereals (corn, multigrain, oat, rice, wheat) as part of a 3 year survey[2]. The average DON level in breakfast cereals from the HC survey was 104 ppb, which is comparable to the targeted survey average values. A 2013 EFSA survey on DON included 1511 samples of breakfast cereals including cereal flakes, mixed cereal, hot cereal (porridge, grits), and "unspecified" cereals. The EFSA reported average DON level in cereal was 81.8 ppb[7]. The EFSA average is lower, however comparable to the targeted survey data when considering disparity in product types, sample size, and calculation parameters.

The levels of DON in breakfast cereals also varied by grain type; wheat and multigrain cereals had the highest average DON levels whereas rice and oat based cereals had lower average levels. Products containing brans (e.g. wheat bran, corn bran) were associated with the highest average DON levels of the cereal types.

Pasta

The range of pasta products sampled in this survey included fresh, dry and frozen samples of spaghetti, lasagna, linguine, penne etc. The distribution of DON levels is shown in Figure 18. Levels from 1.2 ppb to 1660 ppb were found in 147 of the 160 pasta samples (92%) tested. Frozen and fresh pasta samples had lower and consistent levels of DON in comparison to dry pasta. Dry pasta samples were associated with the highest maximum and average levels of DON, with a maximum value of 1660 ppb.



Note: Only values above the limit of detection are shown

Figure 18: Distribution of DON levels in pasta (in order of increasing maximum)

Table 14 summarizes the current targeted survey data on DON levels in pasta products. No pasta products were sampled in previous surveys; however the EFSA has sampled raw pasta samples as part of a 2013 study of DON in food and feed[7]. The EFSA tested

1365 raw pasta products for DON, with a reported mean value of 99.3 ppb. This value agrees well with the average DON levels in pasta products from the current survey. Note that the EFSA study did not specify product form (e.g. frozen, fresh, dried).

Table 14: Summary of targeted survey data on DON levels in pasta

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum (ppb)	Maximum (ppb)	Average* (ppb)
Frozen						
CFIA	***2012-2014***	***17***	***9 (53)***	***1.2***	***143***	***45.7***
Fresh						
CFIA	***2012-2014***	***43***	***41 (95)***	***10.7***	***166***	***78.2***
Dry						
CFIA	***2012-2014***	***100***	***97 (97)***	***2.2***	***1660***	***120.7***

*Average of positive results only

4. Conclusions

A total of 3630 samples were analyzed for the presence of DON. These samples included 386 assorted foods, 543 infant foods, 1284 milled grain products and 1417 processed grain-based products. Twenty-three percent of the samples tested for DON did not contain detectable levels. The detected levels of DON ranged from 1.0 ppb to 4380 ppb, with milled grain products having the highest average levels. Specifically, milled corn products and milled wheat products had the highest average levels of DON. Dried fruit, soy products and infant foods had the lowest average DON levels for the current survey.

The results of the current survey agree well with previous targeted surveys, HC and EFSA data on the levels of DON in selected foods. There are currently no Canadian maximum levels established for DON in finished products, so compliance to a numeric standard could not be evaluated.

All the data generated were shared with Health Canada's Bureau of Chemical Safety for use in performing human health risk assessments. Health Canada's Bureau of Chemical Safety concluded that the levels of DON found in the foods included in this survey were low overall and that short-term exposure to elevated levels of DON in the limited number of samples that were identified in this survey are not expected to pose a safety concern. No product recalls were warranted given the lack of health concern.

5. References

[1] 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* 20 (2003): 494-504.

[2] 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.

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

[4] Scott, P.M., Kanhere, S.R., Weber, D. Analysis of Canadian and imported beers for Fusarium mycotoxins by gas chromatography-mass spectrometry. *Food Additives & Contaminants* 10 (1993): 381-389.

[5] Health Canada's Bureau of Chemical Safety. *Canadian Standards (Maximum Levels) for Various Chemical Contaminants* [online]. Modified June 2012. Accessed September 9, 2014. http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/contaminants-guidelines-directives-eng.php

[6] 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 (CAC/RCP 51-2003). 2003. Accessed September 9, 2014. www.codexalimentarius.org/input/download/standards/406/CXP_051e.pdf

[7] European Food Safety Authority. Scientific Report – Deoxynivalenol in food and feed: occurrence and exposure. *The EFSA Journal.*[online] (2013).Accessed September 9, 2014. www.efsa.europa.eu/efsajournal

[8] Kushiro, M. Effects of Milling and Cooking Processes on the Deoxynivalenol Content in Wheat. *International Journal of Molecular Sciences.* 9.11 (2008): 21217-2145

[9] JECFA. 2001. Safety Evaluation of Certain Mycotoxins in Food. Report of the fifty-sixth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). WHO Food Additive Series: 74. pp. 419-555

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

[11] Canadian Food Inspection Agency. 2009-2010 FSAP Survey: *Ochratoxin A and Deoxynivalenol in Selected Foods*. [online]. Accessed September 9, 2014. http://www.inspection.gc.ca/food/chemical-residues-microbiology/chemical-residues/ochratoxin-a-and-deoxynivalenol/eng/1348258196979/1348258304536

[12] Canadian Food Inspection Agency. 2010-2011 FSAP Survey: *Ochratoxin A and Deoxynivalenol in Selected Foods*. [online]. Accessed September 9, 2014. http://www.inspection.gc.ca/food/chemical-residues-microbiology/chemical-residues/ochratoxin-a-and-deoxynivalenol/eng/1348073248340/1348074414907

[13] Canadian Food Inspection Agency. 2011-2012 FSAP Survey: *Ochratoxin A and Deoxynivalenol in Selected Foods*. [to be published]. Accessed September 9, 2014.