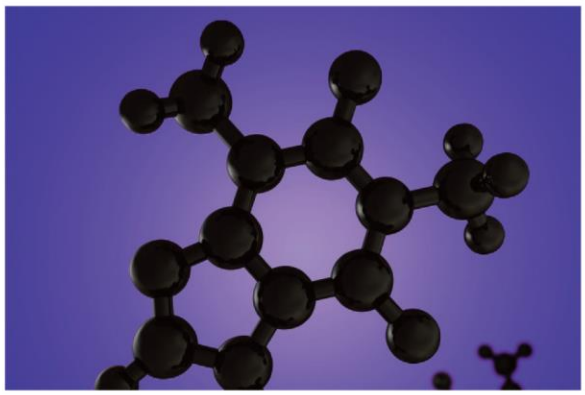
Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2011-2012 Targeted Surveys

Chemistry



Deoxynivalenol in Selected Foods

TS-CHEM-11/12

Canada

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 focussed 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 immunosuppressive and gastrointestinal effects. 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, beer, 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, beer, dried fruit, and grain products found in 2011-2012 with the prevalence found in the 2009-2010 and 2010-2011 CFIA FSAP OTA/DON surveys, where feasible.

A total of 1391 samples were analyzed for the presence of DON. These samples included infant foods (98 infant formulas, 59 infant cereals), milled grain products (126 "other grain" products (e.g., quinoa, buckwheat), 102 wheat products, 73 corn products, and 32 oat products), processed grain-based products (193 breads/baked goods/crackers, 255 breakfast cereals, 150 beer) and other foods (198 soy products, 105 dried fruits).

Thirty-seven 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, except for dried fruits. DON levels ranged from 1.0 ppb to 2460 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 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. As such, no follow-up activity was required.

1. Introduction

1.1. Food Safety Action Plan

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

The Canadian Food Inspection Agency's (CFIA) Food Safety Action Plan (FSAP) is one element of the government's broader FCSAP initiative. The goal of FSAP is to identify risks in the food supply, limit the possibility that these risks occur, improve import and domestic food controls, and identify food importers and manufacturers.

Within the 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 domestic raw grains for DON. Health Canada, which has purview over foods sold in Canada, has conducted surveys of DON that generally focus on finished foods[5,1,2]. The monitoring of finished grain products (whether domestically produced or imported) available at the 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 natural toxins. The current survey also looks to gain insight as to the DON levels in infant formula, beer, dried fruit, soy products, and milled/processed grain products.

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 establishes the health-based maximum levels for chemical residues, contaminants, and natural 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[3]. There are Canadian standards for DON in uncleaned soft wheat. However, these standards are under review by Health Canada's Bureau of Chemical Safety, and there are no established Canadian maximum levels for DON in finished grain products (e.g. flour, bran, baked goods). The established international maximum levels for DON in foods are presented in the Appendix.

Elevated levels of DON in specific foods may be assessed by Health Canada's Bureau of Chemical Safety on a case-by-case basis using the most current scientific data available. If the Bureau of Chemical Safety 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.

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)[4]. This Code of Practice acknowledges that the complete elimination of mycotoxins from foods is not possible. It 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, cereals, and beer). 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[6].

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. In animal studies, long-term exposures to low levels of DON are associated with decreased food intake, weight loss, and effects on the immune system[7].

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, more recently and to a lesser extent, those intended 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 Bureau of Chemical Safety and through other CFIA activities. Health Canada's Bureau of Chemical Safety has conducted surveys of DON in some ingredients and finished foods[5,1,2]. It was deemed appropriate to conduct a larger survey of finished foods available in Canada over multiple years through the CFIA's FSAP project. Previous FSAP OTA/DON surveys conducted by the CFIA have focused on minimally processed grain products[8,9.] This survey supplements data generated in previous surveys by looking for DON in domestic and imported infant formula, beer,

* 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.

dried fruit, soy products, and milled grain products. The possible presence of DON in infant formula is of particular concern, as it may be the sole food source for infants in the first few months of life. There is little data in the scientific literature on the levels of DON in infant formula, soy products, or dried fruits.

2.3. Sample Overview

The current FSAP targeted survey on DON examined domestic and imported infant formula, beer, dried fruit, soy products, and milled grain products. The intent of this survey was to obtain a snapshot of the DON levels in food products that may contribute significantly to DON exposure for Canadians. 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 1391 samples were tested for DON. The 1391 samples were separated into four product categories (infant foods, milled grain products, processed grain-based products, and other food products). Infant foods (157 samples) included infant formulas and infant cereals, including soy-based infant formula and infant cereals. Milled grain products (333 samples) included products derived from wheat, corn, oats, and "other" grains (e.g. quinoa, buckwheat). Processed grain-based products (599 samples) included breakfast cereals, breads/baked goods/crackers, and beer. Other food products (303 samples) included dried fruits and soy products. Soy products included beverages (e.g. soy milk), soybeans (frozen, dried or canned), flour, tofu, miso, soybean paste, and five samples of other soy products (curd, meal replacement, powder, pudding, and spread).

All foods were sampled between April 2011 and March 2012 at grocery and specialty stores in 11 Canadian cities. Of the 1391 samples tested for DON, 697 were domestic samples, 587 were imported products, and 107 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 39 countries, including Canada, with approximately 75% of the samples originating in either Canada or the United States. 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 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 Samples of Domestic Origin	Number of Imported Samples	Number of Samples of Unspecified Origin	Total Number of Samples
Infant Foods	Infant Formulas	8	87	3	98
	Infant Cereals	11	43	5	59
Milled Grain Products	"Other Grain" Products	54	59	13	126
	Wheat Products	74	21	7	102
	Corn Products	25	37	11	73
	Oat Products	23	7	2	32
Processed Grain-based Products	Breads/Baked Goods/Crackers	170	21	2	193
	Breakfast Cereals	143	91	21	255
	Beer	85	64	1	150
Other Food Products	Soy Products	92	91	15	198
	Dried Fruits	12	66	27	105

2.4. Analytical Methods

Samples were analysed by a Canadian laboratory accredited for food testing 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) method used by CFIA. All levels of DON above the LOQ and LOD of 1 ppb were reported for all matrices analysed.

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 1391 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.

All samples were analysed as sold rather than as they would typically be consumed (i.e. not prepared according to manufacturer's instructions).

3. Results and Discussion

3.1 Overview of DON Results

All product categories and product types, except dried fruits, had some samples with a detectable level of DON. The percentage of samples with detectable levels of DON per product type ranged from 4% in infant formulas to 98% in wheat products. Figure 1 shows the number of samples analyzed for DON by product type.

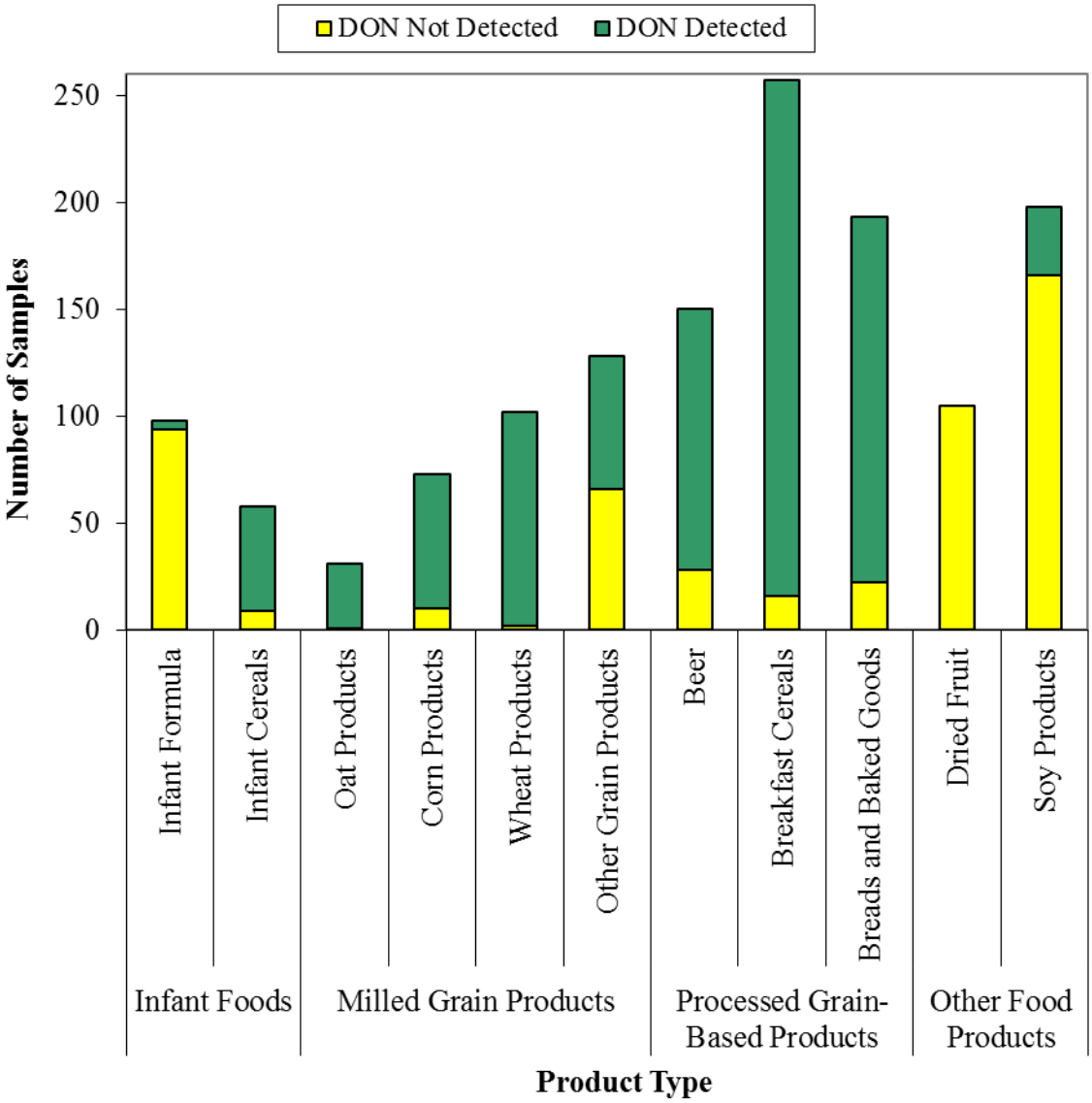
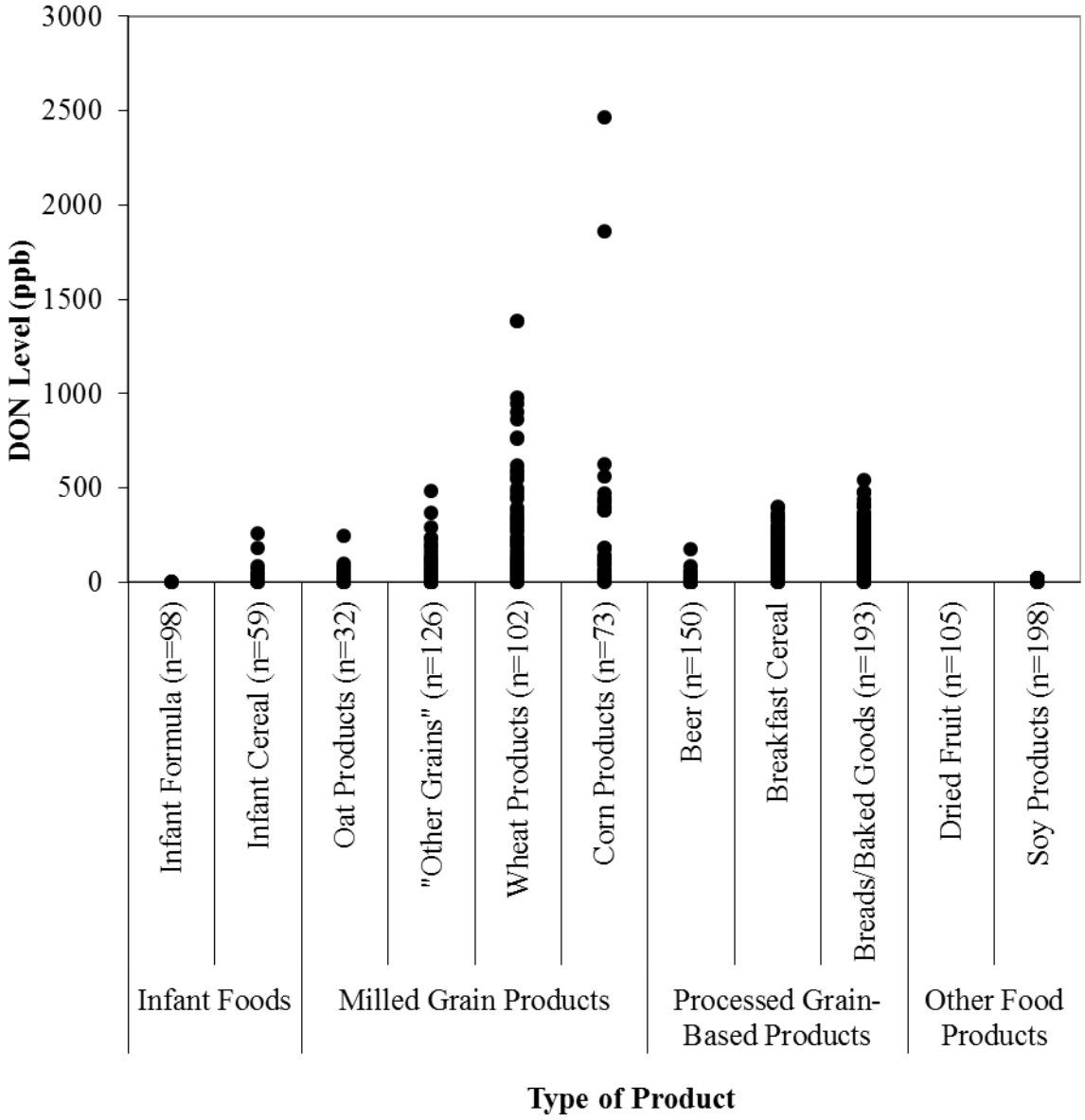


Figure 1. Number of samples analyzed for DON by product type (in order of increasing number of samples per category)

Of the 1391 samples tested for DON, 508 (37%) did not have a detectable level. The levels of DON in the remaining 883 samples ranged from 1.0 ppb to 2460 ppb. There are no Canadian maximum levels for DON in finished products so comparison to a numeric standard could not be evaluated. The lowest DON levels were associated with samples of infant formulas, while the highest DON levels were associated with samples of corn and wheat products (see section 3.2 for more detailed information regarding the DON levels in particular product categories and types). Figure 2 below presents DON level by product type in order of increasing DON concentration.



Note: Only values greater than the reporting limit (1 ppb) are depicted.

Figure 2. DON level by category and by product type (in order of increasing DON level per category)

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 found in the foods included in this survey were low overall and not expected to pose a health concern. The following sections present the analytical results for DON in each of the eleven product types.

3.2 DON Results by Product Type

The results from this targeted survey will be compared to the relevant data from previous FSAP surveys and to the scientific literature in Section 3.3.

3.2.1 DON in Infant Foods

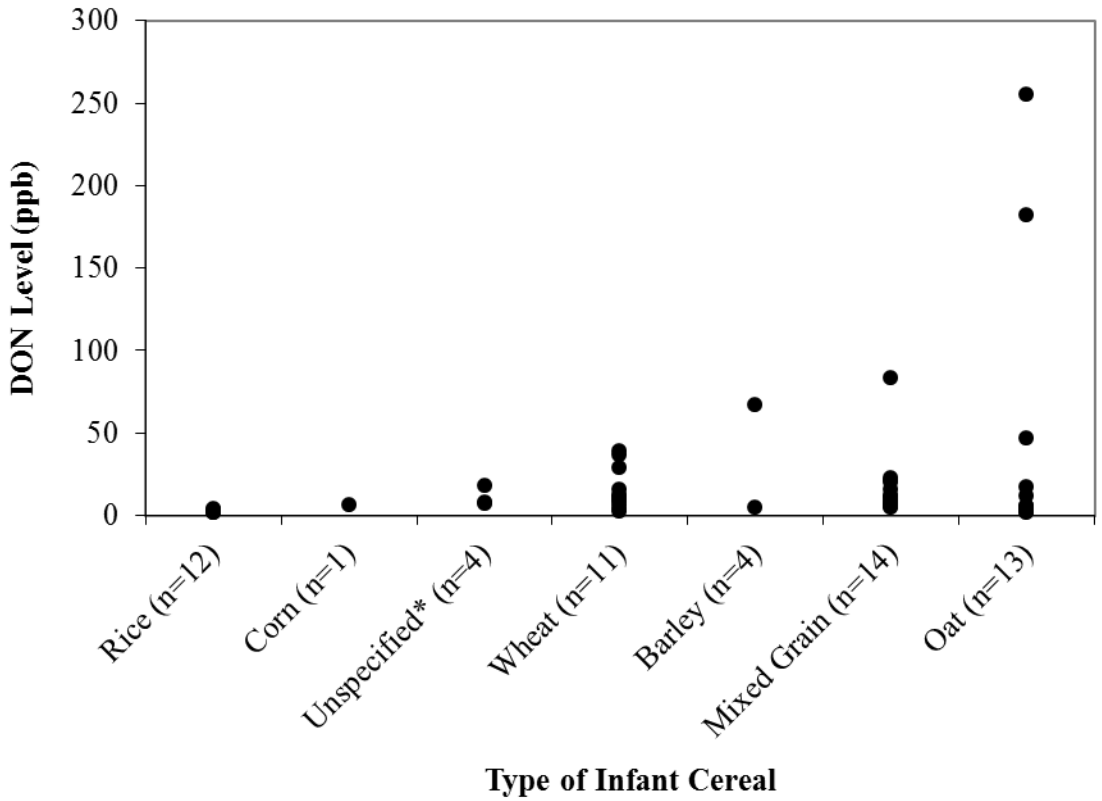
The infant foods category included formulas and infant cereals. Samples from this product category were associated with the lowest DON levels. DON was detected in 53 of the 156 samples tested (34%). All results were forwarded to Health Canada's Bureau of Chemical Safety. Health Canada's Bureau of Chemical Safety determined that all of the samples tested were considered unlikely to pose a concern to human health. No follow up activity was warranted given the lack of a health concern.

3.2.1.1 DON in Infant Formulas

Ninety-eight samples of dairy-based and soy-based infant formula (powdered, liquid concentrate, and ready-to-serve) were tested for DON. The infant formula samples included iron fortified, low iron, nutritional supplement, omega-3/omega-6, and calcium-enriched formula (as available in the marketplace). Two of the 93 samples of milk-based formula had a DON level of 1.0 ppb and 1.4 ppb. Two of the five soy-based infant formulas had a DON level of 1.3 ppb and 1.4 ppb.

3.2.1.2 DON in Infant Cereals

Fifty-nine samples of infant cereals (wheat, rice, corn, barley, mixed grain cereals, with/without fruit/milk, sold as beginner to 12-month cereals) were tested for DON. Forty-nine of the 58 (85%) infant cereal samples were positive for DON, with levels ranging from 1.3 ppb to 255 ppb. Seven samples of rice-based, one sample of unspecified type (identified only as infant cereal), and two samples of barley-based infant cereals did not contain detectable levels of DON. Figure 3 below presents the DON results by grain type in infant cereals. The highest DON levels were associated with samples of oat, barley, and mixed grain infant cereals.



*Unspecified designated products labelled only as "infant cereal".
Note: Only values greater than the reporting limit (1 ppb) are depicted.

Figure 3. DON levels in infant cereal samples by grain type (arranged in order of increasing maximum DON level per grain type)

3.2.2 DON in Milled Grain Products

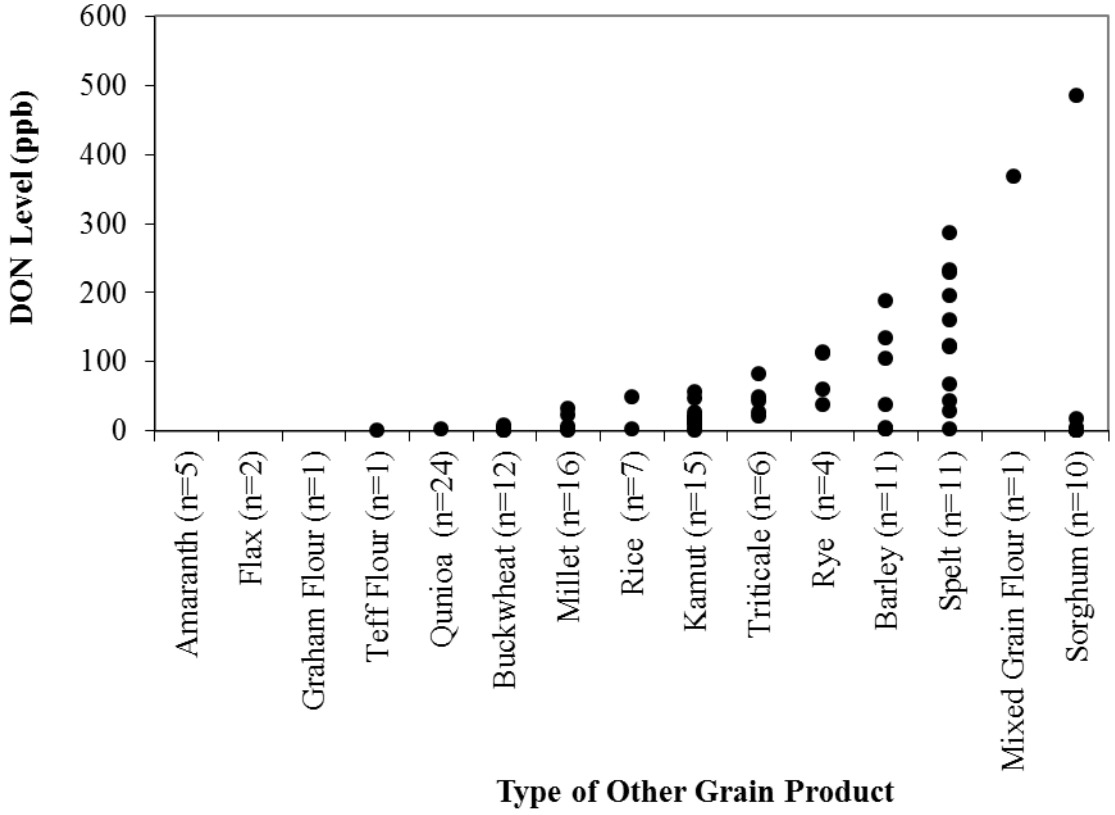
Milled grain products included milled grains, flours, brans, germs, and meals of wheat, corn, oats, and other grains (e.g. buckwheat, quinoa). Samples from this product category were associated with the highest maximum DON level. DON was detected in 76% of the samples tested. The lowest DON level (1 ppb) was associated with an oat product sample and the highest (2460 ppb) DON level was associated with a corn product sample. However, DON prevalence, measured as percentage of positive samples, decreased in the order: wheat (98%), oats (97%), corn (86%), and other grains (48%). The levels of DON in milled grain products were evaluated by Health Canada's Bureau of Chemical Safety and were considered unlikely to pose a concern to human health. No follow up activity was warranted given the lack of a health concern.

3.2.2.1 DON in Other Grain Products

Samples of other grain products included milled/whole grain/flakes/kernels/groats/seeds of barley, buckwheat (kasha), kamut, amaranth, flax, millet, sorghum, spelt, and triticale. Flours of barley, buckwheat, graham, kamut, millet, mixed grains, quinoa, wild rice, rye, sorghum, spelt, teff, and triticale were also sampled and tested. Sixty-two of the 128

(48%) samples of other grain products had a detectable level of DON, ranging from 1.2 ppb to 484 ppb.

Figure 4 provides a summary of DON results in other grain products. DON was not detected in the samples of amaranth products, flax products, and graham flour. Sorghum, mixed grain, and spelt product samples had the highest maximum levels of DON.

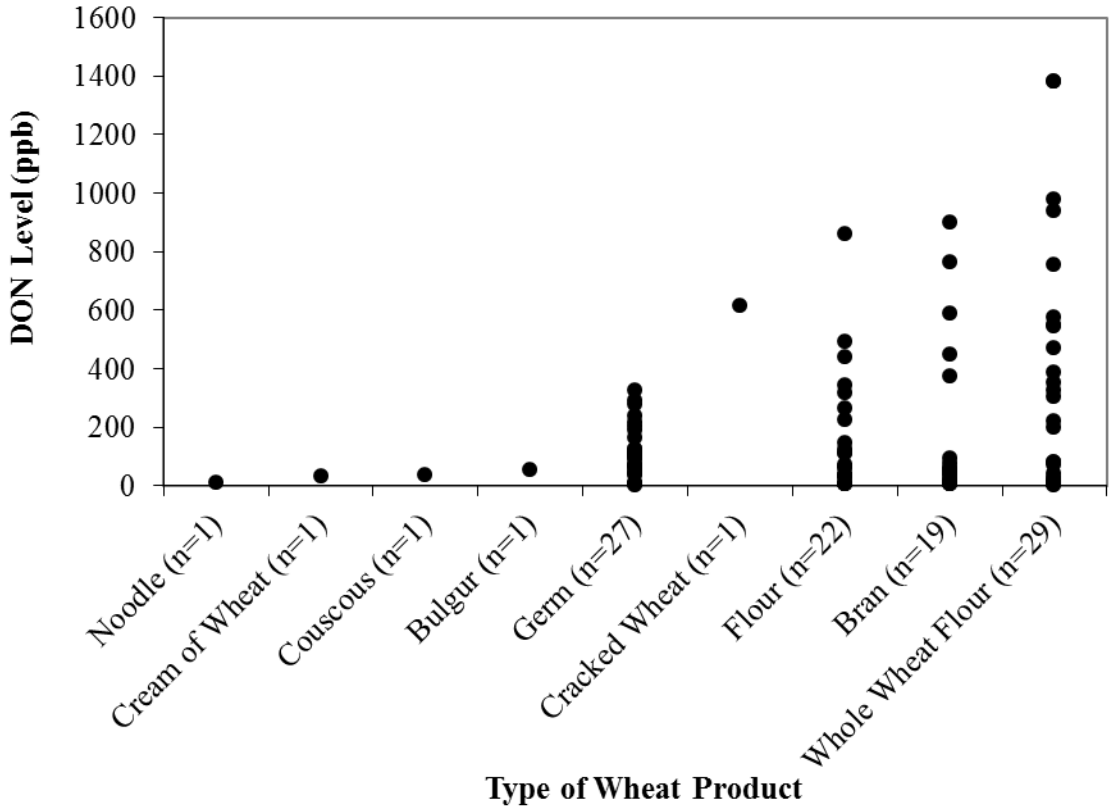


Note: Only values greater than the reporting limit (1 ppb) are depicted.

Figure 4. DON levels in other grain products (arranged in order of increasing maximum DON level per product)

3.2.2.2 DON in Wheat Products

Samples of wheat products included wheat bran, wheat germ, bulgur wheat, couscous, cracked wheat, cream of wheat, wheat noodles, and wheat-based flours. One hundred (100) of the 102 wheat product samples tested (98%) had a detectable level of DON, with values ranging from 1.3 ppb to 1380 ppb. Two samples of whole wheat flour did not have detectable levels of DON. Samples of noodles had the lowest and whole wheat flour had the highest levels of DON. Figure 5 presents the DON results by type of wheat product.

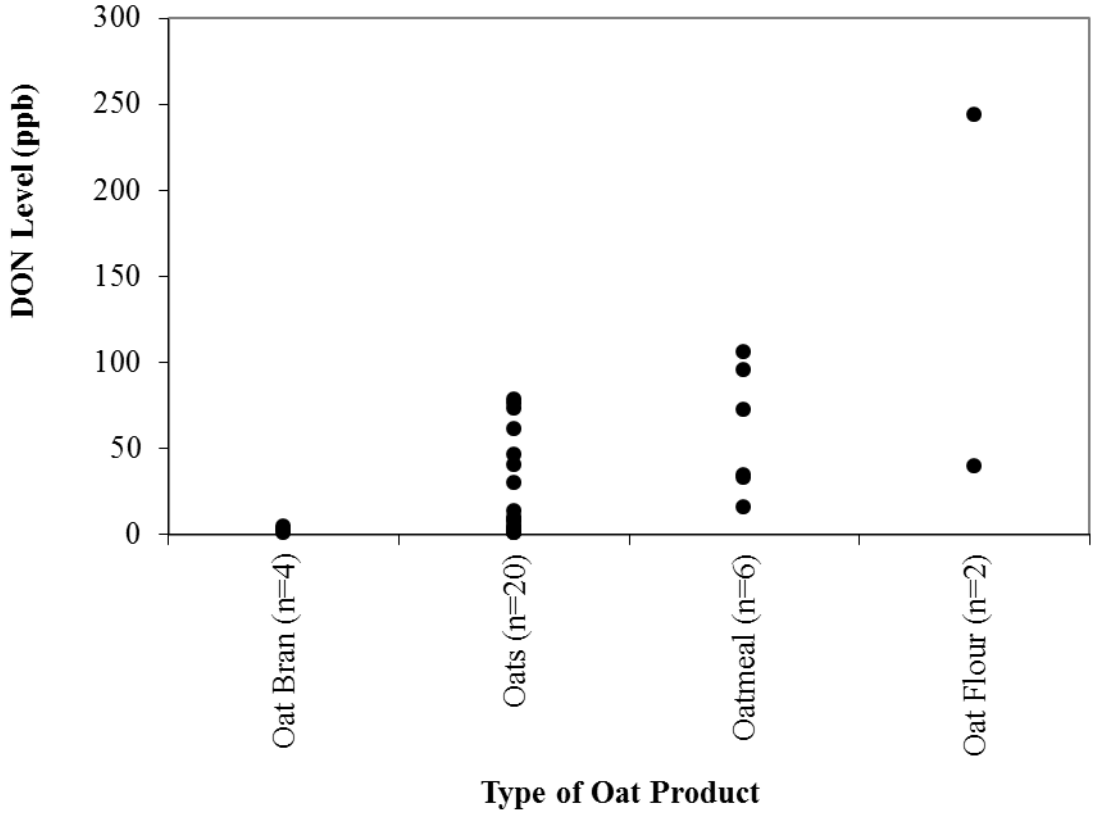


Note: Only values greater than the reporting limit (1 ppb) are depicted.

Figure 5. DON levels in wheat products (arranged in order of increasing maximum DON level per product)

3.2.2.3 DON in Oat Products

Samples of oat products included oat flour, oatmeal, oat bran, and oats (e.g., steel cut, rolled). Thirty-one of the thirty two (97%) oat products tested contained detectable levels of DON ranging from 1.0 ppb to 244 ppb. One sample of oats did not have a detectable level of DON. The highest DON levels were associated with samples of oat flour, however, only two samples of oat flour were analysed in this survey (the DON levels were 40 and 244 ppb). Figure 6 presents the DON results by type of oat product.

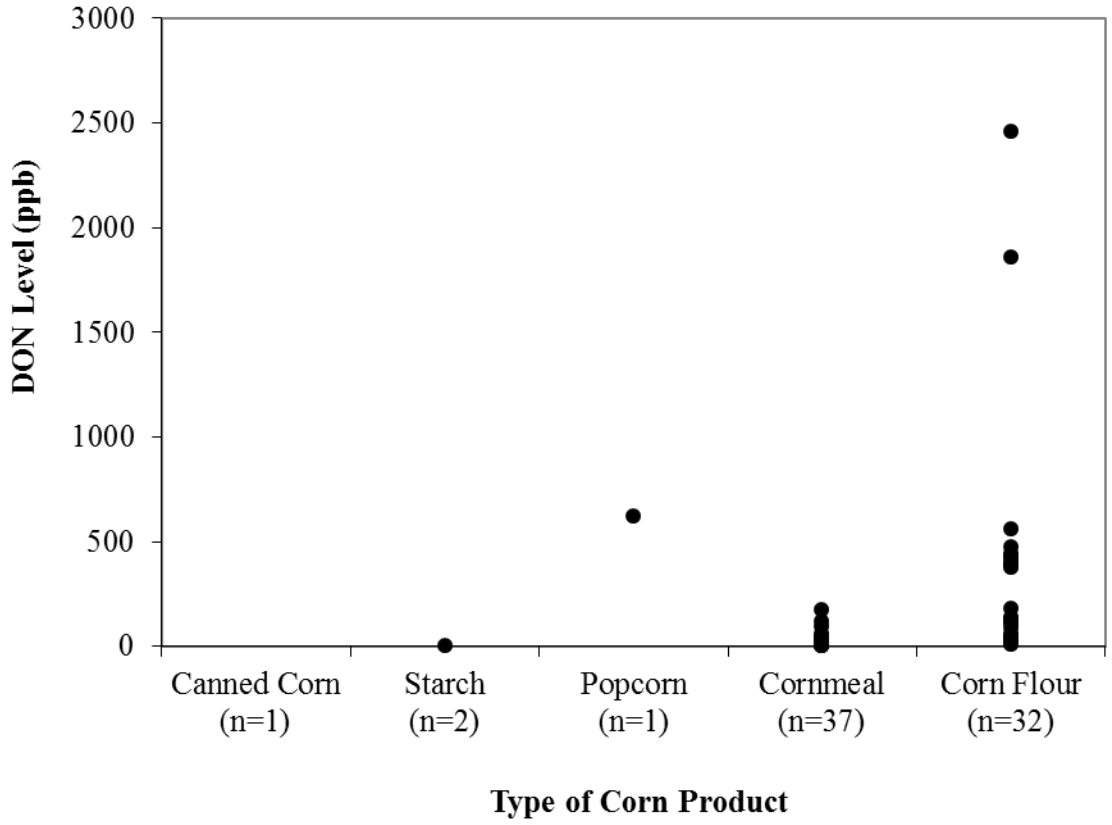


Note: Only values greater than the reporting limit (1 ppb) are depicted.

Figure 6. DON levels in oat products (arranged in order of increasing maximum DON level per product)

3.2.2.4 DON in Corn Products

Samples of corn products included canned corn, popcorn (popped and unpopped), corn starch, cornmeal, and corn flour. Sixty-three of the 73 corn product samples (86%) had a detectable level of DON, ranging from 1.5 ppb to 2460 ppb. Canned corn (1 sample), corn starch (1 sample), cornmeal (7 samples) and corn flour (1 sample) did not contain detectable levels of DON. Figure 7 presents the DON results by type of corn product. The highest DON levels were associated with samples of corn flour.



Note: Only values greater than the reporting limit (1 ppb) are depicted.

Figure 7. DON levels in corn products (arranged in order of increasing maximum DON level per product)

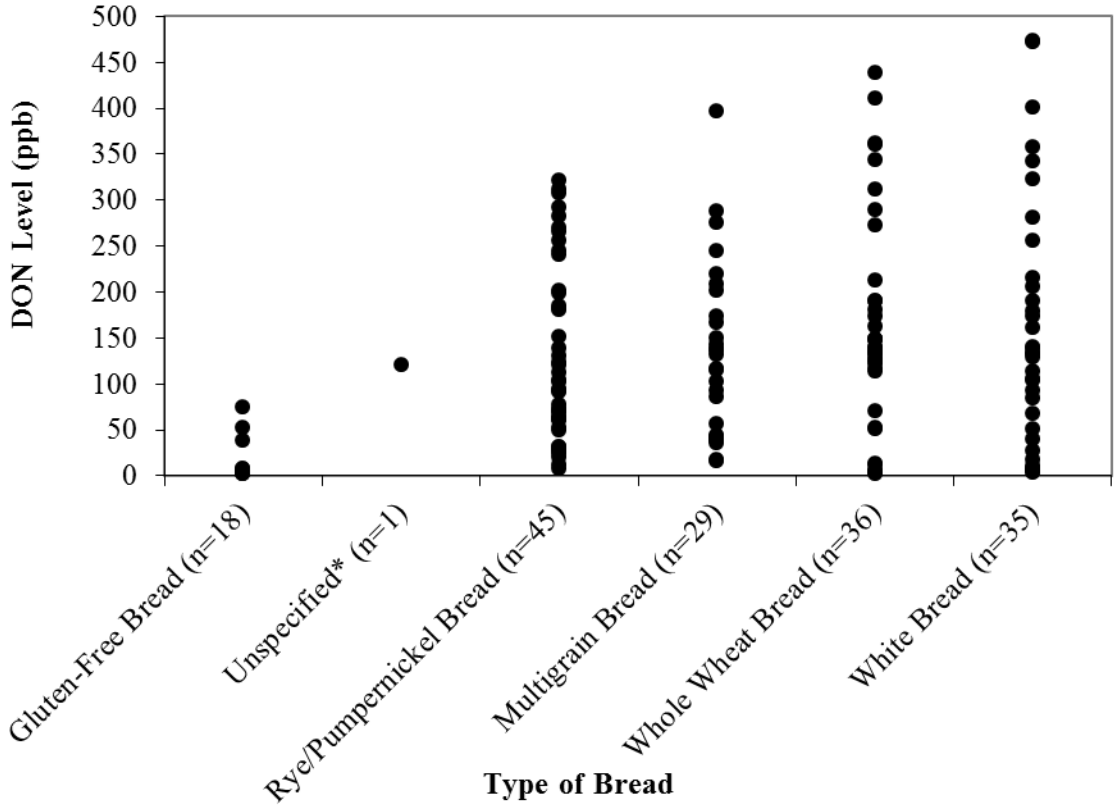
3.2.3 DON in Processed Grain-based Products

Processed grain-based products sampled included breakfast cereals, bread, baked goods, crackers, and beer. This product category was associated with the highest prevalence of DON (90%). However, the maximum DON level in this product category was 542 ppb, which is much lower than the maximum level in milled cereal products (2460 ppb). The DON prevalence, measured as percentage of positive samples, decreased in the order: crackers (100%), breakfast cereals (94%), bread (93%), baked goods (93%), and beer (81%). The levels of DON in processed products were evaluated by Health Canada's Bureau of Chemical Safety and were considered unlikely to pose a concern to human health.

3.2.3.1 DON in Breads/Baked Goods/Crackers

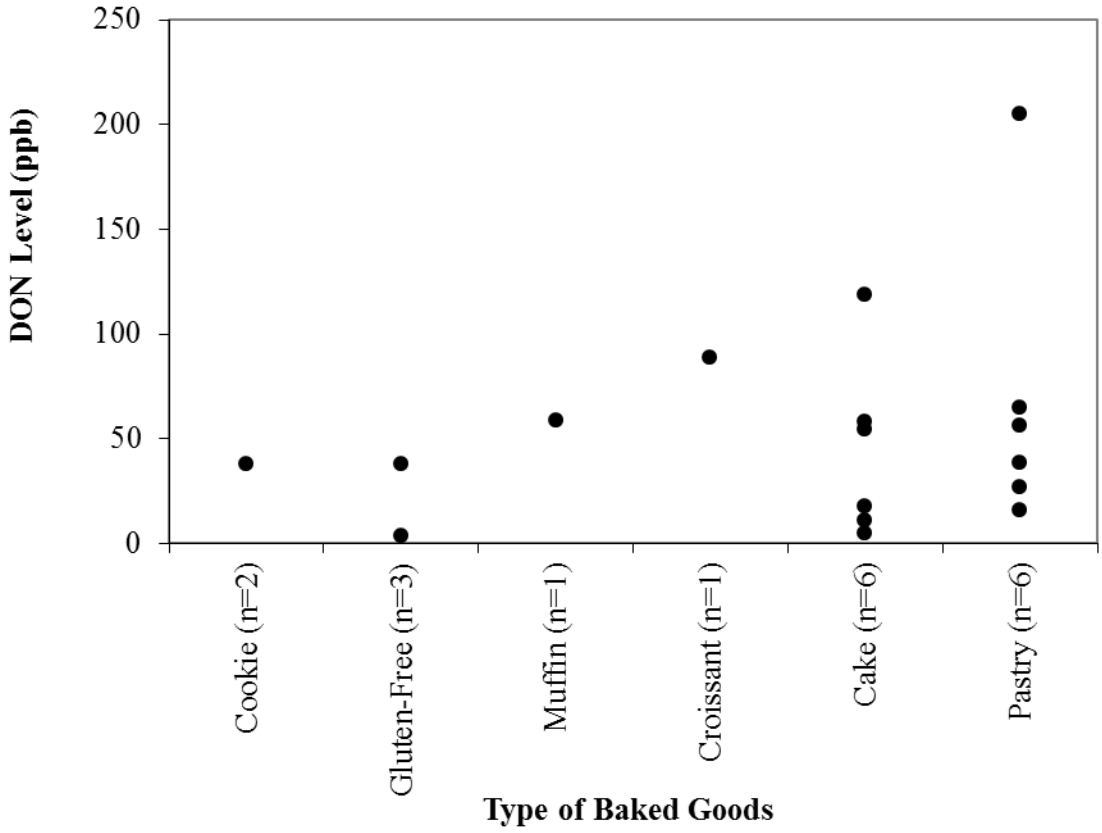
One hundred ninety-three (193) breads and baked goods were sampled and analyzed for DON. Bread samples included toast/sandwich bread (white, whole wheat, rye/pumpernickel, gluten-free), buns, bagels (white, whole wheat, multigrain), English muffins (white and whole wheat), pita bread (wheat/white and whole wheat), tortillas (wheat/white, whole wheat, and multigrain), and naan bread. Baked goods included

cakes, cookies, croissants, muffins, and pastries, and included some gluten-free products. Crackers (e.g. soda crackers) also included crisp breads. One hundred eighty (180) of the 193 (93%) breads/baked goods/crackers sampled had a detectable level of DON, ranging from 1.3 ppb to 542 ppb. One sample each of rye/pumpernickel bread, white bread, cookies, and gluten-free baked goods, and nine samples of gluten-free breads did not contain detectable levels of DON. The baked goods samples generally had much lower levels of DON than bread or cracker samples. Figures 8, 9, and 10 illustrate the DON levels observed as a function of grain type in breads, in baked good products, and in crackers, respectively.



*Unspecified means the sample was labelled only as "bread".
Note: Only values greater than the reporting limit (1 ppb) are depicted.

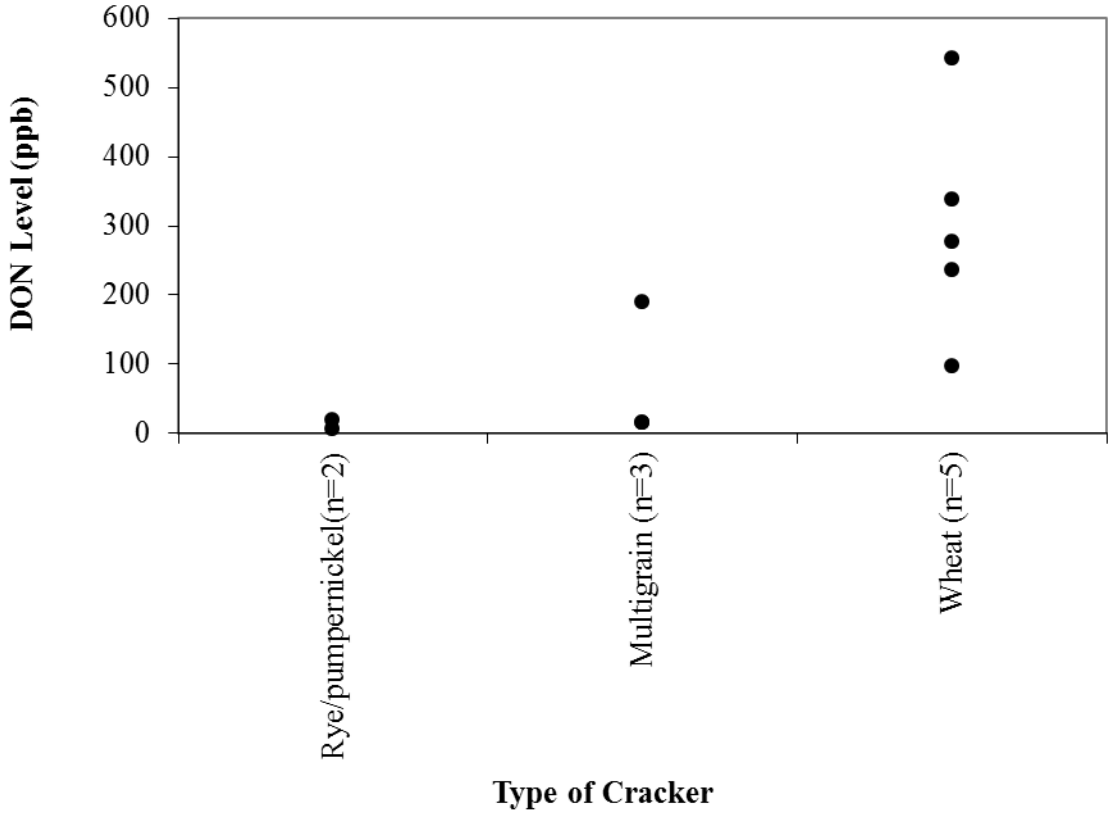
Figure 8. DON levels in breads by grain type (arranged in order of increasing maximum DON level per product)



Note: Only values greater than the reporting limit (1 ppb) are depicted.

Figure 9. DON levels in baked goods by type of product (arranged in order of increasing maximum DON level per product)

One sample of cookies and one sample of gluten-free baked goods did not contain DON. Within the bread and the baked goods category, gluten-free products were associated with the lowest DON levels. In the breads category, DON levels were highest in white bread samples. In baked goods, the highest DON levels were observed in samples of pastry products. Most samples of baked goods (16/19 samples) were made with wheat flour. The remaining three samples of baked goods were gluten-free. Amongst the crackers, rye/pumpernickel cracker and crisp bread samples had the lowest DON levels while wheat cracker samples had the highest DON levels. All cracker samples contained DON. There was no clear relationship between grain type and DON levels in these types of products.

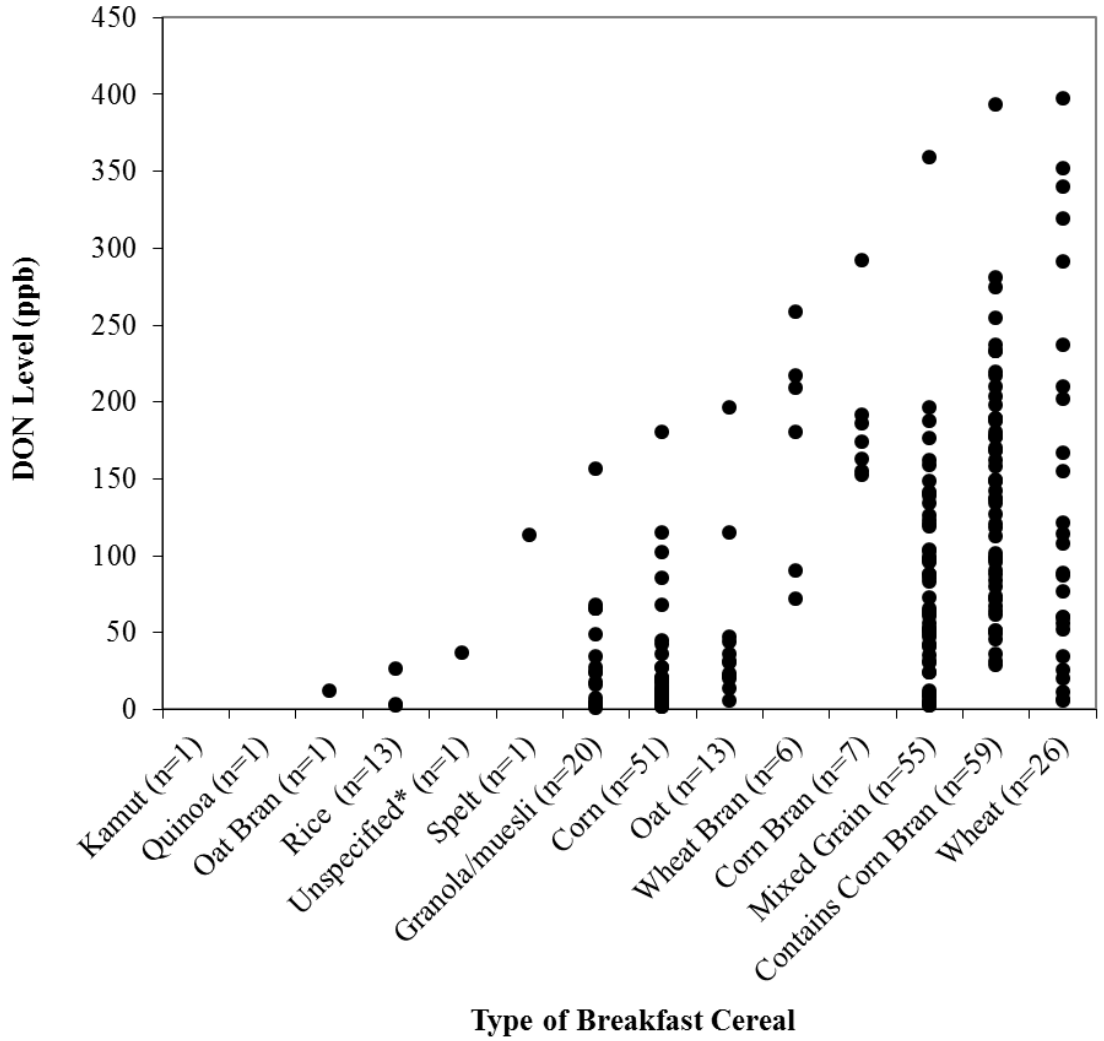


Note: Only values greater than the reporting limit (1 ppb) are depicted.

Figure 10. DON levels in crackers by grain type (arranged in order of increasing maximum DON level per product)

3.2.3.2 DON in Breakfast Cereals

Breakfast cereal samples included single grain (wheat, corn, rice, oats) and mixed grain (granola, muesli) cereals targeted both at adults and at children. Two hundred and forty (240) of the 255 (94%) breakfast cereal samples tested had a detectable level of DON. Kamut (1 sample), quinoa (1 sample), rice (10 samples), granola/muesli (1 sample) and corn (2 samples) cereals did not contain detectable levels of DON. The DON levels ranged from 1.0 ppb to 397 ppb. Figure 11 illustrates the levels of DON observed in breakfast cereals as a function of grain type. Corn-based breakfast cereals listed corn or cornmeal as the main ingredient. Corn bran-based cereals listed corn bran as the main ingredient. "Contains corn bran" refers to a cereal for which corn bran is on the list of ingredients but is not the main ingredient. The highest DON levels were associated with samples of wheat-based breakfast cereals.



*Unspecified means the sample was identified only as a breakfast cereal.
Note: Only values greater than the reporting limit (1 ppb) are depicted.

Figure 11. DON levels in breakfast cereals by grain type (arranged in order of increasing maximum DON level per product)

3.2.3.3 DON in Beer

One hundred fifty (150) beer samples were analyzed in this survey, including domestic and imported major beer brands, and beer samples from brew pubs and microbreweries (ales, pilsners, lagers, dark beers, de-alcoholised beer, wheat beer, stouts, and light beers). The beers originated from at least 17 different countries. DON was detected in 122 of the 150 (81%) beer samples, with levels ranging from 1.0 ppb to 174 ppb. The levels of DON in beer were generally low. There was no apparent relationship between DON level and the style of beer or the country of origin.

3.2.4 DON in Other Food Products

Samples of other food products included dried fruits (e.g. raisins, prunes) and soy-based products (e.g. soy beverages, tofu). This product category was associated with the lowest prevalence of DON (11%). The maximum DON level in this product category was 18.2 ppb, which is considerably lower than the maximum DON level in infant foods (255 ppb), in processed grain-based products (542 ppb), and in milled grain products (2460 ppb).

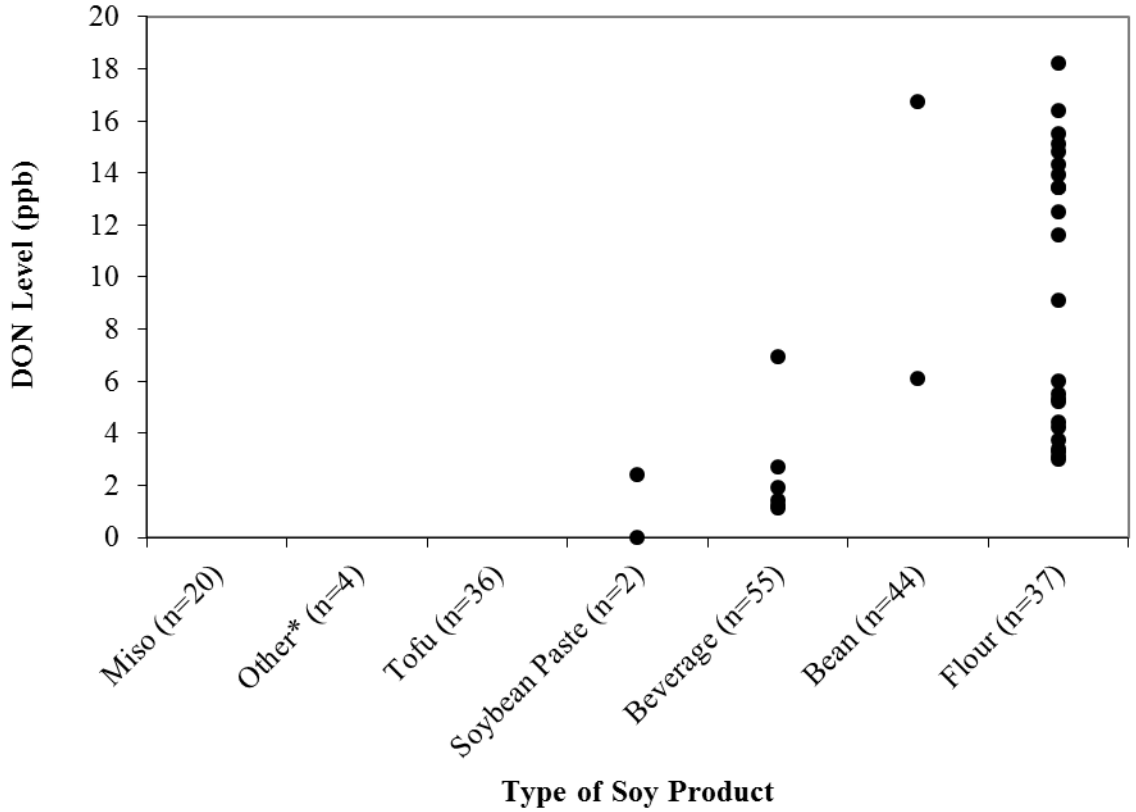
3.2.4.1 DON in Dried Fruits

One hundred and five samples (105) of dried fruit were tested for DON. The dried fruit samples included 25 samples of dates, 20 samples of apricots, 16 samples of raisins, 12 samples of figs, 10 samples of currants, six samples each of mangoes and prunes, two samples each of cherry, cranberry, mixed fruits, and papaya, and one sample each of banana and blueberry. None of the dried fruits sampled in this survey contained a detectable level of DON.

3.2.4.2 DON in Soy Products

The soy product samples included beverages (e.g. soy milk), soybeans (frozen, dried, or canned), flour, tofu, miso, soybean paste, and five samples of other soy products (curd, meal replacement, powder, pudding, and spread). Thirty-two (32) of the 198 (16%) soy product samples tested had a detectable level of DON. DON was not detected in the samples of miso, tofu, or other soy products (soy-based meal replacement, soy powder, soy pudding, and soy spread). The DON levels ranged from 1.1 ppb to 18.2 ppb (see Figure 12 below).

Soy flour and soy beverages were associated with the majority of the positive test results for DON in the soy products category.



*Other includes soy-based meal replacement, soy powder, soy pudding, and soy spread.
Note: Only values greater than the reporting limit (1 ppb) are depicted.

Figure 12. DON levels in soy products (arranged in order of increasing maximum DON level per product)

3.3 Comparison of the results obtained in the 2009-2010, 2010-2011, and 2011-2012 CFIA Surveys on Deoxynivalenol

The results of this survey were compared to the results of previous CFIA FSAP OTA/DON surveys carried out in 2009-2010[8] and 2010-2011[9] and to relevant scientific literature in the absence of previous FSAP data. DON is a toxin that is primarily produced in the field, but the samples in this survey were picked up at retail. As such, the history of the grain-based ingredients in these products with respect to the DON levels in the grain at the time of harvest was unknown.

There was no apparent trend in the year-to-year values. The maximum values for DON in beer, infant cereals, corn products, and oat products were higher in the current survey compared to the previous surveys. The maximum values for infant formulas, breakfast cereals, and wheat products were generally lower in this survey than in previous surveys.

3.3.1 Infant Foods

Table 3 focuses on DON levels in infant foods. In the selected studies, most samples of infant formula did not contain a detectable level of DON. The maximum DON level is lower in infant formulas and higher in infant cereals in the current survey than in the previous survey.

Table 3. Summary of 2009-2010, 2010-2011, and 2011-2012 FSAP survey data and literature examining DON concentrations in infant foods

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum DON Levels (ppb)	Maximum DON Levels (ppb)	Average DON Levels (ppb)
Infant Formulas						
CFIA Survey	2011-2012	98	4 (4)	1.0	1.4	1.3
	2010-2011	98	4 (4)	1.1	2.5	1.7
Infant Cereals						
CFIA Survey	2011-2012	59	49 (83)	1.3	255	22.1
	2010-2011	93	76 (82)	1.1	128	12.1

3.3.2 Milled Grain Products

Table 4 presents the comparison of maximum DON levels in milled grain products. Other grains encompass a number of different types of grain products. The JECFA[†] report included the widest variety of other grain products (barley, buckwheat, rice, rye, spelt, and sorghum). The other studies in the scientific literature focused on one or two of the applicable grain types, resulting in much variability in the observed DON levels in these studies. The maximum level of DON in other grain products in this survey does fall within the range of levels reported in the scientific literature, including the JECFA report. The maximum DON levels in corn products and to a lesser extent, oat products, are higher in the current survey as compared to the previous FSAP surveys. The maximum DON levels in wheat products in the current survey are consistent with the levels observed in the 2010-2011 survey.

[†]JECFA refers to the Joint FAO/WHO Expert Committee on Food Additives which is an international scientific expert committee that is administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). JECFA evaluates the safety of contaminants and additives in foods, including DON. When performing an assessment, JECFA compiles and uses all relevant scientific data submitted by member countries from around the globe.

Table 4. Summary of 2009-2010, 2010-2011, and 2011-2012 FSAP survey data and literature examining DON concentrations in milled grain products

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum DON Levels (ppb)	Maximum DON Levels (ppb)	Average DON Levels (ppb)
Other Grain Products						
CFIA Survey	2011-2012	128	62 (48)	1.2	484	60.6
Almedia[10]	2012	230	18 (8)	<LOD	300	2.78
Bensassi[11]	2011	72	41 (57)	500	3600	1900
Matić[12]	2009	2	1 (50)	250	2000	920
Pan[13]	2007	292	157 (54)	500	10000	2795
Čonková[14]	2005	35	9 (26)	0	530	115
Rasmussen[15]	2003	69	41 (59)	-	257	41
JECFA[16]	2001	2351	1292 (55)	<LOD	34000	455
Wheat Products						
CFIA Survey	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
Oat Products						
CFIA Survey	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
Corn Products						
CFIA Survey	2011-2012	73	63 (86)	1.5	2460	175.2
	2010-2011	76	70 (92)	1.0	1440	147.2
	2009-2010	50	34 (68)	10	1380	230

Note: For the 2010-2011 and 2011-2012 CFIA surveys, the limit of detection (LOD) was 1 ppb and the limit of quantitation (LOQ) was 1 ppb for all matrices tested. For the 2009-2010 CFIA survey, the reporting limit was 10 ppb. Wherever possible, only the detectable values of DON were included in the calculation of the minimum, maximum and average DON levels.

3.3.3 Processed Grain-based Products

Table 5 presents the comparison of DON levels in processed grain-based products. The maximum DON levels in breads, baked goods, crackers, breakfast cereals, and beer in this targeted survey fall within the range of values reported by JECFA. The maximum DON levels in the current survey are higher than in the other scientific literature cited. The maximum DON level was lower in breakfast cereals, but was found to be higher in beer in the current survey as compared to the previous survey results.

Table 5. Summary of 2009-2010, 2010-2011, and 2011-2012 FSAP survey data and literature examining DON concentrations in processed grain-based products

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum DON Levels (ppb)	Maximum DON Levels (ppb)	Average DON Levels (ppb)
Breads/Baked Goods/Crackers						
CFIA Survey	2011-2012	193	180 (93)	1.3	542	132
Matić[12]	2009	5	1 (20)	-	380	-
JECFA[16]	2001	241	204 (85)	<LOD	5400	188
Breakfast Cereals						
CFIA Survey	2011-2012	255	240 (94)	1.0	397	156
	2010-2011	197	190 (96)	1.2	2060	87.8
Beer						
CFIA Survey	2011-2012	150	122 (81)	1.0	174	9.2
	2010-2011	130	103 (79)	1.1	102	9.4

Note: For the 2010-2011 and 2011-2012 CFIA surveys, the limit of detection (LOD) was 1 ppb and the limit of quantitation (LOQ) was 1 ppb for all matrices tested. For the 2009-2010 CFIA survey, the reporting limit was 10 ppb. Wherever possible, only the detectable values of DON were included in the calculation of the minimum, maximum and average DON levels.

3.3.4 Other Food Products

Table 11 presents the comparison of DON levels in other food products. DON was not detected in dried fruits in the current and previous (2010-2011) FSAP surveys. The maximum levels of DON in soy products are lower in the current FSAP survey than the levels reported by JECFA and in the scientific literature. The current survey examined a much wider variety of products than JECFA (which examined soy beans and soy sauce only) or the other studies (which examined mainly soy beans, soy meal, and soy beverages).

Table 6. Summary of 2009-2010, 2010-2011, and 2011-2012 FSAP survey data and literature examining DON concentrations in other food products

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum DON Levels (ppb)	Maximum DON Levels (ppb)	Average DON Levels (ppb)
Dried Fruit						
CFIA Survey	2011-2012	105	0 (0)	Not detected	Not detected	Not detected
	2010-2011	97	0 (0)	Not detected	Not detected	Not detected
Soy Products						
CFIA Survey	2011-2012	198	32 (16)	1.1	18.2	8.0
Matić[12]	2009	11	0 (0)	Not detected	Not detected	Not detected
Rodrigues[17]	2008	78	15 (19)	<LOD	1512	598
JECFA[16]	2001	5	0 (0)	Not detected	Not detected	Not detected
Nesheim[18]	1995	31	17 (55)	160	490	Not reported

4. Conclusions

A total of 1391 samples were tested for DON, and 508 samples (37%) did not have a detectable level of DON. As there are no Canadian maximum levels established for DON in finished products, compliance to a numeric standard could not be evaluated. The DON levels in all samples were assessed by Health Canada's Bureau of Chemical Safety, which was of the opinion that the foods included in this survey contained low levels of DON overall. None of the samples were expected to pose a safety concern so no follow up activity was required.

Appendix

Established Canadian and international DON maximum levels/limits/guidelines in foods

Hazard	Commodity	Canada[Error! Bookmark not defined.]	United States[19]	European Union[20]	Codex[21]
DON (ppb)	Wheat, soft, raw	1000, 2000 (under review)*	-	-	No maximum levels adopted to date
	Wheat, durum, raw	-	-	1750	
	Corn, raw			1750	
	Oats, 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	

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

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] Health Canada's Bureau of Chemical Safety. *Canadian Standards (Maximum Levels) for Various Chemical Contaminants* [online]. Modified June 2012. Consulted February 7, 2013. http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/contaminants-guidelines-directives-eng.php

[4] 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 on September 12, 2013. www.codexalimentarius.org/input/download/standards/406/CXP_051e.pdf

[5] 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.

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

[7] 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.

[8] Canadian Food Inspection Agency. 2009-2010 FSAP Survey: *Ochratoxin A and Deoxynivalenol in Selected Foods*. [online]. Published 2011. Consulted December 3, 2013. http://www.inspection.gc.ca/english/fssa/microchem/resid/2009-2010/otadone.shtml

[9] Canadian Food Inspection Agency. 2010-2011 FSAP Survey: *Ochratoxin A and Deoxynivalenol in Selected Foods* [online]. Consulted December 3, 2013 http://www.inspection.gc.ca/food/chemical-residues-microbiology/chemical-residues/ochratoxin-a-and-deoxynivalenol/eng/1348073248340/1348074414907

[10] Almeida, M.I., Almeida, N.G., Carvalho,K.L., Gonçalves, G.A.A., Silva, C.N., Santos, E.A., Garcia, J.C., Vargas, E.A. Co-occurrence of aflatoxins B_1B_2, G_1 and G_2, ochratoxin A, zearalenone, deoxynivalenol, and citreovidrin in rice in Brazil. *Food Additives and Contaminants* 29.4 (2012): 694-703.

[11] Benassi, F., Rjiba, I., Zarrouk, A., Rhouma, A., Hajlaoui, M.R., Bacha, H. Deoxynivalenol contamination in Tunisian barley in the 2009 harvest. *Food Additives & Contaminants: Part B* 4.3 (2011): 205-211.

[12] Matić, J.J., Mastilović, J.S., Čabarkapa, I.S., Mandić, A.I. *Mycotoxins as a Risk in the Grain Food* [online]. *Proc. Nat. Sci, Matica Srpska Novi Sad*. 117 (2009): 79 – 86. Accessed on September 12, 2013. http://www.doiserbia.nb.rs/img/doi/0352-4906/2009/0352-49060917079M.pdf

[13] Pan, D., Bonsignore, F., Rivas, F., Perera, G., Bettucci, L. Deoxynivalenol in barley samples from Uruguay. *International Journal of Food Microbiology* 114.2 (2007): 149-152.

[14] Čonková, E., Laciaková,A., Štyriak, I., Czerwiecki, L., and Wilczyńska, G. Fungal Contamination and the Levels of Mycotoxins (DON and OTA) in Cereal Samples from Poland and east Slovakia. *Czech*

Journal of Food Science 24.1 (2005): 33-40. http://www.e-malt.com/statistics/ScientificDigest/FungalContaminationPolandAndEastSlovakia.pdf

[15] Rasmussen, P.H., Ghorbani, F., Berg, T. Deoxynivalenol and other *Fusarium* toxins in wheat and rye flours on the Danish market. *Food Additives and Contaminants* 20.4 (2003):396-404.

[16] Joint FAO/WHO Expert Committee on Food Additives. *Deoxynivalenol* [online] 2001. Accessed on September 12, 2013. http://www.inchem.org/documents/jecfa/jecmono/v47je05.htm

[17] Rodrigues, I. BIOMIN GmbH. *BIOMIN Mycotoxin Survey Program 2008* [online]. May 2009. Accessed on September 12, 2013. http://www.ifsqn.com/articles_detail.php?newsdesk_id=656

[18] Nesheim, S., Wood, G.E. Regulatory Aspects of Mycotoxins in soybean and soybean products [online]. *JOACS* 72.12 (1995): 1421-1423. Accessed on September 12, 2013. http://fieldcrops.org/Soybeans/Documents/fulltext(10).pdf

[19] 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 on September 12, 2013. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/NaturalToxins/ucm120184.htm

[20] 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 on September 12, 2013. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1881:EN:NOT

[21] 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 on September 12, 2013. http://www.cclac.org/documentos/CCCF/2011/3%20Documentos/Documentos%20Ingles/cf05_INF.pdf