



Canadian Food Agence canadienne
Inspection Agency d'inspection des aliments

FOOD SAFETY ACTION PLAN

REPORT

2011-2012 TARGETED SURVEYS - CHEMISTRY

Ochratoxin A in Selected Foods

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Executive Summary

The Food Safety Action Plan (FSAP) aims to modernize and enhance Canada's food safety system. As a part of the FSAP enhanced surveillance initiative, targeted surveys are used to examine various foods for specific chemical and microbiological hazards.

This targeted survey focussed on the natural toxin, ochratoxin A (OTA), which can contaminate grains during grain storage. As OTA is heat-stable, if present, finished foods may still contain detectable levels of OTA despite being substantially processed. OTA has been classified as a possible human carcinogen by the International Agency for Research on Cancer.

The main objectives of this survey were to:

- establish baseline surveillance data for OTA 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);
- compare OTA levels in these specific commodities relative to Health Canada's Bureau of Chemical Safety's proposed maximum levels for OTA; and
- compare the prevalence of OTA 2011-2012 with the prevalence in the 2009-2010 and 2010-2011 CFIA FSAP OTA and DON surveys, where applicable.

A total of 1290 samples were analyzed for the presence of OTA. These samples included infant foods (98 infant formulas and 59 infant cereals), milled grain products (126 "other grain" products e.g., quinoa, buckwheat, 102 wheat products, 73 corn products, and 31 oat products), processed cereal products (193 breads/baked goods/crackers, 155 breakfast cereals, and 150 beer) and other foods (198 soy products and 105 dried fruits).

Fifty-six percent of the samples did not contain detectable levels of OTA. The samples with detectable levels of OTA were from all types of products included in this survey. OTA levels ranged from 0.040 parts per billion (ppb) to 28.55 ppb. The OTA levels were compared, where applicable, against Health Canada's Bureau of Chemical Safety's proposed maximum levels for OTA. A total of eighteen samples had elevated levels of OTA - fifteen samples exceeded the proposed maximum levels for OTA and three samples for which there are no proposed maximum levels for OTA. The fifteen samples comprised ten infant cereals, two bread/baked goods (one multi-grain crisp bread, one naan bread), one cake and pastry wheat flour, one wheat bran, and one wheat germ) samples. One soy flour sample contained a level of OTA that was elevated relative to other soy products and to similar cereal-based products in the current survey. Two "other grain" products (buckwheat flour and buckwheat, also called kasha), also contained elevated levels of OTA relative to other buckwheat products and commodities in the "other grain" group.

There was no apparent trend in the year-to-year values. Relative to the previous FSAP survey(s), the maximum OTA level in the current survey was lower in infant formula, infant cereals, oat products, and breakfast cereals but higher in wheat products, corn

products, beer, and dried fruit. For “other grain” products, breads/baked goods/crackers and soy products, there was no comparable Canadian data available for comparison and the degree of agreement was variable.

All the data generated were shared with Health Canada’s Bureau of Chemical Safety for use in performing human health risk assessments. Adverse health effects associated with OTA are associated with long-term exposure, thus periodic, short-term exposure to elevated OTA levels in a limited number of foods would not be considered to pose a safety concern.

In the absence of established tolerances or standards for OTA in foods, elevated levels of OTA in specific foods may be assessed by Health Canada’s Bureau of Chemical Safety (BCS) on a case-by-case basis using the most current scientific data available. If BCS identifies a potential safety concern, the Canadian Food Inspection Agency can exercise follow-up actions. Follow-up actions are initiated in a manner that reflects the magnitude of the health concern. Actions may include further analysis, notification of the producer or importer, follow-up inspections, additional directed sampling, and recall of products. Health Canada’s BCS concluded that the levels of OTA found in the productstested in this survey were overall very low and therefore unlikely to pose an unacceptable health risk. Consequently , 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's) Food Safety Action Plan (FSAP) is one element of the government's broader FCSAP initiative. The goal of FSAP is to identify risks in the food supply, limit the possibility that these risks occur, improve import and domestic food controls, and identify food importers and manufacturers.

Within the 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.

The FSSC has ranked mycotoxins (including ochratoxin A (OTA)) 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 OTA and other mycotoxins. Health Canada, which has purview over foods sold in Canada, has conducted surveys of OTA that generally focus on finished foods^{1,2,3,4}. However, the monitoring of finished grain products (whether domestically produced or imported)

available at the retail level is limited. The present 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 OTA 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 BCS 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. These are available on Health Canada's website⁵.

In 2009, Health Canada's BCS proposed maximum levels for OTA in a variety of foods. These MLs as well as an industry guidance value for OTA in unprocessed cereal grains are still under consideration and remain in "proposed" status⁶. The proposed Canadian standards and guidance value for OTA, and the established international maximum levels for OTA in foods are presented in Appendix 1.

In the absence of established tolerances or standards for OTA in foods, elevated levels of OTA in specific foods may be assessed by Health Canada's BCS on a case-by-case basis using the most current scientific data available. If BCS identifies a potential safety concern, the Canadian Food Inspection Agency can exercise follow-up actions. Follow-up actions are initiated in a manner that reflects the magnitude of the health concern. Actions may include further analysis, notification to the producer or importer, follow-up inspections, additional directed sampling, and recall of products.

2. Survey Details

2.1. OTA

Food around the globe has been known to be contaminated with fungi and toxic secondary metabolites of these fungi (mycotoxins) for centuries. These natural toxins are released by moulds which can grow on agricultural products, such as on cereals (e.g. wheat, oats, corn), legumes, nuts and fruit. The type of agricultural product, the degree of 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.

Research has shown that of the hundreds of mycotoxins associated with food, a small fraction have 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 provide guidance on ways to reduce and prevent mycotoxin contamination in cereals (e.g. wheat, corn, oats, barley)⁷. 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)⁷.

OTA is a naturally occurring metabolite of *Aspergillus* and *Penicillium* moulds. Under favourable moisture and temperature conditions, the fungi can grow on stored material and produce OTA⁸. OTA has been widely detected in cereal grains (wheat, corn, oat, and barley), green coffee, grape juice, beer, wines, cocoa, dried fruits, and nuts⁹. OTA is heat-stable and is only partially destroyed under normal cooking or processing conditions^{10,11}.

The International Agency for Research on Cancer (IARC) has classified OTA as a possible human carcinogen based largely on data from animal studies¹². The mechanism by which OTA causes kidney tumours in rodents has yet to be fully elucidated. In animal studies, OTA has also been shown to have effects on the kidneys, the developing fetus, and the immune system. Health Canada's BCS completed a risk assessment for OTA, and as a result, has proposed maximum levels for OTA in various food commodities¹³ as well as an industry guidance value for OTA in unprocessed cereal grains⁶.

2.2. Rationale

The CFIA does not regularly monitor for the presence of OTA 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 the presence of mycotoxins, pesticides, and certain metals, but does not have jurisdiction over finished or imported grain products. Mycotoxins, including OTA, 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 BCS has conducted some targeted surveys of OTA in certain finished foods^{1,2,3,4}. Therefore, it was deemed appropriate to conduct a larger survey of finished foods available in Canada over multiple years through the CFIA FSAP project. Previous FSAP Ochratoxin A and Deoxynivalenol (OTA/DON) surveys conducted by the CFIA have focused on minimally processed grain products. This survey supplements data generated in previous surveys by looking for OTA in domestic and imported infant formula, beer, dried fruit, soy products, and milled grain products. The

* 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.

possible presence of OTA in infant formula is of particular interest, as it may be the sole food source for infants in the first months of life.

2.3. Sample Overview

The current FSAP targeted survey on OTA 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 OTA levels in food products that may contribute significantly to OTA 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 1290 samples were tested for OTA. The 1290 samples were separated into four product categories (infant foods, milled grain products, processed cereal products, and other food products). Infant foods (157 samples) included infant formula and infant cereals, including soy-based infant formula and infant cereals. Milled grain products (332 samples) included products derived from wheat, corn, oats and “other” grains (e.g. quinoa, buckwheat). Processed cereal products (498 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), soy 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 1290 samples tested for OTA, 640 were domestic samples, 553 were imported products, and 97 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 Formula	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	6	2	31
Processed Cereal Products	Breads/Baked Goods/Crackers	170	21	2	193
	Breakfast Cereals	86	58	11	155
	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 an ISO17025 accredited laboratory under contract with the Government of Canada.

The analytical method used for OTA analysis was based on CFIA laboratory methods. The method is a liquid chromatography-tandem mass spectrometry (LC-MS-MS) method specific for OTA. The limit of detection (LOD) was 0.04 for all matrices tested.

2.5. Limitations

This survey was designed to provide a snapshot of the prevalence and levels of OTA 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 1290 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 OTA 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 OTA Results

All product categories and product types had samples with a detectable level of OTA. Within a given product type, the percentage of samples with a detectable level of OTA ranged from 2% in infant formula to 87% in breads/baked goods/crackers. Figure 1 shows the number of samples analyzed for OTA by product type.

Of the 1290 samples analyzed, 716 (56%) did not have a detectable level of OTA. The level of OTA in the remaining 574 samples ranged from 0.040 ppb to 28.550 ppb. Eighteen samples (nine infant cereal, two "other grain" products (buckwheat flour and buckwheat (kasha)), two bread/baked goods (one multi-grain crisp bread, one naan bread), one wheat flour, one wheat bran, one soy flour, and one wheat germ) had an elevated level of OTA. Results were considered elevated if they exceeded its corresponding proposed Canadian maximum level (ML) for OTA (see Appendix 1 for details)[†] or if the level observed was notably higher than for similar products in this dataset. The lowest OTA levels were associated with infant formula, while the highest OTA levels were associated with some milled grains and wheat products (see section 3.2 for more detailed information regarding the OTA levels in particular product categories and types). Figure 2 below presents OTA level by product type in order of increasing OTA concentration.

[†] There is no existing or proposed maximum level for OTA in beer or soy products; however, the values were compared to the proposed maximum levels for derived cereal products for comparison and information only.

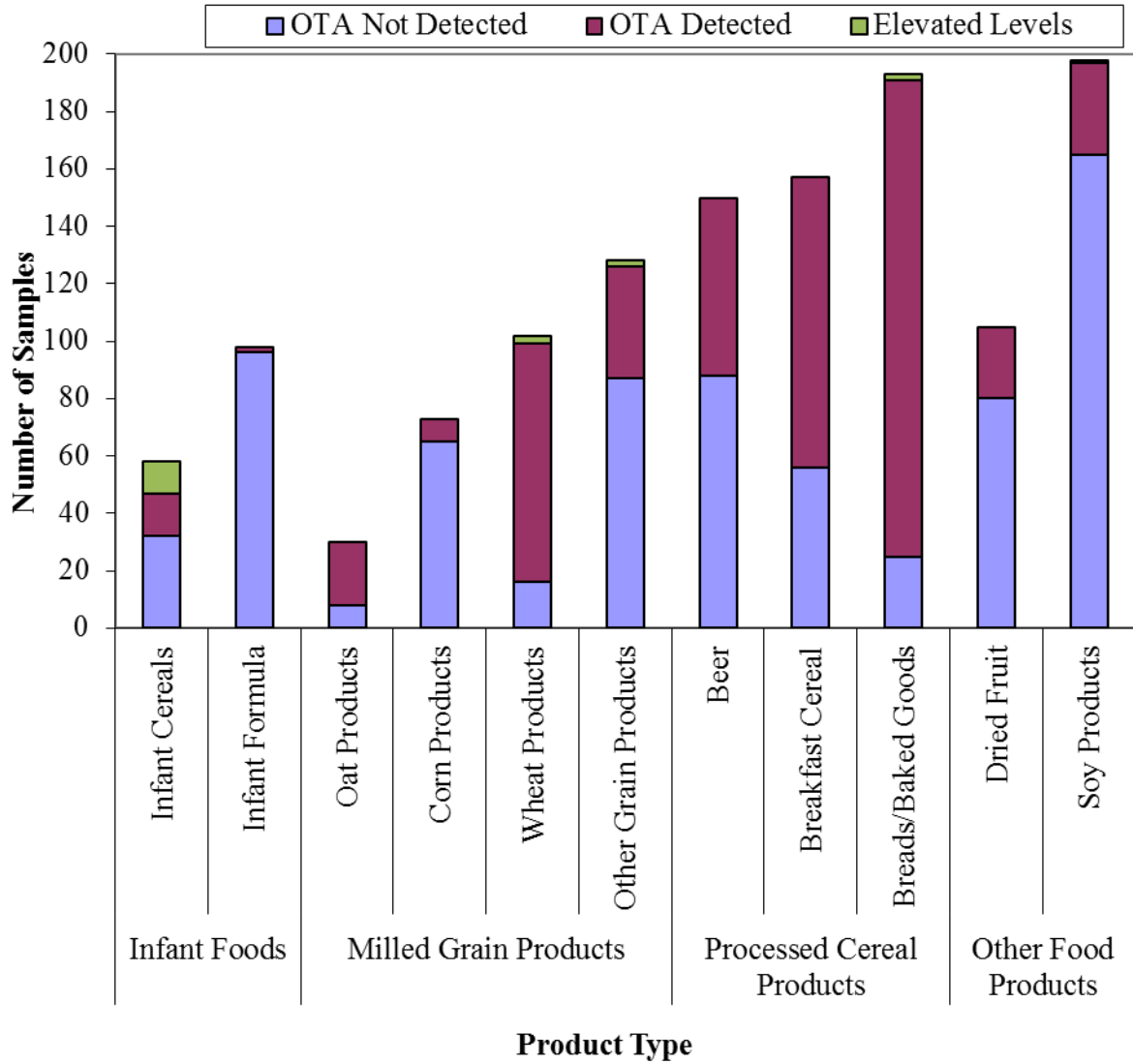
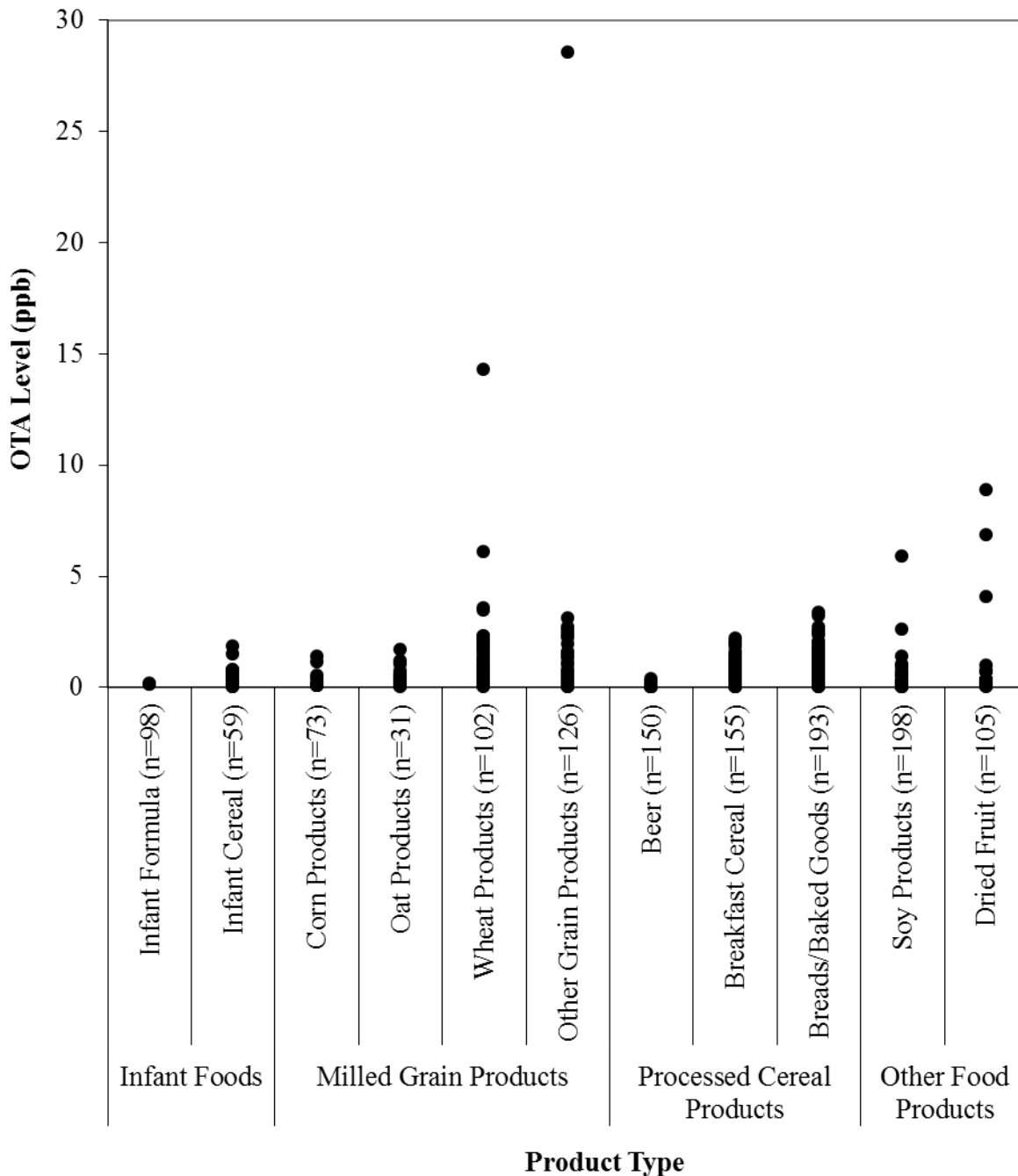


Figure 1. Number of samples analyzed for OTA by product type (in order of increasing number of samples per product category)



Note: Only values above the limit of detection are displayed in the graph

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

Details about the sample type, the level of OTA detected, and the rationale for being considered elevated are provided in Table 2 for the eighteen elevated samples. The results for the eighteen elevated samples, along with the entire dataset, were forwarded to Health Canada’s BCS for a safety assessment. Adverse health effects associated with OTA are

associated with long-term exposure. Periodic, short-term exposures to elevated OTA levels in a limited number of foods would not be considered to pose a safety concern. Health Canada's BCS is of the opinion that the levels of OTA in the products tested in this survey are very low overall and therefore unlikely to pose an unacceptable health risk. The following sections present the analysis results for OTA in each of the eleven product types.

Table 2. Summary of elevated OTA results by product type

Category	Product Type	Sample Type	Level of OTA (ppb)	Rationale for being considered elevated
Infant Foods	Infant Cereal	Oat	1.850	Exceeds BCS's proposed maximum level of 0.5 ppb OTA in cereal-based foods for infants and young children ⁶
			1.472	
			0.758	
			0.689	
			0.682	
			0.537	
		Mixed Grain	0.757	
			0.721	
Barley	0.549			
	0.543			
Milled Grain Products	Other Grain Products	Buckwheat Flour	28.550	Exceeds BCS's proposed maximum level of 3 ppb OTA for cereal-derived products ⁶
		Buckwheat (Kasha)	3.092	Exceeds BCS's proposed maximum level of 3 ppb OTA for directly consumed grains ⁶
	Wheat products	Wheat Bran	14.300	Exceeds BCS's proposed maximum level of 7 ppb OTA in wheat bran ⁶
		Wheat Germ	6.113	Exceeds BCS's proposed maximum level of 3 ppb OTA cereal-derived products ⁶
		Flour	3.543	Exceeds BCS's proposed maximum level of 3 ppb OTA cereal-derived products ⁶
Processed Cereal Products	Breads/ Baked Goods/ Crackers	Naan Bread	3.335	Exceeds BCS's proposed maximum level of 3 ppb OTA for cereal-derived products ⁶
		Multi-grain Crisp Bread	3.183	Exceeds BCS's's proposed maximum level of 3 ppb OTA for cereal-derived products ⁶
Other Food Products	Soy Products	Soy Flour	5.897	No proposed maximum levels for this product type ⁶ ; highest level observed for soy products in this survey

3.2 OTA Results by Product Type

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

3.2.1 OTA in Infant Foods

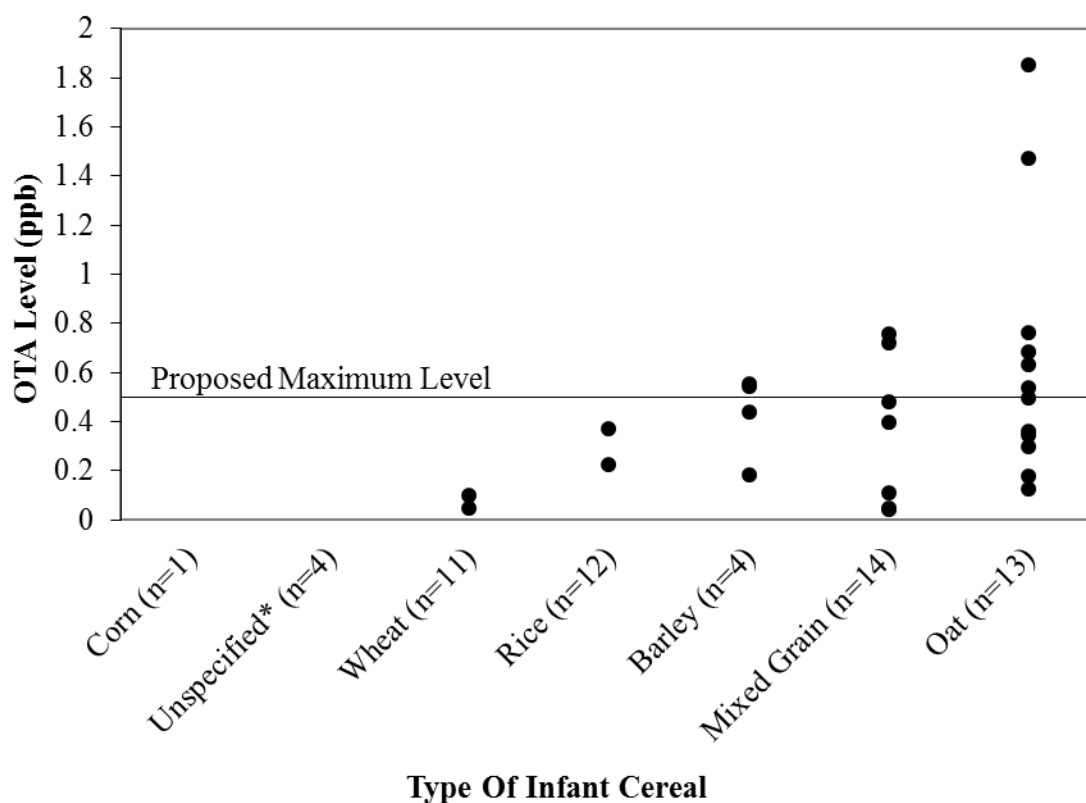
The infant foods category included formulas and cereals. This product category was associated with the lowest OTA levels. OTA was detected in 28 of the 157 samples tested (18%). All of the infant formula samples and 83% of the infant cereal samples tested were below the Canadian proposed maximum level of 0.5 ppb OTA in baby foods and processed cereal-based foods for infants and young children. It was determined that none of the samples tested, including those exceeding the proposed maximum levels, were considered likely to pose a concern to human health. No follow up activity was warranted given the lack of a health concern.

3.2.1.1 OTA in Infant Formula

Ninety-eight samples of dairy-based and soy-based infant formula (powdered, liquid concentrate, and ready-to-serve) were tested for OTA. The infant formula samples included iron fortified, low iron, nutritional supplement, omega-3/omega-6, and calcium-enriched formulas (as available in the marketplace). OTA was not detected in any of the 93 milk-based formulas. Two of the five soy-based infant formulas had an OTA level of 0.134 ppb and 0.190 ppb, respectively, which was well below the applicable proposed maximum level of 0.5 ppb.

3.2.1.2 OTA 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 OTA. Twenty-six of the 59 (44%) infant cereal samples tested positive for OTA, with levels ranging from 0.041 ppb to 1.85 ppb. Ten samples (16%) of infant cereal had a level of OTA above the proposed OTA maximum level of 0.5 ppb in baby foods and processed cereal-based foods for infants and young children. Figure 3 below presents the OTA results by grain type in infant cereals. The highest OTA levels were associated with oat, barley, and mixed grain cereals.



* Products classified as “unspecified” were identified only as “infant cereal”. : Only values above the limit of detection are displayed in the graph. Corn, unspecified, nine samples of wheat cereal, ten samples of rice cereal, seven samples of mixed grain cereals, and one sample of oat cereal did not contain detectable levels of OTA.

Figure 3. OTA levels in infant cereals by grain type

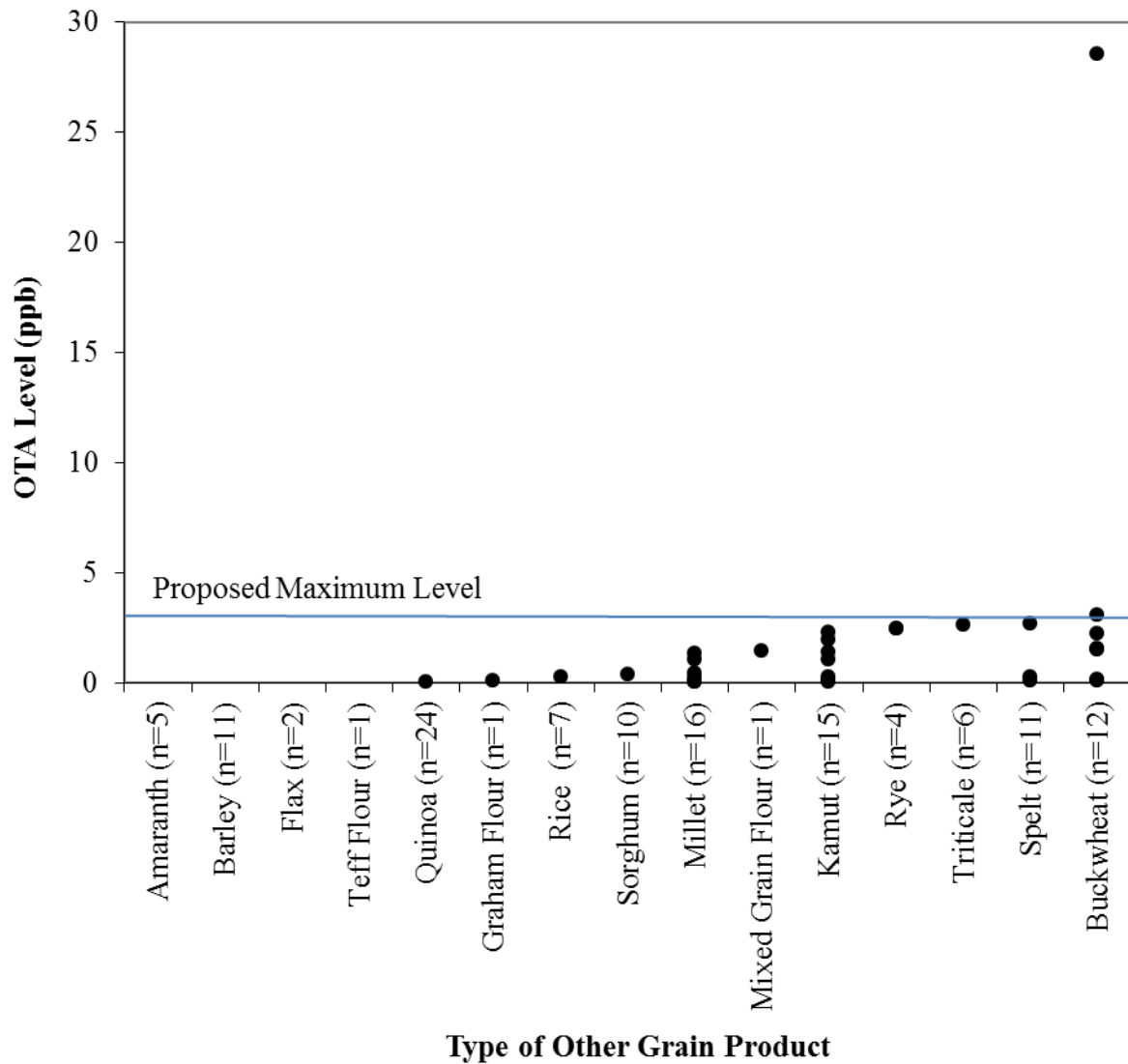
3.2.2 OTA in Milled Grain Products

Milled grain products included milled grains, flours, brans, germs, and meals of wheat, corn, oats and other grains (e.g. buckwheat, quinoa). This product category was associated with the highest maximum OTA level. OTA was detected in 41% of the samples tested. The lowest (0.041 ppb) and highest (28.55 ppb) OTA levels were associated with other grain products. However, OTA prevalence, which was measured as the percentage of positive samples, decreased in the following order: wheat (85%), oats (73%), other grains (16%), and corn (11%). All of the corn and oat product samples (100%), 98% of the other grain products, and 97% of the wheat products were below the Canadian proposed maximum levels (3 ppb OTA for cereal-derived products and directly consumed cereal grains; 7 ppb for wheat bran). Note that the proposed Canadian maximum level of 3 ppb OTA in cereal-derived products applies specifically to wheat, barley, oats, and rice, which are the cereal grains included in the Kuiper-Goodman (2010) risk assessment.⁸ The levels of OTA in milled products were evaluated by Health Canada’s BCS 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 OTA in Other Grain Products

Samples of other grains 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. Twenty-one of the 126 (17%) other grain products had a detectable level of OTA, ranging from 0.041 ppb to 28.550 ppb. One sample of buckwheat flour (28.550 ppb) exceeded the proposed maximum level of 3 ppb for cereal-derived products and one buckwheat/kasha sample (3.092 ppb) exceeded the proposed maximum level of 3 ppb for directly consumed grains.

Figure 4 provides a summary of OTA results in other grain products. OTA was not detected in amaranth products, barley products, flax products, and teff flour. Of all the other grain products tested, buckwheat, spelt, and triticale products had the highest maximum levels of OTA.

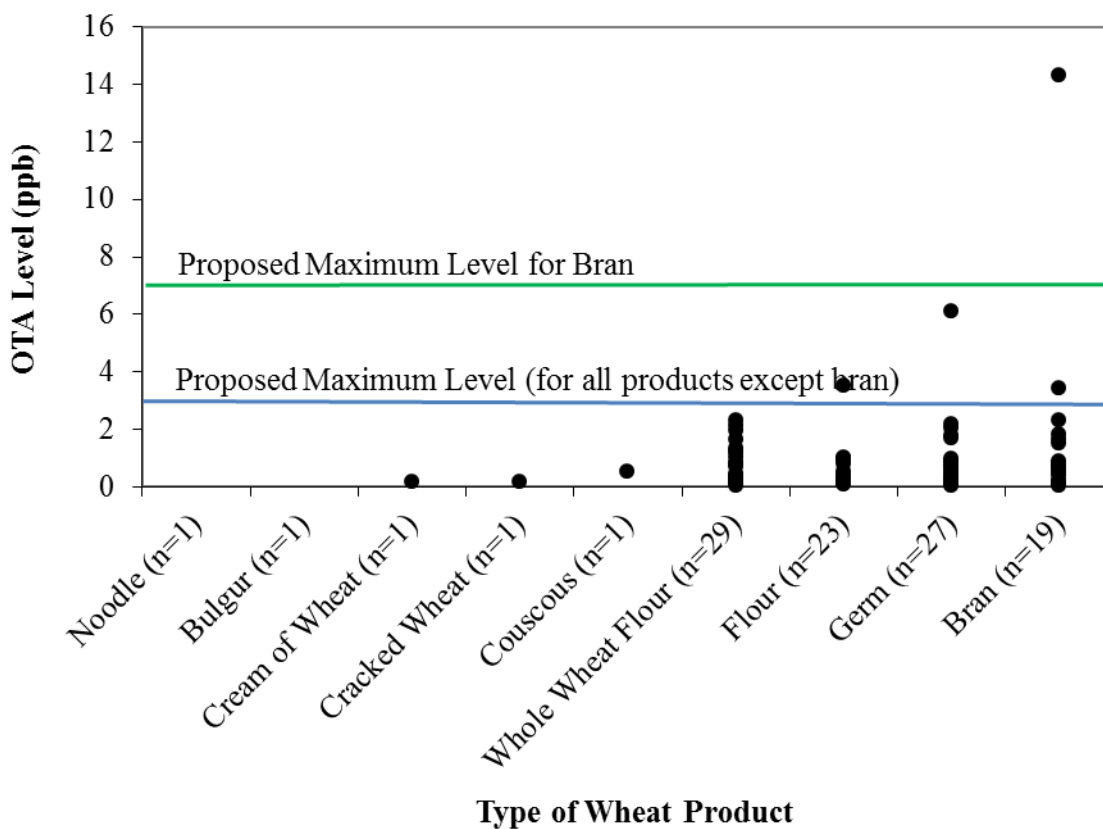


Note: Only values above the limit of detection are displayed in the graph

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

3.2.2.2 OTA in Wheat Products

Wheat products included wheat bran, wheat germ, bulgur, couscous, cracked wheat, cream of wheat, noodles, and flours. Eighty-six of the 102 wheat product samples tested (84%) had a detectable level of OTA, with values ranging from 0.042 ppb to 14.300 ppb. One sample of wheat bran exceeded the proposed maximum level of 7 ppb for wheat bran. One sample of white flour exceeded the proposed maximum level of 3 ppb OTA in cereal-derived products, such as flour. One sample of wheat germ exceeded the 3 ppb limit for OTA in cereal-derived products. Figure 8 below presents the OTA results by type of wheat product.

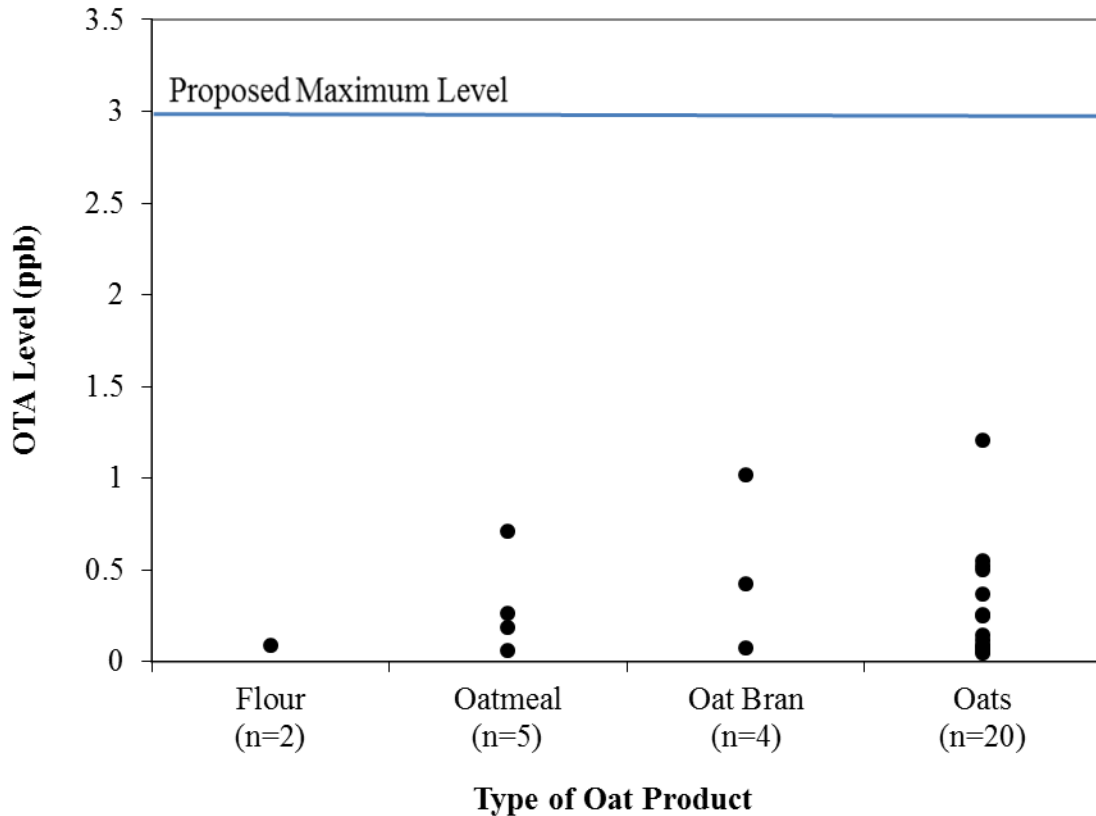


Note: Only values above the limit of detection are displayed in the graph. Noodles, bulgur wheat, six samples of whole wheat flour, four samples of flour, three samples of wheat germ, and one sample of wheat bran did not contain detectable levels of OTA.

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

3.2.2.3 OTA in Oat Products

Oat products included oat flour, oatmeal, bran, and oats (e.g., steel cut, rolled). Twenty-two of the 31 (71%) oat product samples had a detectable level of OTA, ranging from 0.042 ppb to 1.206 ppb. None of the oat products had an OTA level in excess of the applicable proposed Canadian maximum level of 3 ppb. Figure 6 presents the OTA results by type of oat product.

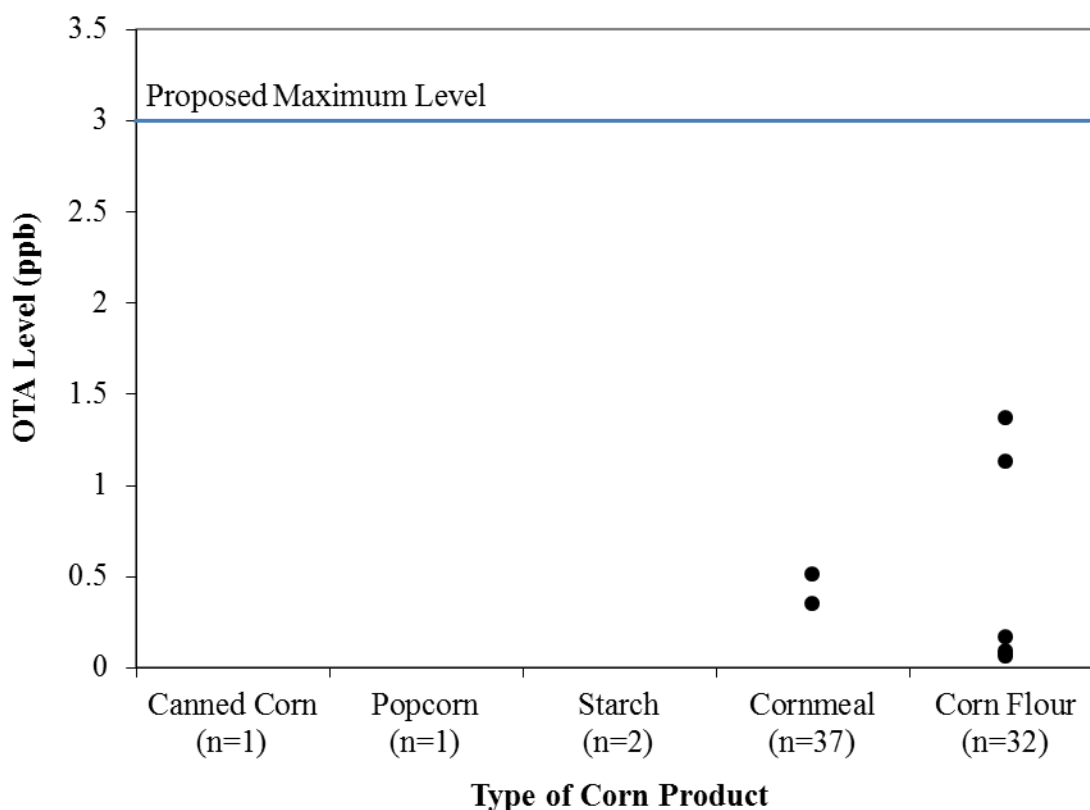


Note: Only values above the limit of detection are displayed in the graph. One sample of oat flour, one sample of oatmeal, one sample of oat bran, and six samples of oats did not contain detectable levels of OTA.

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

3.2.2.4 OTA in Corn Products

Corn products included canned corn, popcorn (popped and unpopped), corn starch, cornmeal, and flour. Eight of the 73 corn product samples (11%) had a detectable level of OTA, ranging from 0.062 ppb to 1.366 ppb. Although there is no proposed Canadian maximum level for OTA in corn products, for comparative purposes these results are below the maximum level of 3 ppb OTA in cereal-derived products. Figure 7 presents the OTA results by type of corn product. The highest OTA levels were associated with the dried/ground whole corn products (cornmeal and corn flour).



Note: Only values above the limit of detection are displayed in the graph. Canned corn, popcorn, corn starch, 35 samples of cornmeal, and 26 samples of corn flour did not contain detectable levels of OTA.

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

3.2.3 OTA in Processed Cereal Products

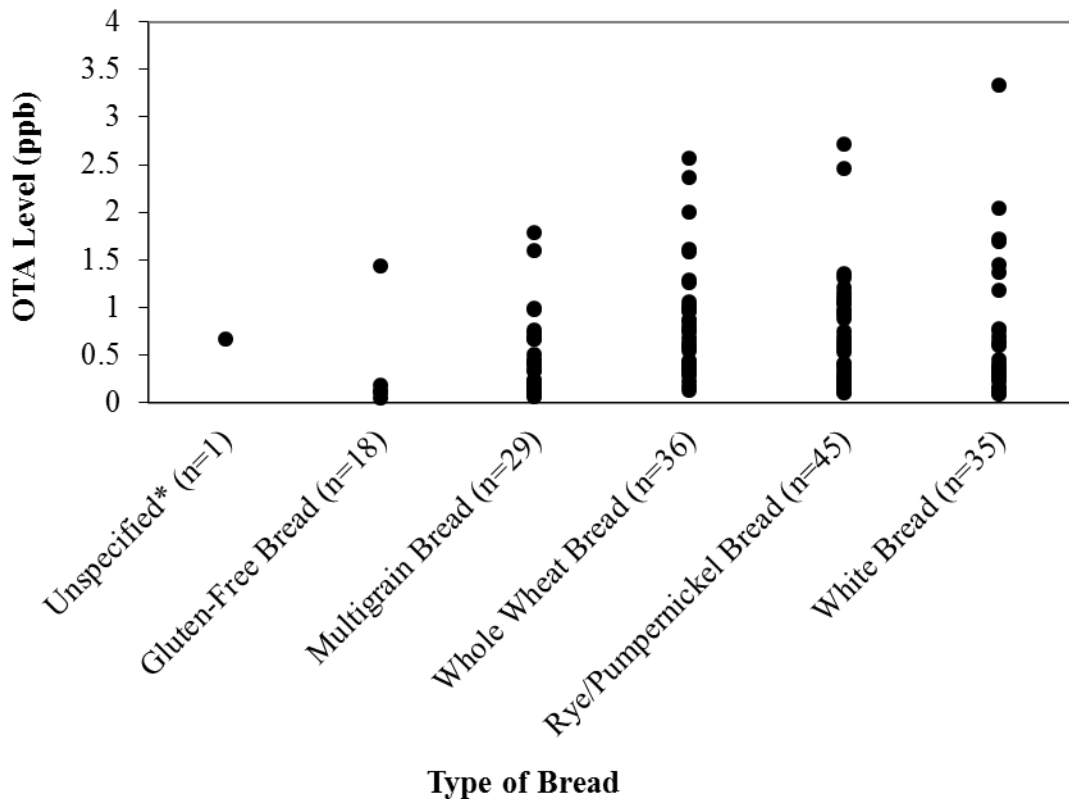
Processed cereal products included breakfast cereals, breads, baked goods, crackers, and beers. This product category was associated with the highest prevalence of OTA (66%). However, the maximum OTA level in this product category was 3.335 ppb, which is much lower than the maximum level in milled cereal products (28.55 ppb). The OTA prevalence, measured as percentage of positive samples, was found to be in the following order: crackers and crisp breads (100%), bread (88%), baked goods (68%), breakfast cereals (64%), and beer (41%). The maximum level for these product types would fall into the category of cereal-derived products, for which there is a proposed Canadian maximum levels for OTA of 3 ppb. The levels of OTA 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 OTA in Breads/Baked Goods/Crackers

In total, 193 breads and baked goods were sampled and analyzed for OTA. Bread samples included toast/sandwich bread (white, whole wheat, rye/pumpernickel, gluten-

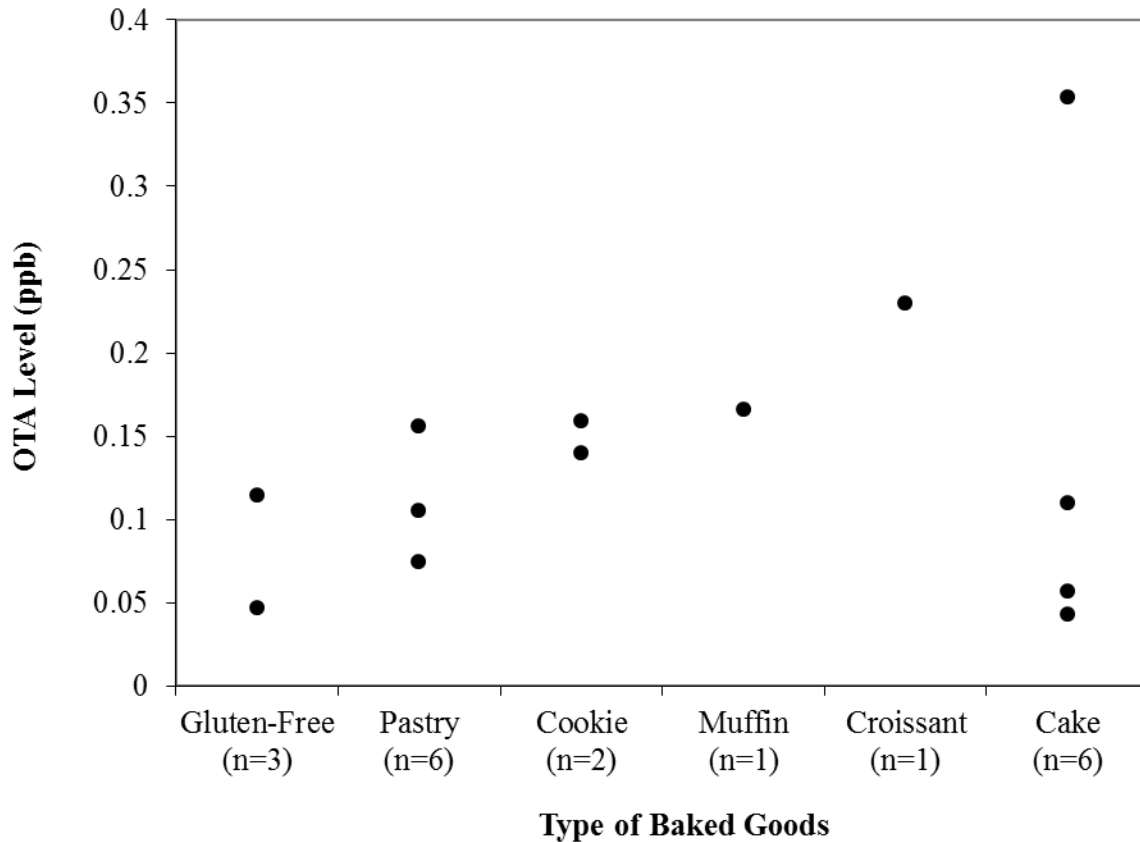
free), buns, bagels (white, whole wheat, multigrain), English muffins (white and whole wheat), pita bread (white/wheat and whole wheat), tortillas (white/wheat, whole wheat, and multigrain), and naan bread. Baked goods included cakes, cookies, croissants, muffins, and pastries, and included some gluten-free products, as well. Crackers (e.g. soda crackers) also included crisp breads. In total, 168 of the 193 (87%) breads/baked goods/crackers sampled had a detectable level of OTA, ranging from 0.043 ppb to 3.335 ppb. The baked goods generally had much lower levels of OTA than bread or cracker samples. One sample of naan bread (3.335 ppb) and one sample of multigrain crisp bread (3.183 ppb) were considered to have an elevated OTA level relative to other products in this category. Figures 8, 9, and 10 illustrate the OTA levels observed in relation to the grain type in breads, in baked goods, and crackers and crisp breads, respectively.

There is a proposed maximum level of 3 ppb for OTA in cereal-derived products such as flour and finished foods.



* Unspecified designate a products labelled only as “bread”. Only values above the limit of detection are displayed in the graph. Thirteen samples of gluten-free bread, one sample of multigrain bread, three samples of rye bread, and two samples of white bread did not contain detectable levels of OTA.

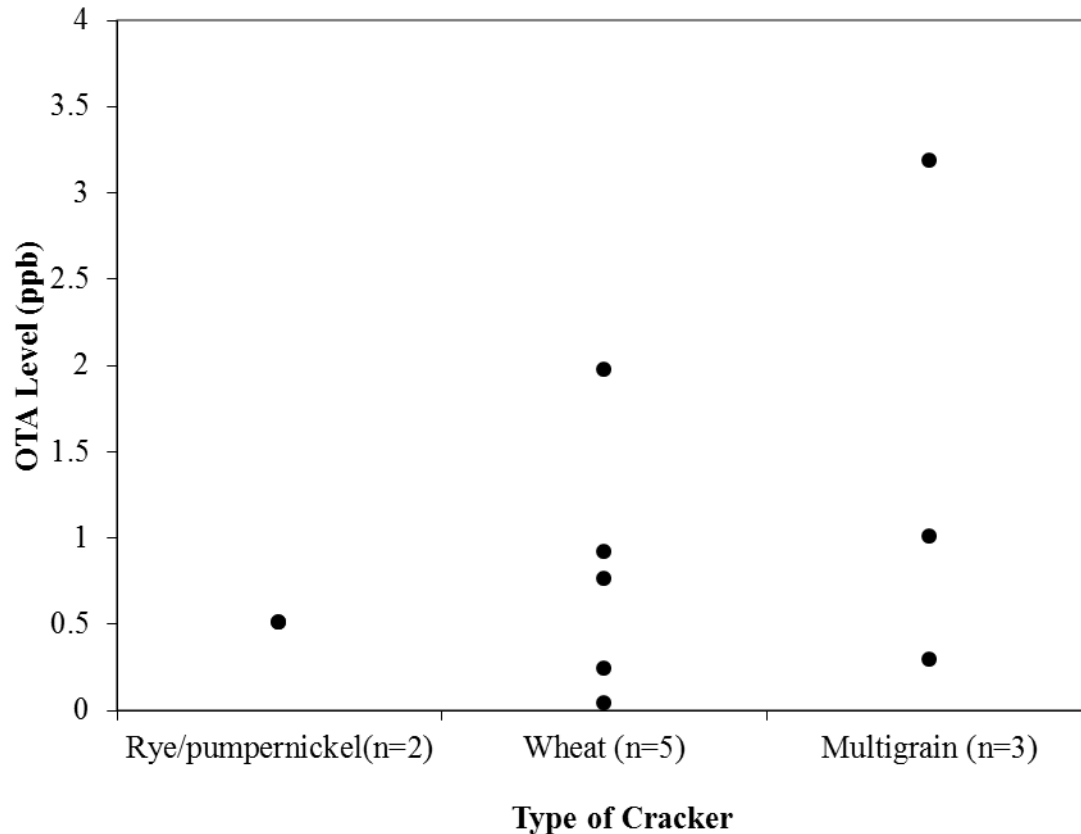
Figure 8. OTA levels in breads by grain type (arranged in order of increasing maximum OTA level per product)



Note: Only values above the limit of detection are displayed in the graph. One sample of gluten-free baked goods, three samples of pastry, and two samples of cake did not contain detectable levels of OTA.

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

Within the bread and the baked goods category, gluten-free products were associated with the lowest OTA levels. In the breads category, the most elevated OTA levels were detected in samples of white breads. In baked goods, the highest OTA levels were observed in cakes. Most baked goods (16/19 samples) were made with wheat flour. The remaining baked goods were gluten-free (3 samples). Amongst the crackers, rye/pumpernickel crackers and crisp breads had the lowest OTA levels while multigrain crackers and crisp breads had the highest OTA levels. There was no clear relationship between grain type and OTA levels in these types of products.

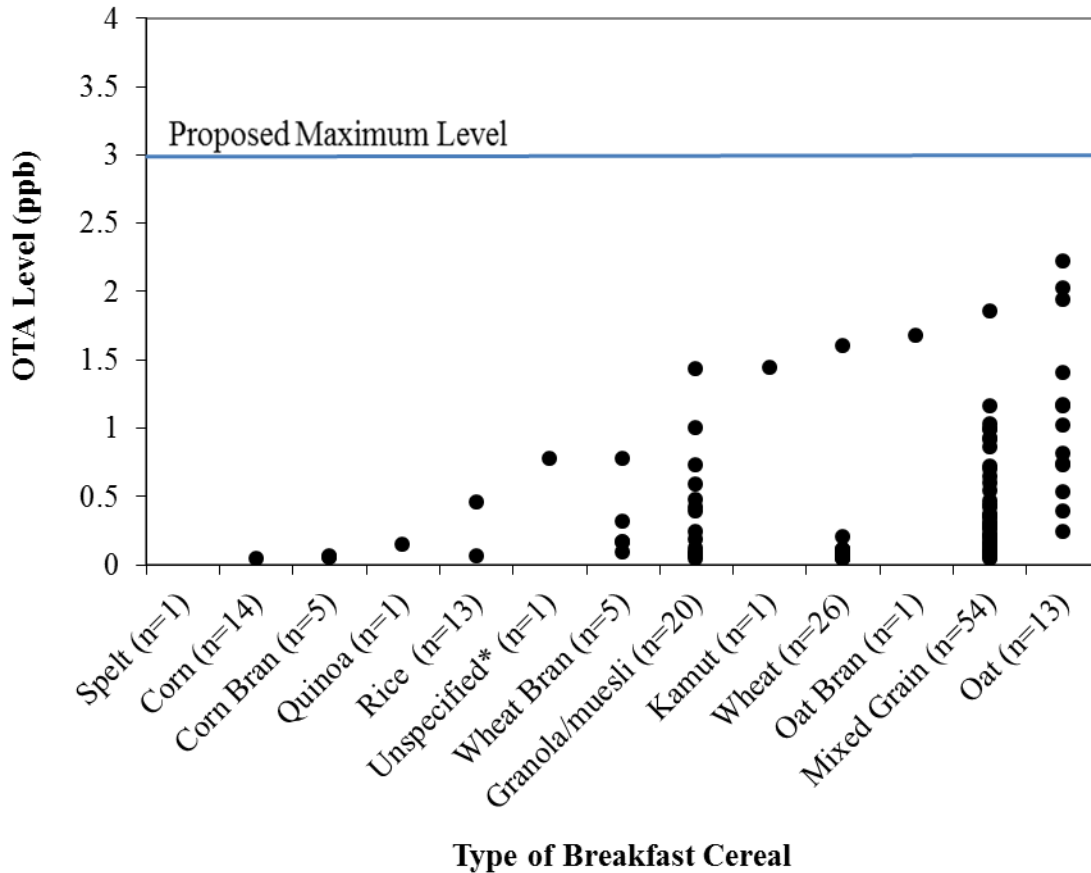


Note: Only values above the limit of detection are displayed in the graph.

Figure 10. OTA levels in crackers and crisp breads by grain type (arranged in order of increasing maximum OTA level per product)

3.2.3.2 OTA in Breakfast Cereals

Breakfast cereals included single grain (wheat, corn, rice, oats, etc.), and mixed grain (granola, muesli) cereals targeted both at adults and at children. In total, 100 of the 155 (65%) breakfast cereal samples tested had a detectable level of OTA. The OTA levels ranged from 0.041 ppb to 2.219 ppb. One sample of spelt, 13 samples of corn, two samples of corn bran, 11 samples of rice, five samples of granola/muesli, 11 samples of wheat, and 12 samples of mixed grain breakfast cereals did not contain detectable levels of OTA. All of the breakfast cereals positive for OTA had a level below the Canadian proposed maximum level for OTA in cereal-derived products (3 ppb). Figure 11 presents the OTA results by type of breakfast cereal product. The lowest OTA levels were associated with spelt-based and corn/corn bran-based breakfast cereals. The highest OTA levels were associated with oat-based breakfast cereals.



* Unspecified designated products labelled only as “breakfast cereal”.
 Note: Only values above the limit of detection are displayed in the graph.

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

3.2.3.4 OTA in Beer

One hundred fifty beer samples were analyzed in this survey, including major domestic and imported beer brands, along with beers 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. OTA was detected in 62 of the 150 (41%) beer samples, with levels ranging from 0.040 ppb to 0.396 ppb. The levels of OTA in beer were generally low. There was no apparent relationship between OTA level and style of beer or country of origin.

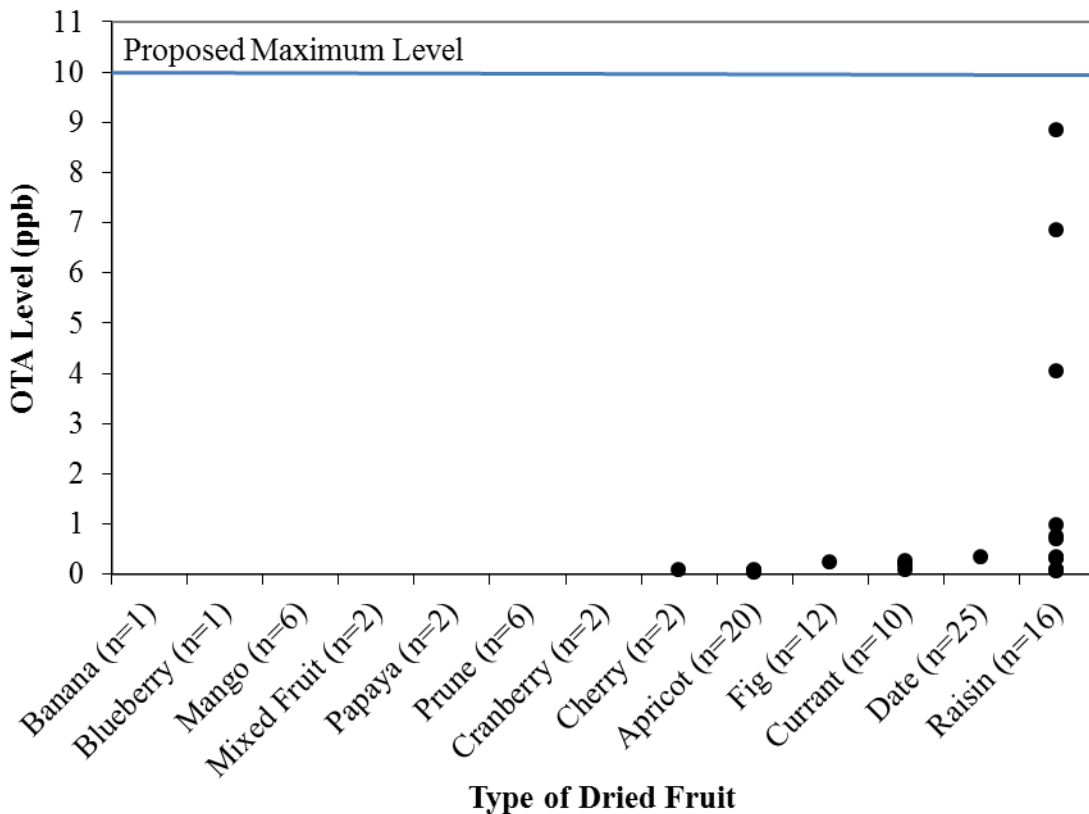
3.2.4 OTA in Other Food Products

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 OTA (19%). The maximum OTA level in this product category was 8.849 ppb, which is higher than the maximum OTA level in processed cereal products (3.335 ppb) but lower than the maximum level in milled cereal products (28.55 ppb). The prevalence of OTA, measured as percentage of positive samples, was lower in soy

products (17%) than in dried fruits (24%). The levels of OTA in other food products were evaluated by Health Canada’s BCS and were considered unlikely to pose a concern to human health. No follow up activity was warranted given the lack of a health concern.

3.2.4.1 OTA in Dried Fruits

Dried fruits included apricot, banana, blueberry, cherry, mango, cranberry, currants, date, fig, mixed fruits, papaya, prune, and raisins. Twenty-five of the 105 dried fruit samples (24%) had a detectable level of OTA, ranging from 0.041 ppb to 8.849 ppb. OTA was not detected in dried banana, blueberry, cranberry, mango, mixed fruits, papaya, and prune samples. There is a proposed maximum level of 10 ppb for OTA in dried vine fruit (currants, raisins, sultanas) which would apply to some of the samples tested herein. None of the dried vine fruit tested had an OTA level in excess of the proposed Canadian limit. With respect to the dried fruits other than vine fruit tested in this survey, the maximum OTA level observed was 0.326 ppb (which is, for comparison purposes only, almost 30-fold below the proposed maximum level of OTA for vine fruit). Figure 12 below presents a summary of OTA results by type of dried fruit.

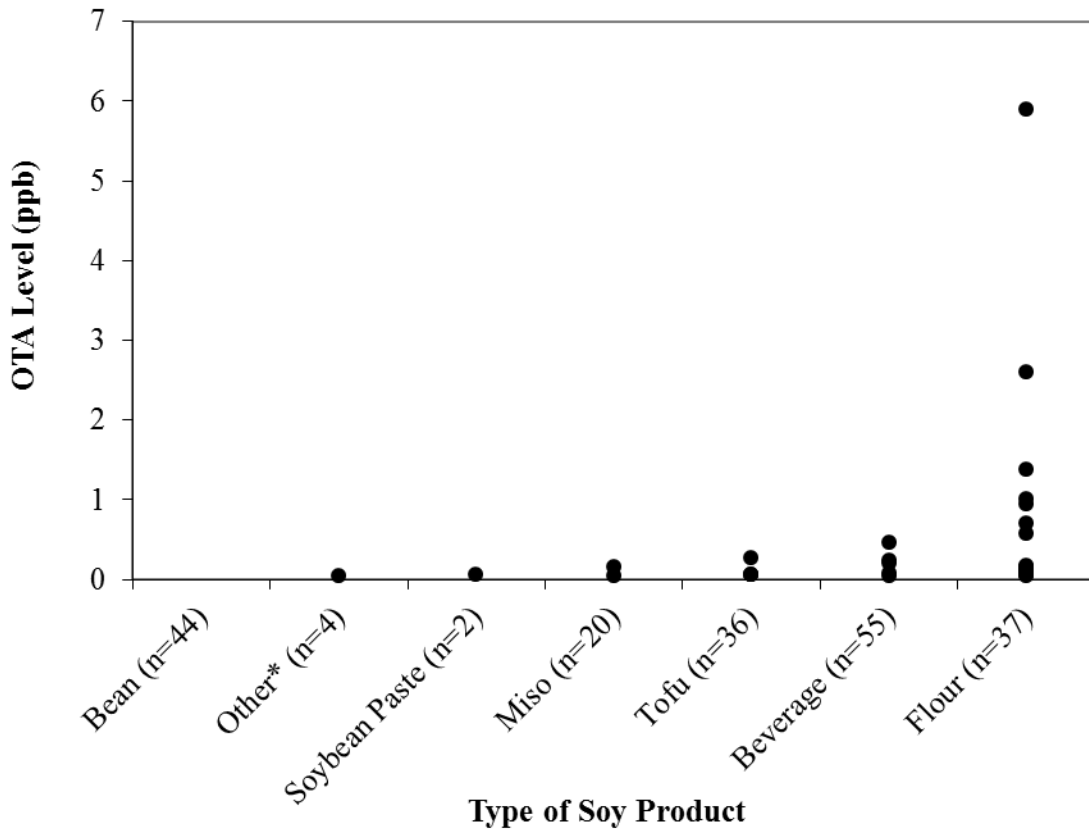


Note: Only values above the limit of detection are displayed in the graph. Banana, blueberry, mango, mixed fruit, papaya, prune, cranberry, cherry (1 sample), apricot (14 samples), fig (11 samples), currant (6 samples), date (24 samples), and raisin (4 samples) did not contain detectable levels of OTA.

Figure 12. OTA levels by type of dried fruit (arranged in order of increasing maximum OTA level per product)

3.2.4.2 OTA in Soy Products

The soy product samples included beverages (e.g. soy milk), soybeans (frozen, dried or canned), flour, tofu, miso, soybean paste, and four samples of other soy products (meal replacement, powder, pudding, and spread). Thirty-three of the 198 (17%) soy product samples tested had a detectable level of OTA. The OTA levels ranged from 0.041 ppb to 5.897 ppb (see Figure 13 below). There are no specific Canadian maximum levels established or proposed for OTA in soy products. With the exception of four soy flours, soy products positive for OTA had a level below 1 ppb. One soy flour sample had a level of OTA (5.897 ppb) that was considered elevated relative to levels in other soy products in this survey. This soy flour was evaluated by Health Canada's Bureau of Chemical Safety and was considered unlikely to pose a concern to human health.



* Other includes soy-based meal replacement, soy powder, soy pudding and soy spread.

Note: Only values above the limit of detection are displayed in the graph. Soybeans (all samples), Other (3 samples), soybean paste (1 sample), miso (18 samples), tofu (32 samples), beverage (50 samples), and flour (17 samples) did not contain detectable levels of OTA.

Figure 13. OTA levels in soy products (arranged in order of increasing maximum OTA level per product)

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

The results of this survey were compared to the results of previous CFIA FSAP OTA/DON surveys carried out in 2009-2010¹⁴ and 2010-2011¹⁵, and to relevant scientific literature in the absence of previous FSAP data. OTA is a toxin that predominately forms under specific conditions during storage. Given that the samples in this survey were picked up at retail, the history of the product with respect to storage, as well as the storage of the product's ingredients prior to being incorporated into the finished food could not be determined.

There was no apparent trend in the year-to-year values. Relative to the previous FSAP survey(s), the maximum OTA level in the current survey was lower in infant formula, infant cereals, oat products, and breakfast cereals but higher in wheat products, corn products, beer, and dried fruit.

3.3.1 Infant Foods

Table 3 focuses on OTA levels in infant foods. In the selected studies, most samples of infant formula did not contain detectable levels of OTA. The maximum levels of OTA in both infant formula and infant cereals in the current survey are within the range of the results reported in previous FSAP surveys.

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

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum OTA Level (ppb)	Maximum OTA Level (ppb)	Average OTA Level (ppb)
Infant Formula						
CFIA Survey	2011-2012	98	2 (2)	0.134	0.190	0.162
	2010-2011	98	3 (3)	0.063	0.370	0.192
	2009-2010	75	1 (1)	-	0.4	-
Infant Cereals						
CFIA Survey	2011-2012	59	26 (44)	0.041	1.85	0.465
	2010-2011	93	26 (28)	0.043	1.587	0.343
	2009-2010	75	19 (25)	0.3	4.1	0.82

Note: For the 2010-2011 and 2011-2012 CFIA surveys, the limit of detection (LOD) was 0.04 ppb for all matrices tested. For the 2009-2010 CFIA survey, the reporting limit was 0.3 ppb. Only the detectable values of OTA were included in the calculation of the minimum, maximum and average OTA levels.

3.3.2 Milled Grain Products

Table 4 presents the comparison of OTA levels in milled grain products. The “other grains” category encompasses a number of different types of grain products. The cited

JECFA[‡] report included the widest variety of other grain products (barley, buckwheat, rice, rye, spelt, and sorghum). Other studies in the scientific literature focused on one or two grain types, resulting in much variability in the OTA levels reported in Table 4 from various literature sources. The maximum level of OTA in other grain products in this survey does fall within the range of levels reported by JECFA and some of the other scientific literature. With the exception of one wheat product sample analyzed in 2011-2012 (14.3 ppb is more than double the next highest level of 6.1 ppb), the OTA levels in the current survey are consistent with the levels observed in similar commodities tested 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 OTA. 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 OTA concentrations in milled grain products

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum OTA Levels (ppb)	Maximum OTA Levels (ppb)	Average OTA Levels (ppb)
Other Grain Products						
CFIA Survey	2011-2012	126	21 (17)	0.041	28.55	1.500
Ibáñez-Vea ¹⁶	2012	123	71 (58)	-	3.53	0.10
Bansal ¹⁷	2011	299	44 (15)	-	0.49	0.12
Aoyama ¹⁸	2010	325	92 (28)	-	2.59	0.40
Matić ¹⁹	2009	2	1 (50)	-	15.9	15.9
Sangare-Tigori ²⁰	2006	43	43 (100)	9	92	64
Čonková ₂₁	2005	35	4 (11)	0	0.038	0.0036
Park ²²	2002	62	4 (6)	0	11	Not reported
Jørgensen ₂₃	2002	320	271 (85)	0.11	68	1.28
JECFA ²⁴	2001	1680	595 (35)	0.017	121.0	1.22
Wheat Products						
CFIA Survey	2011-2012	102	86 (84)	0.042	14.3	0.973
	2010-2011	96	90 (94)	0.044	6.773	0.907
	2009-2010	75	22 (29)	0.3	3.5	1.1
Oat Products						
CFIA Survey	2011-2012	31	22 (71)	0.042	1.206	0.391
	2010-2011	17	13 (76)	0.042	0.735	0.233
	2009-2010	25	7 (28)	0.3	8.2	2.6
Corn Products						
CFIA Survey	2011-2012	73	8 (11)	0.062	1.366	0.470
	2010-2011	76	7 (9)	0.047	1.328	0.346
	2009-2010	50	2 (4)	0.5	0.9	0.7

Note: For the 2010-2011 and 2011-2012 CFIA surveys, the limit of detection (LOD) was 0.04 ppb for all matrices tested. For the 2009-2010 CFIA survey, the reporting limit was 0.3 ppb.

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

3.3.3 Processed Cereal Products

Table 5 presents the comparison of OTA levels in processed cereal products. The OTA levels in breads/baked goods/crackers in this targeted survey fall within the range of values reported by JECFA but are higher than in the scientific literature cited. The

maximum OTA level decreased in breakfast cereals and increased in beer by relatively small amounts 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 OTA concentrations in processed cereal products

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum OTA Levels (ppb)	Maximum OTA Levels (ppb)	Average OTA Levels (ppb)
Breads/Baked Goods/Crackers						
CFIA Survey	2011-2012	193	168	0.044	3.335	0.635
Matic ¹⁹	2009	5	1	-	1.81	-
JECFA ²⁴	2001	986	891	0.16	5.54	0.176
Breakfast Cereals						
CFIA Survey	2011-2012	155	100	0.041	2.219	0.460
	2010-2011	197	123	0.040	3.077	0.470
Beer						
CFIA Survey	2011-2012	150	62	0.040	0.396	0.084
	2010-2011	130	29	0.041	0.285	0.080
	2009-2010	50	0	Not detected	Not detected	Not detected

Note: For the 2010-2011 and 2011-2012 CFIA surveys, the limit of detection (LOD) was 0.04 ppb and the limit of quantitation (LOQ) was 0.1 ppb for all matrices tested. For the 2009-2010 CFIA survey, the reporting limit was 0.3 ppb.

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

3.3.4 Other Food Products

Table 6 presents the comparison of OTA levels in other food products. The levels of OTA in dried fruit are higher in the current survey than in the previous FSAP survey. The maximum levels of OTA in soy products are higher 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 soy products than the JECFA study (which examined soy beans and soy sauce only) or the other studies (which examined mainly soy beans, soy meal, and soy beverages), which may account for the difference in maximum values observed.

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

Study Author	Year	Number of Samples	Number (%) of Positive Samples	Minimum OTA Levels (ppb)	Maximum OTA Levels (ppb)	Average OTA Levels (ppb)
Dried Fruit						
CFIA Survey	2011-2012	105	25 (24)	0.042	8.849	1.002
	2010-2011	97	21 (22)	0.049	3.82	0.487
Soy Products						
CFIA Survey	2011-2012	198	33 (17)	0.041	5.897	0.485
Matić ¹⁹	2009	11	2 (18)	3.72	4.88	4.3
Rodrigues ²⁵	2008	72	9 (13)	-	6	3
Government of Hong Kong ²⁶	2006	6	Not reported	-	0.015	0.01
JECFA ²⁴	2001	55	26 (47)	-	0.10	0.06

4. Conclusions

A total of 1290 samples were tested for OTA. Of these samples, 574 samples (44%) had a detectable level of OTA, ranging from 0.040 ppb to 28.550 ppb. Where feasible, sample results were compared against Health Canada’s Bureau of Chemical Safety’s applicable proposed maximum levels for OTA. A total of eighteen samples had elevated levels of OTA - fifteen samples exceeded the proposed maximum levels for OTA and three samples for which there are no proposed maximum levels for OTA. The fifteen samples comprised ten infant cereals, two bread/baked goods (one multi-grain crisp bread, one naan bread), one cake and pastry wheat flour, one wheat bran, and one wheat germ) samples. One soy flour sample contained a level of OTA that was elevated relative to other soy products and to similar cereal-based products in the current survey. Two “other grain” products (buckwheat flour and buckwheat, also called kasha) also contained elevated levels of OTA relative to other buckwheat products and commodities in the “other grain” group.

There was no apparent trend in the year-to-year values. Relative to the previous FSAP survey(s), the maximum OTA level in the current survey was lower in infant formula, infant cereals, oat products, and breakfast cereals but higher in wheat products, corn products, beer, and dried fruit. For “other grain” products, breads/baked goods/crackers and soy products, there was no comparable Canadian data available for comparison and the degree of agreement was variable.

The OTA levels in all samples were assessed by Health Canada's BCS. Adverse health effects associated with OTA are associated with long-term exposure, thus periodic, short-term exposure to elevated OTA levels in a limited number of foods would not be considered to pose a safety concern. Health Canada's BCS concluded that the levels of OTA found in the products tested in this survey were overall very low and therefore unlikely to pose an unacceptable health risk. Health Canada's Bureau of Chemical Safety determined that none of the samples were associated with a human health concern for any population group. No follow up activity was warranted given the lack of a health concern.

5. Appendix 1

Proposed Canadian and established international OTA maximum levels/levels/guidelines in foods

Contaminant	Commodity	Canada† ⁶ (proposed)	United States ²⁷	European Union ²⁸	Codex ²⁹
OTA (ppb)	Raw/unprocessed cereal grains*	5	No maximum levels adopted to date	5	5
	Grains for direct consumption	3		3	No maximum levels adopted to date
	Derived cereal products (e.g. flour, bread, breakfast cereal)	3		3	
	Wheat bran	7			
	Cereal-based foods for infants and young children	0.5		0.5	
	Wheat gluten not sold directly to the consumer			8.0	
	Dried vine fruit (raisins, currants, sultanas)	10		10	
	Ground roasted coffee	-		5	
	Instant coffee	-		10	
	Grape juice and related products (and as ingredients in other beverages)	2		2	
	Wine	-		2	
	Spices, including dried spices: (White and black pepper, nutmeg, ginger, turmeric)	-		15	
	Spices, including dried spices: Capsicum spp. (dried fruits thereof, whole or ground, including chillies,	-		30 ppb until 31/12/2014; 15 ppb from 1/01/2015	

Contaminant	Commodity	Canada†⁶ (proposed)	United States²⁷	European Union²⁸	Codex²⁹
	chilli powder, cayenne and paprika)				
	Spices, including dried spices: Mixtures of spices containing one of the abovementioned spices	-		15	
	Liquorice (Glycyrrhiza glabra, Glycyrrhiza inflata and other species)	-		20	
	Liquorice root, ingredient for herbal infusion	-		20	
	Liquorice extract for use in food in particular beverages and confectionary	-		80	

†Proposed maximum level

*Proposed guidance value, which would not be formally adopted but would be used as an industry guidance value⁶

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