

Food Safety Action Plan

REPORT

2011-2012 Targeted Surveys

Chemistry





Lead in Candy, Chocolate and Cocoa Powder

TS-CHEM-11/12



Table of Contents

| xecutiv | ve Summary | 2 |
|---------|---|--|
| | | |
| 1.1 | | |
| 1.2 | | |
| 1.3 | | |
| Su | | |
| 2.1 | Lead | 5 |
| 2.2 | Rationale | 7 |
| 2.3 | Sample Distribution | 7 |
| 2.4 | | |
| 2.5 | Limitations | 10 |
| Re | sults and Discussion | 10 |
| 3.1 | Overview of Lead Results | 10 |
| 3.2 | | |
| 3.3 | | |
| 3.4 | Cocoa Powder | 15 |
| Co | nclusions | 16 |
| Re | ferences | 17 |
| | Int 1.1 1.2 1.3 Su: 2.1 2.2 2.3 2.4 2.5 Re 3.1 3.2 3.3 3.4 Co | 1.2 Targeted Surveys 1.3 Acts and Regulations Survey Details 2.1 Lead 2.2 Rationale 2.3 Sample Distribution 2.4 Method Details 2.5 Limitations Results and Discussion 3.1 Overview of Lead Results 3.2 Candy 3.3 Chocolate |

Executive Summary

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

The diet as a source of lead exposure is documented on the Health Canada web page which states that: "Lead is a naturally occurring metal found in rock and soil, and also has many industrial applications. Due to both its natural occurrence and long history of global use, lead is present in air, water and soil, as well as in food, drinking water and household dust. Levels of lead in the environment have declined significantly over the past few decades due to the discontinued use of lead in paint, gasoline and the solder used in food cans. Since the phase-out of leaded gasoline and the subsequent reduction of airborne lead, food and drinking water are currently the primary sources of lead exposure to adults within the general population".

Lead is not permitted to be added to foods sold in Canada; however, due to its widespread presence in the environment, it is detected in all foods, generally at very low levels. Lead can enter the food chain through various pathways, such as uptake from soil into plants and from man-made uses (e.g. processing equipment).

Lead levels in meat, dairy products, eggs, honey, fruits and vegetables (processed and fresh) are monitored annually under the Canadian Food Inspection Agency's National Chemical Residue Monitoring Program (NRCMP). The NCRMP does not test finished and/or manufactured foods such as candy, chocolate and cocoa powder, for lead. Therefore, the main objective of the current survey was to generate baseline surveillance data on the level of lead in candy, chocolate and cocoa powders available on the Canadian retail market.

The 2011-2012 FSAP Lead survey targeted domestic and imported candy, chocolate and cocoa powders. A total of 297 samples were collected from grocery and specialty stores in 11 Canadian cities between April 2011 and March 2012. The samples collected included 24 cocoa powder (intended for baking, not milk/hot chocolate mixes), 124 chocolate (e.g. baking chocolate, chocolate bars, chocolate chips), and 149 candy (e.g. marshmallows, gummy and hard candies, lollipops) samples.

Of the 297 samples analyzed for lead, 118 (40%) did not contain any detectable level of lead. The remaining 179 samples had detectable, low lead levels ranging from 0.0032 to 0.2359 parts per million (ppm). While the method of analysis cannot identify the sources of the lead found in these samples, the sources were likely from natural and manmade.

All foods sold in Canada must comply with Section 4 of the Canadian *Food and Drugs Act*. In the case of lead, the Government of Canada recognizes that there can be multiple sources that account for the presence of lead in food. Whether from natural or man-made sources, all food industries are expected to minimize the presence of lead by any and all processes available to them. This is consistent with the ALARA (As Low As Reasonably

Achievable) principle. Given the wide variety of processes, procedures and sources of raw materials, the means of implementing the ALARA principle will be company-specific.

All the data generated were shared with Health Canada for use in performing human health risk assessments. The levels of lead found in the candy, chocolate and cocoa powder products tested in this survey were unlikely to pose an unacceptable health concern. Follow up actions could include additional sampling, additional inspections or ultimately the recall of the product from the Canadian market place. No product recalls were warranted given the lack of a health concern.

1 Introduction

1.1 Food Safety Action Plan

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

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

Within the FSAP, there are twelve main areas of activity, one of which is risk mapping and baseline surveillance. The main objective of this area is to better identify, assess and prioritize potential food safety hazards through risk mapping, information gathering and analysis of foods in the Canadian marketplace. Targeted surveys are one tool used to test for the presence and level of a particular hazard in specific foods.

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 hazards in defined food commodities. The surveys are designed to answer specific questions. Therefore, unlike monitoring activities, testing for 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 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 CFIA regularly monitors metal analytes, including lead, in a variety of fresh and processed products under the National Chemical Residue Monitoring Program (NCRMP) and the Children's Food Project. Targeted surveys focus mainly on products not

monitored under these two programs. The purpose of this targeted survey was to establish baseline data on the level of lead in candy, chocolate and cocoa powder products available on the Canadian retail market. The scope of this survey is complementary to the NCRMP and Children's Food Project monitoring of processed products in that it includes additional commodities (i.e., candy, chocolate, cocoa powder) not routinely monitored under those programs.

1.3 Acts and Regulations

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

Health Canada establishes the health-based maximum levels for chemical residues and contaminants in food sold in Canada. Certain maximum levels for chemical contaminants in food appear in the Canadian *Food and Drug Regulations (FDR)*, where they are referred to as tolerances. Tolerances are established as a risk management tool, and generally only for foods that significantly contribute to the total dietary exposure. There are also a number of maximum levels that do not appear in the regulations and are referred to as standards. There are, at present, metal tolerances established in the *FDR* (Section B.15.001-Table I) for arsenic, lead and tin in specific commodities ¹. As part of Health Canada's risk management strategies for lead, the lead tolerances in Table I of Division 15 are being updated².

Health Canada has not identified candy, chocolate and cocoa powder as major dietary sources of lead, therefore a maximum level, tolerance, or standard for lead in these products has not been established. The U.S. Food and Drug Administration (U.S. FDA) does not have an established tolerance for lead in candy, chocolate and cocoa powder. Past incidents of high lead levels in candy, especially in chili- and tamarind-based candy from Mexico, have been reported in the United States (USA)^{7, 9,10,11,12,13}. The FDA has provided guidance to industry recommending that lead levels in these types of candy not exceed 0.1 parts per million (ppm)³.

Elevated levels of lead in candy, chocolate and cocoa powder foods may be assessed by Health Canada on a case-by-case basis using the most current scientific data available. 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 Lead

Lead is a metal that occurs naturally in the earth. It has many industrial uses and is found in trace amounts throughout the human environment. The amount of lead in the

environment increased during the Industrial Revolution, and again in the 1920s with the introduction of leaded gasoline. However, levels of lead in the Canadian environment have gone down significantly over the past 30 years ^{4,5,6}. Recent studies have also shown a decline of over 70% in blood lead levels in Canadians since the 1970s ^{4,5,6}. Everyone is exposed to trace levels of lead through food, drinking water, air, household dust, and soil. Before leaded gasoline was phased out in Canada in the 1990s, lead in the air was the main source of exposure for Canadians. It is still a source of low-level lead exposure, but now adults are exposed mainly through food and drinking water ^{4,5,6}. For infants and children, the main sources are food and drinking water, household dust, soil and mouthing of products containing lead ^{4,5,6}.

Lead is not deliberately added to food, however, low levels have been found in a variety of foods^{4,5,6}. Lead may enter the food chain from the soil, water or air, and may also contaminate foods during transport and processing^{4,5,6}. In Canada and most other countries, food manufacturers have stopped using lead-soldered food cans, which has greatly reduced dietary exposure to lead^{4,5,6}. Inappropriate food packaging materials or inks used on packaging materials have previously been identified as a possible source of lead in candy sold in the USA^{7,8,9,10}. Lead can also be present in food products as a result of processing or from the addition of contaminated ingredients^{11,12,13}.

Short-term exposure to very high levels of lead can cause vomiting, diarrhoea, convulsions, coma, or even death. Ongoing exposure to even very small amounts of lead can be harmful, especially to infants and young children, who have considerably higher absorption rates of ingested lead and less effective renal excretion than adults^{4,5,6}. Infants and children are at risk because they are vulnerable to the adverse effects of lead on the development of the nervous system. Other health effects associated with elevated lead exposure include anaemia, kidney toxicity and damage to the brain. Because children are the most sensitive subpopulation, consideration of lead effects against this group is considered protective of all age groups in Canada.

Health Canada supports reducing dietary lead levels to the lowest possible level. This is consistent with the ALARA (as low as reasonably achievable) principle. Given the wide variety of processes, procedures and sources of raw materials, the means of implementing the ALARA principle will be company-specific. In Canada, although there are no maximum levels set for lead in cocoa powder, chocolate products, or candy, these foods are regulated under Section 4 of the *Food and Drugs Act*.

The Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives (JECFA) and the European Food Safety Authority (EFSA)¹⁴ have not established a threshold for critical lead-induced effects. The Codex Alimentarius has several maximum levels for lead in various foods, ranging from 0.05 to 1.5 ppm, but has not set maximum levels set for chocolate, cocoa, or candy¹⁵. Codex Alimentarius has established a code of practice for the prevention and reduction of lead in foods, which states that lead dyes or lead-based printing inks should not be used for packaging candy¹⁶. Lead levels in cocoa powder, chocolate products and candy are not regulated in the European Union, Australia, or New Zealand.

2.2 Rationale

The main objective of this survey was to generate baseline surveillance data on the level of lead in candy, chocolate and cocoa powder products available on the Canadian retail market. According to Statistics Canada, the total consumption of sugar ranges from 100-120 grams/day in children aged 1 to 8 years of age, 130-180 grams/day for children aged 9 to 18 years, and from 85-140 grams/day for adults¹⁷. The contribution of candy, chocolate and cocoa powder to that total sugar intake is 8.7% in children aged 1 to 8 years of age, 10.3% in children aged 9 to 18 years of age and 5.3% in adults¹⁷. Canadian consumption of chocolate was 3.90 kilograms of chocolate per person per year in 2005¹⁸, and Canada imports an average of 48 000 tonnes of cocoa per year¹⁹.

A Total Diet Study (TDS) conducted in 1991-2005 by the U.S. FDA examined lead levels in 280 food items. Chocolate products analyzed in that study were associated with the highest levels of lead²⁰. Those levels were consistent with reports of elevated levels of lead in cocoa by the Cocoa Producer's Alliance²¹, who supply 75% of the world's cocoa beans. A study comparing lead concentrations of cocoa beans grown in Nigeria with finished chocolate products found that lead levels were 60 times higher in finished chocolate products than in the cocoa bean²². The contamination of the products was tentatively attributed to environmental contamination from gasoline releases²².

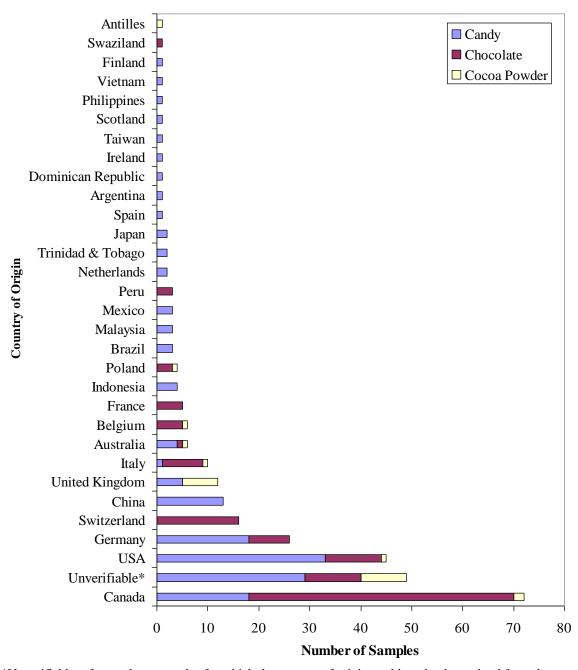
Other studies have demonstrated that tamarind seeds, chili, and inks used on candy wrappers may be sources of lead in candies. Out of 140 samples of imported candy (mainly Mexican-style candy) in a U.S. retail market survey, 87.5% were found to exceed the guidance level of 0.1 ppm lead in candy set by U.S. FDA¹¹, and the levels of lead in the products were as high as 2.2 ppm¹¹. In another study, candy wrappers were reported to contain lead levels reaching 27,125 ppm⁷, and the candy enclosed in these wrappers contained up to 1.17 ppm lead⁷. Leaching of lead from the packaging was suggested as the source of the metal in these candy products. Candy and chocolate were analyzed for lead in Health Canada's TDS of trace elements in foods from 1993 to 2007²⁴. The levels of lead in these studies ranged from 0.00354 to 0.0239 ppm in candy, and from 0.00892 to 0.01772 ppm²⁴ in chocolate bars.

2.3 Sample Distribution

The 2011-2012 Lead survey targeted domestic and imported candy, chocolate and cocoa powder products. A total of 297 samples were collected from grocery and specialty stores in 11 Canadian cities between April 2011 and March 2012. The 297 samples collected included 24 cocoa powders, 124 chocolate, and 149 candy samples.

The 297 samples collected included 72 domestic products, 176 imported products and 49 products of unverifiable origin. Cocoa is not grown in Canada, so cocoa powders and some chocolate products listed as domestic were likely manufactured or processed in Canada using imported ingredients. It is important to note that the products sampled often contained the statement "processed in Country X", "imported for Company A in Country

Y" or "manufactured for Company B in Country Z". Although the labelling is accurate, it does not identify the true origin of the product ingredients with certainty. Only those products labelled with a clear statement of "Product of Country A" were considered as being from a specific country of origin. The distribution of samples collected in this survey with respect to the country of origin (as recorded on the sampling documentation or indicated on the product label) is depicted in Figure 1.



^{*}Unverifiable refers to those samples for which the country of origin could not be determined from the product label or sample information.

Figure 1. Distribution of candy, chocolate and cocoa powder product samples by country of origin (arranged by increasing number of samples)

2.4 Method Details

Samples were analyzed by a laboratory under contract with the Government of Canada. The laboratory is accredited to ISO/IEC 17025, *General Requirements for the Competence of Testing and Calibration Laboratories* (or its equivalent) by the Standards Council of Canada (SCC).

Samples were tested as sold, meaning that the product was not prepared as per the package instructions (if applicable). The laboratory used one of two methods based on microwave digestion and inductively coupled plasma mass spectroscopy to analyze and quantify metal analytes in the samples. The limit of detection (LOD) for lead ranged from 0.002 ppm to 0.01 ppm. The limit of quantitation (LOQ) for lead ranged from 0.002 ppm to 0.01 ppm.

2.5 Limitations

The current targeted survey was designed to provide a snapshot of the levels of lead in candy, chocolate and cocoa powder products available for sale in Canada, and had the potential to highlight commodities that warrant further investigation. The limited sample sizes analyzed represent a small fraction of the products available to Canadian consumers. Therefore, care must be taken when interpreting and extrapolating these results. Regional differences, impact of product shelf-life, packaging and storage conditions, or cost of the commodity on the open market were not examined in this survey. Country of origin was assigned for most samples (otherwise designated as "Unverifiable") based on information provided on the documentation accompanying the sample or indicated on the product label.

3 Results and Discussion

The levels of lead detected in samples in this survey are presented and discussed in the following sections. Lead was measured as part of a multi-analyte method that simultaneously analyses for 19 metals, including lead. All survey data was shared with Health Canada for use in conducting human health risk assessments of lead.

3.1 Overview of Lead Results

The 2011-2012 FSAP Lead survey consisted of testing 297 samples obtained at the retail level. Products collected included 24 cocoa powders, 124 chocolate, and 149 candy samples of both domestic and imported origin. One hundred and eighteen (40%) samples did not have a detectable level of lead, while the remaining 179 samples had lead levels ranging from 0.0032 to 0.2359 ppm. Currently, no maximum level, tolerance, or standard has been established by Health Canada for lead levels in candy, chocolate and cocoa powder food, so compliance to a numerical standard could not be assessed. Health Canada determined that these samples were not associated with an unacceptable health concern to any segment of the Canadian population. Follow up actions could include

additional sampling, additional inspections or ultimately the recall of the product from the Canadian market place. No product recalls were warranted given the lack of a health concern.

Candy samples were associated with both the lowest percentage of samples with detectable lead levels (38%) and the lowest average lead level (0.0305 ppm) (refer to Figures 2 and 3 below). Only the positive results were used to calculate the average lead level. Eighty percent of chocolate samples had a detectable level of lead, with an average lead level of 0.0375 ppm. Cocoa powder samples were associated with the highest percentage of samples with detectable lead levels (100%) and the highest average lead levels (0.0544 ppm).

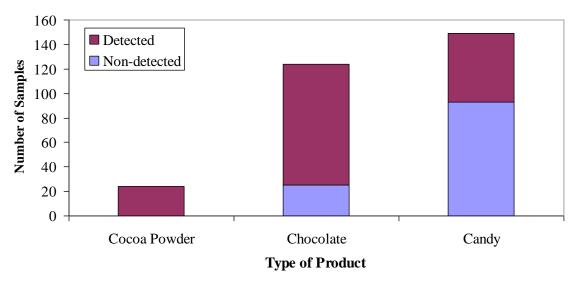


Figure 2. Distribution of samples by candy, chocolate and cocoa powder type (arranged by increasing number of samples)

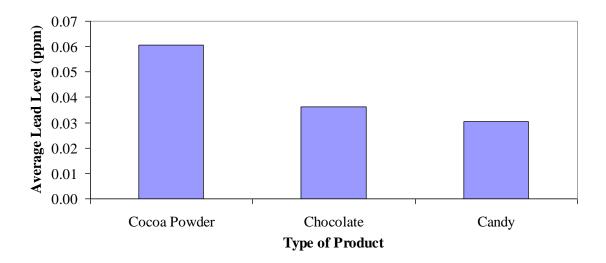


Figure 3. Average lead level by candy, chocolate and cocoa powder type (arranged by decreasing average lead level).

*Only the positive results were used to calculate the average lead level.

Results by product type are presented in the following sections, with comparison to results obtained under the CFIA Children's Food Project (2009-2010²³ and 2011-2012 (unpublished data)) and Health Canada's TDS²⁴, where feasible.

3.2 Candy

Of the 149 candy samples analyzed in this survey, 93 did not have a detectable level of lead. The remaining 56 samples had lead levels ranging from 0.0032 to 0.2059 ppm. Health Canada determined that these levels of lead in candy products were not associated with an unacceptable health concern to any segment of the Canadian population. Follow up actions could include additional sampling, additional inspections or ultimately the recall of the product from the Canadian market place. No product recalls were warranted given the lack of a health concern.

The 149 candy samples were divided into hard candy (40 samples, including mints), fruit-flavoured or fruit-containing candy (31 samples), soft candy (28 samples, including chewy/gummy candy and marshmallows), lollipops (26 samples), liquorice (nine samples including 4 samples of red liquorice, 3 samples of allsorts, 1 sample of black liquorice, and a sample of red and yellow twists), jelly candy (eight samples), "other" candy (five samples, including hot coffee chews, sour zingers, and butter toffee), chili-containing candy (one sample), and tamarind candy (one sample). The minimum, maximum and average levels of lead in the candy samples tested in this survey are presented in Table 1.

Lead was not detected in the chili or tamarind candy (one sample each) analyzed in this survey. On average, the lowest levels of lead were detected in lollipops (0.0226 ppm) and

hard candy (0.0227 ppm). The highest average lead levels were detected in liquorice (0.0548 ppm).

Table 1. Minimum, maximum, and average levels of lead in candy samples (in order of decreasing average levels)

| Candy Type | Number of Samples | Number of Samples with Detectable Levels | Percentage of Samples with Detected Levels | Minimum (ppm) | Maximum (ppm) | Average (ppm) |
|---------------|-------------------------|--|--|------------------|------------------|---------------|
| Liquorice | 9 | 3 | 33 | 0.0223 | 0.0793 | 0.0548 |
| Soft | 27 | 17 | 63 | 0.0102 | 0.2059 | 0.0348 |
| Fruit | 31 | 8 | 26 | 0.0122 | 0.1241 | 0.0334 |
| Jelly | 8 | 6 | 75 | 0.0032 | 0.0954 | 0.0299 |
| Other* | 5 | 4 | 80 | 0.016 | 0.0333 | 0.0242 |
| Hard | 41 | 10 | 24 | 0.0104 | 0.0584 | 0.0227 |
| Lollipop | 26 | 8 | 31 | 0.0101 | 0.0489 | 0.0226 |
| Chili | 1 | 0 | 0 | | < LOD | |
| Tamarind | 1 | 0 | 0 | | < LOD | |

^{*}Other category included hot coffee chews, sour zingers, and butter toffee

Fifteen candy samples in the current survey had higher levels of lead than similar candy samples (25 samples) analyzed under the Children's Food Project (2009-2010²³ and 2011-2012 (unpublished data)). Similar candy samples analyzed under the Children's Food Project (CFP) had detectable lead levels ranging from 0.0023 ppm to 0.0340 ppm. The analytical methods used to test CFP samples were slightly different from that used in the current survey, and had limits of detection for lead ranging from 0.001 to 0.01 ppm.

Health Canada's TDS results from the 1993-2007 sampling periods²⁴ included a number of candy samples. The results were based on a single composite sample of candy (4 brands for each type of candy in the composite and likely only a couple of types of candy) for each year sampled. The reported levels of lead ranged from 0.00354 to 0.0239 ppm, with an overall average lead concentration of 0.0102 ppm. The TDS maximum lead level is lower than the maximum level in candy found in this survey (Table 1), but the

< LOD = not detected at the limit of detection (0.01 ppm)

Only the positive results were used to calculate the average lead level.

range of lead values found in the Health Canada TDS overlap with the range of lead values detected in this survey as shown in Table 1 (Table 1 range for candy types is 0.0032 to 0.2059 ppm while the TDS range was 0.00354 to 0.0239 ppm).

3.3 Chocolate

Of the 124 chocolate samples analyzed in this survey, 25 samples did not have a detectable level of lead. The remaining 99 samples had lead levels ranging from 0.0101 to 0.1586 ppm. Health Canada determined that these samples were not associated with an unacceptable health concern to any segment of the Canadian population. Follow up actions could include additional sampling, additional inspections or ultimately the recall of the product from the Canadian market place. No product recalls were warranted given the lack of health concern.

The 124 chocolate samples were divided into milk chocolate (45 samples), baking chocolate (26 samples), chocolate chips (21 samples), dark chocolate (19 samples), "other" chocolate (8 samples), and chocolate bars (5 samples). "Other" chocolate included all samples of chocolate for which there was insufficient information available to otherwise classify them. The minimum, maximum and average levels of lead in the chocolate samples tested in this survey are presented in Table 2.

Lead was detected in all types of chocolate. On average, the lowest levels of lead were detected in milk chocolate (0.0184 ppm). The highest average lead levels were detected in baking chocolate (0.0575 ppm).

Table 2. Minimum, maximum, and average levels of lead in chocolate samples (in order of decreasing average levels)

| Chocolate Type | Number of Samples | Number of Samples with Detectable Levels | Percentage of Samples with Detected Levels | Minimum (ppm) | Maximum (ppm) | Average (ppm) |
|-------------------|-------------------------|--|--|------------------|------------------|---------------|
| Baking | 26 | 26 | 100 | 0.0144 | 0.1074 | 0.0575 |
| Other* | 8 | 8 | 100 | 0.0101 | 0.1027 | 0.0446 |
| Dark | 19 | 17 | 90 | 0.0159 | 0.1218 | 0.0360 |
| Chips | 21 | 20 | 95 | 0.0105 | 0.0587 | 0.0286 |
| Bar | 5 | 4 | 80 | 0.0172 | 0.0514 | 0.0279 |
| Milk | 45 | 24 | 54 | 0.0102 | 0.0470 | 0.0184 |

^{*&}quot;Other" chocolate included all samples of chocolate for which there was insufficient information available to otherwise classify them.

Eleven samples in the current survey had higher levels of lead than similar chocolate samples (27 samples) analyzed under the under the CFP (2009-2010²³ and 2011-2012 (unpublished data)). Similar chocolate samples analyzed under the CFP had detectable lead levels ranging from 0.0025 ppm to 0.0739 ppm. As previously stated, the analytical methods used to test CFP samples were slightly different from that used in the current survey, and had limits of detection for lead ranging from 0.001 to 0.01 ppm.

Health Canada's TDS results from the 1993-2007 sampling periods²⁴ included 9 composite samples (4 chocolate products per composite) of chocolate. The lead levels ranged from 0.00892 ppm to 0.01592 ppm, with an overall average lead level of 0.0177 ppm. These lead levels are lower than the levels observed in the current survey.

3.4 Pure Cocoa Powder

All 24 cocoa powder samples analyzed in this survey contained detectable levels of lead. These were samples labelled as "pure cocoa powder" and did not include chocolate milk or hot chocolate mix powder. The lead levels ranged from 0.0222 to 0.2359 ppm. The average lead level was 0.0606 ppm. Health Canada determined that these samples were not associated with an unacceptable health concern to any segment of the Canadian population. Follow up actions could include additional sampling, additional inspections

Only the positive results were used to calculate the average lead level.

or ultimately the recall of the product from the Canadian market place. No product recalls were warranted given the lack of health concern.

The analysis for lead levels was completed on cocoa powder as available on the Canadian retail market. The cocoa powder was not used in the preparation of cocoa beverages or of baked goods. Therefore, the results should only be interpreted as cocoa powder available as sold and cocoa as consumed.

Cocoa powder was not analyzed as part of the CFP²³ or in Health Canada's TDS²⁴. A scientific study²² examined levels of lead in cocoa beans, cocoa bean shells, soil, chocolate products, and manufactured cocoa. The levels of lead in the four samples of manufactured cocoa powder analyzed in that study were as high as 0.2300 ppm²². This is similar to the results found in cocoa powder in this targeted survey.

4 Conclusions

The 2011-2012 FSAP lead survey generated baseline surveillance data on the levels of lead in candy, chocolate and cocoa powder products available on the Canadian retail market. Samples collected included 24 cocoa powder, 124 chocolate and 149 candy samples of both domestic and imported origin.

One hundred and eighteen (40%) samples did not have a detectable level of lead. In the remaining 179 samples, cocoa powder had the highest percentage of samples with detectable lead levels (100%) and also had the highest maximum level of lead detected (0.2359 ppm); followed by chocolate, which had an 80% detection rate and a maximum of 0.1586 ppm detected. Candy had the lowest detection rate (38%) and a maximum lead level of 0.2059 ppm. Compliance with a numerical standard was not evaluated in this survey as no maximum level, tolerance, or standard has been established by Health Canada for lead levels in candy, chocolate and cocoa powder foods.

All data generated were shared with Health Canada for use in performing human health risk assessments. The levels of lead found in the various candy, chocolate and cocoa powder products tested in this survey were unlikely to pose an unacceptable health concern. Follow up actions could include additional sampling, additional inspections or ultimately the recall of the product from the Canadian market place. No product recalls were warranted given the lack of health concern.

In the case of lead, the Government of Canada recognizes that there can be multiple sources that account for the presence of lead in food. Whether from natural or man-made sources, all food industries are expected to minimize the presence of lead by any and all processes available to them. This is consistent with the ALARA (As Low As Reasonably Achievable) principle. Given the wide variety of processes, procedures and sources of raw materials, the means of implementing the ALARA principle must be company-specific.

5 References

¹ Department of Justice Canada. *Food and Drug Regulations* [online]. Modified September 2012. Accessed October 10, 2012. http://laws.justice.gc.ca/eng/regulations/C.R.C., c. 870/page-155.html?term=lead

² Health Canada. Food *Directorate Updated Approach for Managing Dietary Exposure to Lead* [online]. October 2011. Accessed October 9, 2012. http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/environ/lead_strat_plomb_strat-eng.php

³ U.S. Food and Drug Administration. *Lead in Candy Likely To Be Consumed by Small Children: Guidance for Industry: Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy* [online]. Revised November 2006. Accessed October 9, 2012. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ChemicalContaminantsandPesticides/ucm077904.htm

⁴ Health Canada. *Lead and Human Health* [online]. Modified February 2013. Accessed April 15, 2013. http://hc-sc.gc.ca/hl-vs/iyh-vsv/environ/lead-plomb-eng.php

⁵ Health Canada. *Final Human Health State of the Science Report on Lead* [online]. January 2013. Accessed March 27, 2013. http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/dhhssrl-rpecscepsh/indexeng.php#a74

⁶ Health Canada. *Lead* [online]. October 2011. Accessed March 27, 2013. http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/environ/lead_plomb-eng.php

⁷ Lynch R.A., Boatright D.T., Moss S.K. Lead-Contaminated Imported Tamarind Candy and Children's Blood Lead Levels. *Public Health Reports*. 115 (2000): 537 – 543.

⁸ Centers for Disease Control and Prevention. *Lead* [online]. June 2009. Accessed April 22, 2013. http://www.cdc.gov/nceh/lead/tips/candy.htm

⁹ McKim, J.B., Sharon, K. and Heisel, W. Toxic Treats: Part 1- Hidden Threat. *Orange County Register*. Published: Nov. 13, 2009 Updated March 27, 2013. Accessed April 22, 2013. http://www.ocregister.com/articles/candy-219217-lead-truck.html

¹⁰ McKim, J.B. Mexican candy wrappers also contaminated with lead. *Orange County Register*. Published: Nov. 17, 2009 Updated March 27, 2013. Accessed April 22, 2013. http://www.ocregister.com/articles/lead-219758-wrappers-candy.html

¹¹ Maxwell E.D., Neumann C.M. Lead-tainted candy: A possible source of lead exposure to children. *Toxicological and Environmental Chemistry*. 90.2 (2008): 301 – 313.

¹² Godines, V. and McKim, J.B. Toxic Treats: Part 2 - The Chili Fields. *Orange County Register*. *Published: Nov. 13, 2009 Updated: March 27, 2013*. Accessed April 22, 2013. http://www.ocregister.com/articles/chili-219220-lead-chilies.html

¹³ McKim, J.B., and Heisel, W. Toxic Treats: Part 3 - The Candy Makers. *Orange County Register*. *Published: Nov. 13*, 2009 *Updated: March 27*, 2013 *Published: Nov. 13*, 2009 *Updated: March 27*, 2013. Accessed April 22, 2013. http://www.ocregister.com/articles/treats-219223-candy-makers.html

¹⁴ European Food Safety Authority. *Scientific Opinion on Lead in Food* [online]. 2010. Accessed October 9, 2012. http://www.efsa.europa.eu/en/scdocs/doc/1570.pdf

¹⁵ Codex Alimentarius. *Codex Standard 193-1995* [online]. Adopted 1995. Revised 1997, 2006, 2008, 2009. Amended 2010. Accessed December 5, 2012. www.codexalimentarius.net/input/download/standards/17/CXS_193e.pdf

¹⁶ Codex Alimentarius. *Code of Practice for the Prevention and Reduction of Lead Contamination in Foods* [online]. CAC/RCP 56-2004. 2004 Accessed December 5, 2012. www.codexalimentarius.org/input/download/standards/10099/CXP 056e.pdf

¹⁷ Statistics Canada. *Sugar consumption among Canadians of all ages*. [online]. 82-003-X . Modified September 2012. Accessed October 10, 2012. http://www.statcan.gc.ca/pub/82-003-x/2011003/article/11540-eng.htm

¹⁸ Workman, D. Chocolate Covered Countries. *Suite 101: International Trade*[online]. November 2007. Accessed October 10, 2012. http://suite101.com/article/chocolate-covered-countries-a26240

¹⁹ Food and Agriculture Organization. Economic and Social Development Department. *Cocoa* [online]. Accessed October 10, 2012. http://www.fao.org/docrep/006/y5143e/y5143e0x.htm

²⁰ U.S. Food and Drug Administration. Total Diet Study - *Market Baskets 1991-3 through 2005-4* [online]. 2007. http://www.fda.gov/downloads/food...totaldietstudy/ucm184301.pdf

²¹ COPAL. 2004. Cocoa Producers' Alliance Homepage. http://www.copal-cpa.org/index.php
(Please note that this was cited as "COPAL 2004a. Cocoa Producers' Alliance Homepage. Lagos, Nigeria: Cocoa Producers' Alliance. Available: http://www.copal-cpa.org/index.html [accessed 26 January 2005]" in reference 18 below. However, the webpage associated with the COPAL survey is no longer available).

²² Rankin C.W., Nriagu J.O., Aggarwal J.K., Arowolo T.A., Adebayo K., Flegal A.R. Lead Contamination in Cocoa and Cocoa Products: Isotopic Evidence of Global Contamination. *Environmental Health Perspectives* 113.10 (2005): 1344 – 1348.

²³ Canadian Food Inspection Agency. *Children's Food Project – 2009-2010 Report on sampling* [online]. Modified September 2012. Accessed October 12, 2012. http://www.inspection.gc.ca/food/chemical-residues/children-s-food-project/eng/1348240784372/1348241294879

²⁴ Health Canada. Food and Nutrition Surveillance. Canadian Total Diet Study. *Concentration of Contaminants and Other Chemicals in Food Composites* [online]. Trace Elements: Montreal July 1993 – Vancouver 2007. Accessed September 16, 2012. http://www.hc-sc.gc.ca/fn-an/surveill/total-diet/concentration/index-eng.php