

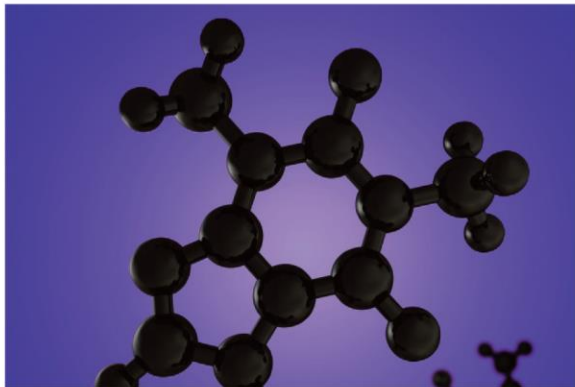


Food Safety Action Plan

REPORT

2011-2012 Targeted Surveys

Chemistry



Lead in Dried Herbs and Spices

TS-CHEM-11/12

Table of Contents

Executive Summary	2
1 Introduction.....	4
1.1 Food Safety Action Plan	4
1.2 Targeted Surveys	4
1.3 Acts and Regulations	5
2 Survey Details.....	6
2.1 Lead.....	6
2.2 Rationale	7
2.3 Sample Distribution	8
2.4 Method Details.....	8
2.5 Limitations	8
3 Results and Discussion.....	8
3.1 Lead Results.....	9
3.2 Comparison to Relevant Studies.....	11
4 Conclusions.....	12
5 Appendix 1.....	13
6 Appendix 2.....	14
7 References.....	15

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. Contamination of food could also occur during food manufacture (e.g., from the use of inappropriate food storage materials, processing equipment, etc.).

Lead levels in meat, dairy products, eggs, honey, fruits and vegetables (processed and fresh), and fresh herbs are monitored annually under the Canadian Food Inspection Agency's National Chemical Residue Monitoring Program (NRCMP). The NRCMP does not routinely test finished and/or manufactured foods, such as dried herbs and spices. There is limited Canadian data available from other sources (i.e. Health Canada's Total Diet Study) and high lead levels have been reported for some spices in the United States and in the European Union by the media and in the scientific literature. Therefore, the main objective of the current survey was to generate baseline surveillance data on the level of lead in dried herbs and spices available on the Canadian retail market.

The 2011-2012 FSAP Lead survey targeted domestic and imported dried herbs and spices. A total of 148 samples were collected from grocery and specialty stores in 11 Canadian cities between April 2011 and March 2012. The samples collected included 90 spices and 58 dried herb samples.

All of the 148 samples analyzed contained a detectable level of lead, with concentrations ranging from 0.013 parts per million (ppm) to 8.476 ppm. Currently, no maximum level, tolerance, or standard has been established by Health Canada for lead in dried herbs and spices so compliance to a numerical standard could not be assessed.

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 of lead in food. Nonetheless, all food industries are expected to minimize the presence of lead by any and all processes and practices 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. Health Canada concluded that the levels of lead found in the dried herbs and spice products tested in this survey were unlikely to pose a health concern. No follow up action 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 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 residues, contaminants and/or natural toxins 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.

In the most recent FSSC meeting, lead was ranked as a high priority due to its harmful health effects. The CFIA regularly monitors metals, including lead, in a variety of

processed food products under the National Chemical Residue Monitoring Program (NCRMP) and the Children's Food Project. 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., dried herbs and spices) that are not routinely monitored. Dried herbs and spices were selected in part because of recent media reports regarding elevated levels of lead in dried herbs and spices available on the United States (US) market^{1,2,18}. There is little information available on the levels of lead in spices and dried herbs in the Canadian marketplace. Where possible, the lead levels observed in this survey were compared with relevant data from Health Canada's Total Diet Study (TDS)²⁵, the NCRMP (unpublished data), and international data^{26,27}.

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* and *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. These are referred to as standards and they are available on Health Canada's website. There are, at present, metal tolerances established in the *FDR* (Section B.15.001-Table I) for arsenic, lead, and tin in specific commodities³. As part of Health Canada's risk management strategy for lead, the lead tolerances in Table I of Division 15 are being updated⁴.

Health Canada has not identified dried herb and spices as major dietary sources of lead, therefore a maximum level, tolerance, or standard for lead in these products has not been established. There are no established tolerances for lead in dried herbs and spices in the United States, Australia, or New Zealand. The European Union does regulate the levels of lead in fresh herbs but not in dried herbs and spices. See Appendix 1 for a summary of the international regulations/maximum levels/guidelines for lead in spices and fresh/dried herbs.

Elevated levels of lead in dried herbs and spices 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^{5,6,7}. Recent studies have also shown a decline of over 70% in blood lead levels in Canadians since the 1970s^{5,6,7}. 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. Today, the primary sources of exposure to low levels of lead in adults within the general population are food and drinking water^{5,6,7}. For infants and children, the main sources of lead exposure are food and drinking water, household dust, soil, and mouthing of products containing lead^{5,6,7}.

Lead is not deliberately added to food, however, low levels have been found in a variety of foods^{5,6,7}. Lead may enter the food chain from the soil, water, or air. Contamination of food can result during food manufacture from, for example, the use of inappropriate food storage materials, transport materials, processing equipment, food packaging materials, or food ingredients^{5,6,7}. In Canada and most other countries, food manufacturers have stopped using lead-soldered food cans, which has greatly reduced dietary exposure to lead^{5,6,7}. Foods manufactured or processed in Canada generally have very low levels of lead. However, 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^{8,9,10,11}. Lead can also be present in food products as a result of processing or from the addition of contaminated ingredients, as has been shown in the case of Mexican candy imported into the US^{12,13,14}.

For spices and herbs in particular, differences in background levels of lead may be due to differences in lead uptake by the plant, the portion of the plant that is prepared for use as a spice or herb (e.g., leaf, seed, etc.), the geographic source of the product, etc. The literature has noted as a lead source, in relation to ground chili, possible contamination with soil that contains lead¹³ as well as processing equipment¹⁴.

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^{5,6,7}. Infants and children are at greater 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 neurological effects. Identification of infants and children as a susceptible subpopulation and the use of neurodevelopmental effects as the critical health effect are considered protective for other adverse health effects of lead across the entire population.

Health Canada supports reducing dietary exposure to lead to the lowest possible levels. This is consistent with the ALARA (as low as reasonably achievable) principle. In Canada, although there are no maximum levels set for lead in dried herbs and spices, these foods must comply with Section 4(1) of the *Food and Drugs Act*.

Health Canada, the Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives (JECFA) and the European Food Safety Authority (EFSA)¹⁵ have not established a threshold for critical lead-induced effects. The Codex Alimentarius Commission has several maximum levels for lead in various foods ranging from 0.05 to 1.5 ppm, but has not set maximum levels for dried herbs or spices¹⁶. Codex Alimentarius has established a code of practice for the prevention and reduction of lead in foods, which states that lead should be removed from surface of foods and that lead solder not be used¹⁷. There are no established tolerances for lead in dried herbs and spices in the United States, Australia, or New Zealand. The European Union does regulate the levels of lead in fresh herbs but not in dried herbs and spices.

2.2 Rationale

The main objective of this targeted survey was to generate baseline surveillance data on the level of lead in dried herbs and spices available on the Canadian retail market. Spices are made from seeds, fruit, stems, bark, or vegetables while herbs are leafy plants. Although spices and dried herbs are not staple foods, they are used as ingredients or flavouring agents in a large variety of food products. The consumption patterns of spices and dried herbs vary widely by product type and sub-population (i.e., ethnic groups adhering to traditional diets).

Although there have been no reports of elevated levels of lead in foods or herbal remedies sold in Canada, media reports and scientific studies have shown elevated levels of lead in spices^{18,19} and in herbal remedies^{20,21} sampled in the US and in Bulgaria. In some of these cases, the lead levels were high enough to result in temporary illness^{11,21}. In October 2013, turmeric in the US was recalled for excessively high levels of lead (between 28 and 42 ppm)²². These reports are part of the reason why the CFIA conducted this FSAP survey.

Spices in a Total Diet Study from Chile were reported to contain low levels of lead²³. Limited results for the lead levels in herbs and spices are available from HC's Total Diet Study (TDS), which indicate that detectable, low levels of lead are present in certain herbs/spices²⁵.

Spices and herbs are generally sold as dried products. During the drying process, up to a 77% reduction of water content can occur²⁴. Because metals are generally stable in the plant tissues during this drying process, any trace elements, such as lead, will be concentrated as the raw materials undergo the drying procedure.

2.3 Sample Distribution

The 2011-2012 Lead in Dried Herbs and Spices survey targeted domestic and imported dried herb and spice products. A total of 148 samples were collected from grocery and specialty stores in 11 Canadian cities between April 2011 and March 2012.

The 148 samples collected included 43 domestic products, 20 imported products (from at least six countries) and 85 products of unspecified origin, meaning the country of origin could not be confirmed based on the available information recorded during sampling. 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”, and though the labelling meets the intent of the regulatory standard, it does not specify the true origin of the product ingredients. Only those products labelled with a clear statement of “Product of”, “Prepared in”, “Made in”, “Processed in”, and “Manufactured by” were considered as being from a specific country of origin.

2.4 Method Details

Samples were analyzed by an ISON 17025 accredited laboratory under contract with the Government of Canada. The laboratory used microwave digestion and inductively coupled plasma mass spectroscopy to analyze the samples as sold. Both the limit of detection (LOD) and limit of quantitation (LOQ) for lead were 0.01 ppm.

2.5 Limitations

The current targeted survey was designed to provide a snapshot of the levels of lead in dried herbs and spices available for sale in Canada, and had the potential to highlight commodities that warrant further investigation. The limited number of samples analyzed represents 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 based on information provided on the documentation accompanying the sample or indicated on the product label or otherwise designated as “unspecified” if this information was not available.

3 Results and Discussion

The levels of lead detected in samples in this survey are presented and discussed in the following sections. All survey data was shared with Health Canada for use in conducting human health risk assessments for lead.

3.1 Lead Results

The 2011-2012 FSAP Lead in Dried Herbs and Spices survey consisted of testing 148 samples of dried herbs and spices of both domestic and imported origin obtained at the retail level. All 148 samples had a detectable level of lead, ranging from 0.013 ppm to 8.476 ppm. Health Canada determined that these levels of lead in dried herb or spice products were not associated with a health concern for any segment of the Canadian population. No follow-up action was warranted given the lack of a health concern associated with these products. Follow-up action, when warranted, can include additional sampling, additional inspections, or ultimately the recall of the product from the Canadian market place.

The 148 samples were separated into 23 different categories based on the label description (e.g., ground, whole, and seed products). Table 1 presents the minimum, maximum, and average level of lead detected for each category. See Appendix 2 for a graph which depicts the lead level by the type of product analyzed in the survey.

Table 1. Minimum, maximum, and average level of lead in dried herb and spice samples (in order of decreasing average lead level)

Product Type	Number of Samples*	Minimum (ppm)	Maximum (ppm)	Average (ppm)
Paprika	6	0.068	8.476	1.732
Mint	4	0.481	3.947	1.463
Ginger	5	0.618	1.770	0.960
Thyme	5	0.282	1.699	0.824
Cinnamon	7	0.038	4.335	0.678
Bay Leaves	6	0.216	1.065	0.586
Parsley	8	0.101	2.007	0.575
Fennel Seeds	5	0.058	1.193	0.570
Basil	8	0.408	0.743	0.539
Curry Powder	7	0.143	1.696	0.466
Oregano	10	0.031	0.612	0.424
Dill	6	0.081	0.739	0.350
Rosemary	8	0.204	0.623	0.327
Coriander/Cilantro	4	0.041	0.725	0.311
Chive	3	0.111	0.525	0.290
Pepper – Hot**	16	0.031	1.090	0.282
Cumin	5	0.081	0.595	0.252
Turmeric	7	0.054	0.416	0.187
Black Pepper	5	0.050	0.333	0.144
Cardamom	5	0.052	0.225	0.115
Anise Seeds	5	0.023	0.245	0.115
Garlic (powder or salt)	8	0.030	0.196	0.101
Caraway Seed	5	0.013	0.028	0.020
Overall	148	0.013	8.476	0.469

*All samples had detectable levels of lead, LOD = 0.01 ppm

**Includes cayenne and chili powders

Samples of caraway seeds had the lowest minimum, maximum, and average levels of lead, while paprika had the highest average and maximum levels of lead. Curry powder (which had an intermediate level of lead) is generally comprised of coriander, turmeric,

cumin, fenugreek, and red pepper. In this targeted survey, both curry powders and their ingredients (except fenugreek) were analysed and, in general, the common ingredients of curry powder had lower levels of lead than the curry powders. One possible reason for this difference may be that the components of the finished curry powders analysed in this survey were from different sources than the corresponding single components tested herein.

The degree of dietary exposure to lead is a function of the lead level in a food, and the rate at which the food is typically consumed (e.g., amount of food per unit time). Consumption rates of herbs and spices are generally low. It is for this reason that spices, even those with relatively high lead levels, would not contribute significantly to total dietary exposure to lead.

3.2 Comparison to Relevant Studies

Health Canada's Total Diet Study (TDS) results for years spanning the 2000-2007 sampling periods²⁵ included composite samples of selected dried herbs and spices (specifically, equal proportions of black pepper, oregano, basil, and cinnamon). The TDS lead levels in those herb and spice samples ranged from 0.292 ppm to 0.6011 ppm. The range of lead levels was smaller and the maximum lead levels were lower in the TDS study than the levels observed in each of black pepper, oregano, basil, and cinnamon samples analysed in this targeted survey (0.031 ppm to 4.335 ppm).

The lead levels reported in this survey were also compared to the results of a Scientific Cooperation (SCOOP) survey²⁶ carried out in 2004 by EFSA. The SCOOP survey examined 665 samples of dried herbs and spices (the types of herbs and spices were not specified), where the average lead level observed was 0.873 ppm and the maximum level of lead was 379.2 ppm. The average (0.469 ppm) and the maximum lead levels (8.476 ppm) in this targeted survey were significantly lower than those observed in the EFSA survey.

Previous media and scientific reports have indicated that 25% of spices and food products from India (most relevant to this study were cardamom, fenugreek, and chili powder) tested had in excess of 1 ppm lead^{18,27}. As previously stated, fenugreek was not tested in the current survey. However, 100% of cardamom samples and 95% of chili powders tested in this targeted survey had lead levels below 1 ppm. It was not possible ascertain of the origin of the cardamom and chili powders tested in this survey, for reasons outlined in section 2.3. The difference in these lead levels may be related to different countries of origin of the spices.

In another media report, 92% of Mexican chili powders tested had detectable levels of lead, ranging from 0.3 ppm to 4 ppm¹³. In that report, the laboratory analysed lead levels in the soil, the harvested chilies, dried chilies, and chili powders. The media report¹³ and a United States (U.S.) Food and Drug Administration²⁸ report indicate that the major source of the lead in the finished chili powders is lead-contaminated soil deposits on the chilies. According to the reports^{10,12,14}, lead is thought to accumulate on peppers during

growing and handling in open fields, and that it may not be removed by a washing step prior to drying (which also concentrates the lead) and grinding the peppers into chili powder. Another source of lead may be contamination from grinding equipment (e.g. lead solder)¹³. In this targeted survey, lead levels in hot peppers (which included chili peppers) ranged from 0.031 ppm to 1.09 ppm, which is lower than the range (0.3 ppm to 4 ppm) reported in the media report on Mexican chili powders²⁰. The difference in positive rates and lead levels may also be related to different brands, and/or countries of origin of the chili powders.

There have been reported cases of lead compounds being added to foods to fraudulently enhance the colour and to make the product heavier for economic gain²⁹. This has been observed with turmeric, cayenne, paprika, and spice mixtures. In 1994, the adulteration of paprika with lead caused a number of deaths and illnesses in Hungary³⁰. None of the samples tested in this targeted survey had lead levels that would indicate intentional addition of lead.

4 Conclusions

The 2011-2012 FSAP Lead in Dried Herbs and Spices survey generated baseline surveillance data on the levels of lead in dried herbs and spices available on the Canadian retail market. Samples included 148 dried herbs and spices of both domestic and imported origin. All of the samples had a detectable level of lead ranging from 0.013 ppm to 8.476 ppm.

All data generated were shared with Health Canada for use in performing human health risk assessments. Health Canada concluded that the levels of lead found in the dried herbs and spices tested in this survey were unlikely to pose a health concern. No follow-up actions were warranted given the lack of health concern associated with these products.

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.

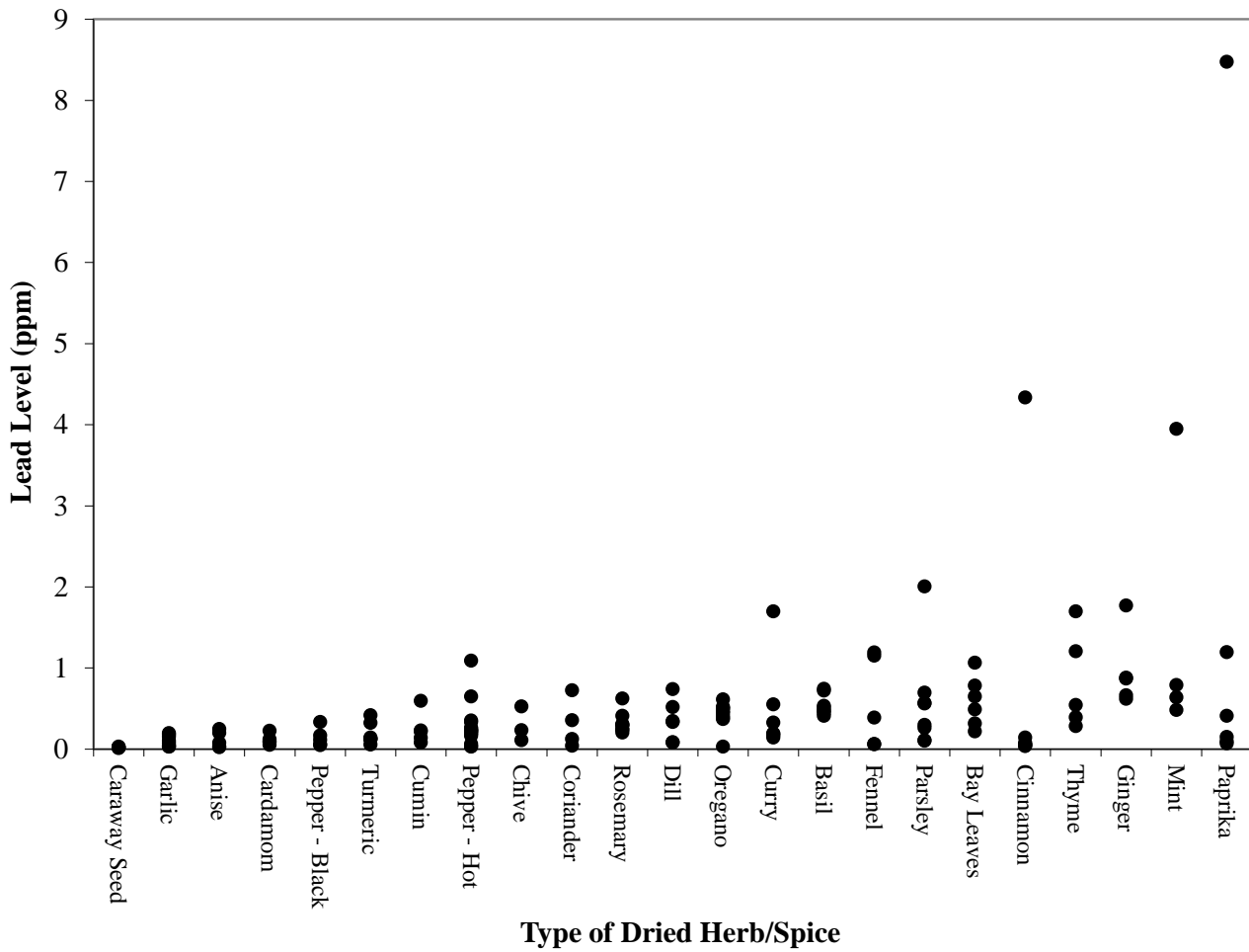
5 Appendix 1

Summary of regulations, maximum levels, and guidelines for lead in selected commodities

Commodity	Country/Organisation	Lead (ppm)
Fresh herbs	European Union (EU) ³¹	0.10
Dried herbs	Ireland ³²	10
Ground, dried spices	Ireland ³²	20
Other spices, not ground	Ireland ³²	10

6 Appendix 2

Distribution of lead levels in survey samples (arranged in order of increasing maximum lead level)



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