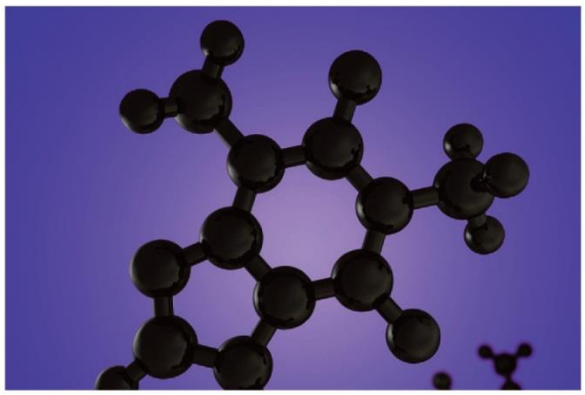
Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2011-2012 Targeted Surveys

Chemistry



Coumarin in Cinnamon and Cinnamon-Containing Products

TS-CHEM-11/12

Canada

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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 chemical and microbiological hazards.

The main objective of this targeted survey was to generate baseline surveillance data on the level of coumarin in cinnamon and cinnamon-containing products available on the Canadian retail market.

Coumarin is a natural, fragrant compound found in plants such as cinnamon, tonka beans, and sweet clover. Coumarin has been utilized as a flavouring/aromatic compound in the food and perfume industry for many years until evidence related to its toxicological properties (namely, adverse health effects in rodents and dogs[3,4]) led to its use in food being discontinued or banned in a number of countries, such as Canada[1] and the United States[2]. The direct addition of coumarin to food is not permitted in Canada. It is understood that low exposure to coumarin from natural sources is expected and not anticipated to represent a health risk.

The 2011-2012 Coumarin survey targeted domestic and imported cinnamon and cinnamon-containing products. A total of 193 samples were collected from grocery and specialty stores in 11 Canadian cities between April 2011 and March 2012. All products sampled contained cinnamon in their list of ingredients. The samples collected included ground cinnamon, cinnamon sticks, spice mixes (such as pumpkin pie spice, curry mixes, Chinese five spice), breakfast cereals, baking mixes (muffin and cake mixes), baked goods (cookies, granola/breakfast bars), baby foods (such as infant cereals and purées), and dried tea.

Coumarin was detected in 98% of the survey samples. This is not unexpected, as all products were known to contain cinnamon and cinnamon is known to naturally contain low concentrations of coumarin. Unusually high concentrations of coumarin in a product relative to the overall dataset may indicate that coumarin has been directly added to a product, and may highlight the need for more detailed follow-up. This was not observed in any of the products tested in this survey. The highest concentrations of coumarin were observed in ground cinnamon (7816 ppm) and cinnamon sticks (6823 ppm), followed by spice mixes (2014 ppm), tea (1040 ppm), baked goods (95.3 ppm), breakfast cereals (56.7 ppm), baking mixes (45.8 ppm) and baby food (14.9 ppm), respectively. Coumarin concentrations reported in this survey were similar to coumarin levels reported in recent scientific articles. The results were evaluated by Health Canada. None of the samples were determined to pose an unacceptable concern to human health, and no follow-up actions were deemed necessary.

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 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 FSAP there are 12 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 legislated under specific Acts. These are referred to as federally registered commodities. Under the current regulatory framework, the non-federally registered commodities encompass approximately 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 contaminants (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 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 comprised of federal, provincial and territorial subject matter experts in the area of food safety.

Monitoring studies in Europe[5,6] have reported that coumarin levels in some cinnamon-containing products could result in exceedance of the tolerable daily intake established[7] and recently re-evaluated by the European Food Safety Authority (EFSA)[8]. There is little

data available describing the levels of coumarin observed in cinnamon and cinnamon-containing products in Canada. This coumarin survey was initiated in consultation with Health Canada to establish baseline data in cinnamon and cinnamon-containing foods of domestic and imported origin available on the Canadian retail market.

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 *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.

In the case of coumarin, section B01.046(1) of the *FDR* states:

> *"A food is adulterated if any of the following substances or classes of substances are present therein or have been added thereto:… (b) coumarin, an extract of tonka beans, the seed of Dipteryx odorata Willd. Or Dipteryz oppositifolia Willd."*

The direct addition of coumarin to food has been discontinued due to the potential human health risks that may be associated when ingested at high concentration. However, it is understood that low dietary exposure to coumarin may occur as a result of its natural presence in food ingredients. This premise is also shared by a number of other international food regulatory bodies. There are a number of countries that have specific regulations regarding addition of coumarin to food. The United States has prohibited the direct addition of coumarin to food since 1954[2], and the European Union (EU) has a regulatory limit for desserts (5 mg/kg), fine bakery ware (15 mg/kg), breakfast cereals including muesli (20 mg/kg), and traditional and/or seasonal bakery ware containing a reference to cinnamon in the labelling (50 mg/kg)[10].

Elevated levels of coumarin in specific 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. No such results were found in this survey; therefore no follow-up actions were required.

2. Survey Details

2.1. Coumarin

Coumarin is a natural, fragrant compound found in various plants such as cinnamon, *tonka* beans, and sweet clover. Coumarin naturally occurs in cassia cinnamon (also known as Chinese cinnamon), and to a lesser extent in Ceylon cinnamon. The name 'cinnamon' is correctly used to refer to Ceylon cinnamon (*Cinnamonum verum/zeylanicum* species). True cinnamon is known to be primarily cultivated in Sri Lanka[13]. Cassia cinnamon is primarily cultivated in Indonesia, China, India, and Vietnam to a lesser extent[13]. After harvesting and drying the bark, the product may be shipped globally to be further processed or incorporated as an ingredient into other goods. Ceylon cinnamon is typically more expensive than cassia cinnamon, and has a milder flavour/spice profile. Therefore, due to economics and a preference of the public for a "spicier flavour profile", most of the cinnamon sold today is cassia cinnamon.

In order to achieve a consistent flavour profile in processed foods, the use of flavouring extracts has been a common practice in the food industry. Coumarin (either naturally derived or synthetically produced) has been used as a flavouring agent in the past. However, the use of coumarin in food has been discontinued based on reports of adverse health effects in rats and dogs[3,4]. Although the deliberate addition of coumarin to foods is not permitted in Canada, plants or herbs with naturally occurring coumarin may be added to foods as flavours. The primary source of naturally occurring coumarin in the human diet is cinnamon[4,5]. Relatively low doses of coumarin can lead to elevation of liver enzymes in sensitive individuals, and in severe cases to inflammation of the liver and liver damage[3].

In 2004, the European Food Safety Authority (EFSA) established a Tolerable Daily Intake (TDI) for coumarin[7]. In 2006, Germany's Federal Institute of Risk Assessment (BfR) concluded that high cinnamon consumption would result in excessive exposure to coumarin, and warned against consuming cassia cinnamon due to its relatively high content of coumarin[11]. The Norwegian Scientific Committee for Food Safety also conducted a risk assessment on coumarin and concluded that children and adults who regularly consume even moderate amounts of cinnamon may be at risk of elevated intake of coumarin[12]. That study also indicated that consumption of cinnamon-based tea may result in a coumarin intake in excess of the TDI[12]. In light of new information regarding the toxicity of coumarin, EFSA re-evaluated the substance again in 2008, and determined that the TDI was still valid. Furthermore, they concluded that exposure to coumarin resulting in an intake 3 times higher than the TDI for 1-2 weeks was not of safety concern[8].

2.2. Rationale

The main objective of this targeted survey was to generate baseline surveillance data on the level of coumarin in cinnamon and cinnamon-containing products available on the

Canadian retail market. The survey also allowed comparison of the levels of coumarin observed in products sampled with those reported in recent scientific literature.

Limited data is available on the occurrence of coumarin in foods containing cinnamon intended for human consumption. Cinnamon is a frequently used spice, and is often included in foods intended for consumption by children. Therefore, it was considered important to examine the coumarin levels in commonly available cinnamon-containing products to ensure that the populations consuming these foods are not at risk.

All the survey data was shared with Health Canada.

2.3. Sample Distribution

The 2011-2012 Coumarin in Cinnamon and Cinnamon-Containing Products survey targeted ground cinnamon, spice mixes, cinnamon sticks, baked goods, breakfast cereal, dried tea, baby foods, and baking mixes of both domestic and imported origin. All samples collected were cinnamon or had cinnamon listed as an ingredient. A total of 193 samples were collected in grocery and specialty stores in 11 Canadian cities between April 2011 and March 2012.

As cinnamon is not produced in Canada, all of it is imported. The distinction between import and domestic is the origin of the finished product and not the source of cinnamon. The 193 samples collected included 56 domestically produced products, 56 imported products (from at least 13 countries) and 81 products of unverifiable 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 identify the true origin of the product ingredients. Only those products labelled with a clear statement of “Product of Country A” were considered as being from a specific country of origin.

The samples collected included 87 samples of ground cinnamon, 24 spice mixes (i.e., curry mix, tikka masala, apple pie spice blend), 20 cinnamon stick samples, 20 baked goods (including granola bars and cookies), 15 breakfast cereals, 11 dried tea (loose and bagged) samples, nine baby foods (including baby cereal and jarred purée), and seven baking mixes (including muffin and cake mix). Table 1 illustrates the distribution of samples by category and by country of origin (as listed on the product label).

Table 1. Distribution of survey samples by category and by country of origin (in order of decreasing number of samples)

Country of Origin	Ground Cinnamon	Spice Mix	Cinnamon Sticks	Baked Goods	Breakfast Cereal	Dried Tea	Baby Food	Baking Mixes	Grand Total
Unverifiable*	53	3	12	3	5	4	1		81
Canada	12	11	3	13	1	2	8	6	56
United States	1	3	2	3	9	3		1	22
Indonesia	8		1						9
India	3	2							5
Sri Lanka	4		1						5
United Kingdom		1				2			3
Vietnam	3								3
China	2								2
Thailand		1	1						2
El Salvador		1							1
Pakistan	1								1
Poland		1							1
Portugal				1					1
Taiwan		1							1
Grand Total	87	24	20	20	15	11	9	7	193

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

2.4. Method Details

Samples were analyzed by CFIA using a method which quantitatively determines coumarin concentration in various cinnamon matrices by high-performance liquid chromatography (HPLC) with a photodiode array detector (PDA). The method has a limit of detection (LOD) for coumarin, in all survey matrices, of 0.29 parts per million (ppm) and a limit of quantitation (LOQ) of 0.74 ppm. Samples were tested as sold, meaning that the product was not prepared as per the package instructions (if applicable).

2.5. Limitations

The current survey was designed to provide a snapshot of the levels of coumarin in targeted foods available in Canada. The limited sample sizes analyzed represent a small fraction of products available to Canadian consumers. Therefore, care must be taken when interpreting and extrapolating these results. Regional differences, impact of product shelf-life, storage conditions, or cost of the commodity on the open market were not examined in this survey. It should also be noted that the analytical method used detects total coumarin content of a product, and cannot distinguish between a natural level of coumarin and the deliberate addition of coumarin.

3. Results and Discussion

3.1. Overview of Coumarin Results

The 2011-2012 Coumarin in Cinnamon and Cinnamon-Containing Products survey consisted of testing 193 samples obtained at the Canadian retail level.

All samples were analyzed as sold, meaning they were not prepared/diluted as per the manufacturer's instructions. It is important to note that the concentration of coumarin in the prepared food item (such as tea, baking mixes, infant cereals tested herein) would be lower than the concentration reported in the unprepared products.

Coumarin was detected in 98% of the samples. This result is expected, as all of the products sampled contained cinnamon, which is known to be a natural source of coumarin. Coumarin concentrations ranged from 1.2 ppm to 7816 ppm. Figure 1 illustrates the range of coumarin concentrations detected in survey samples.

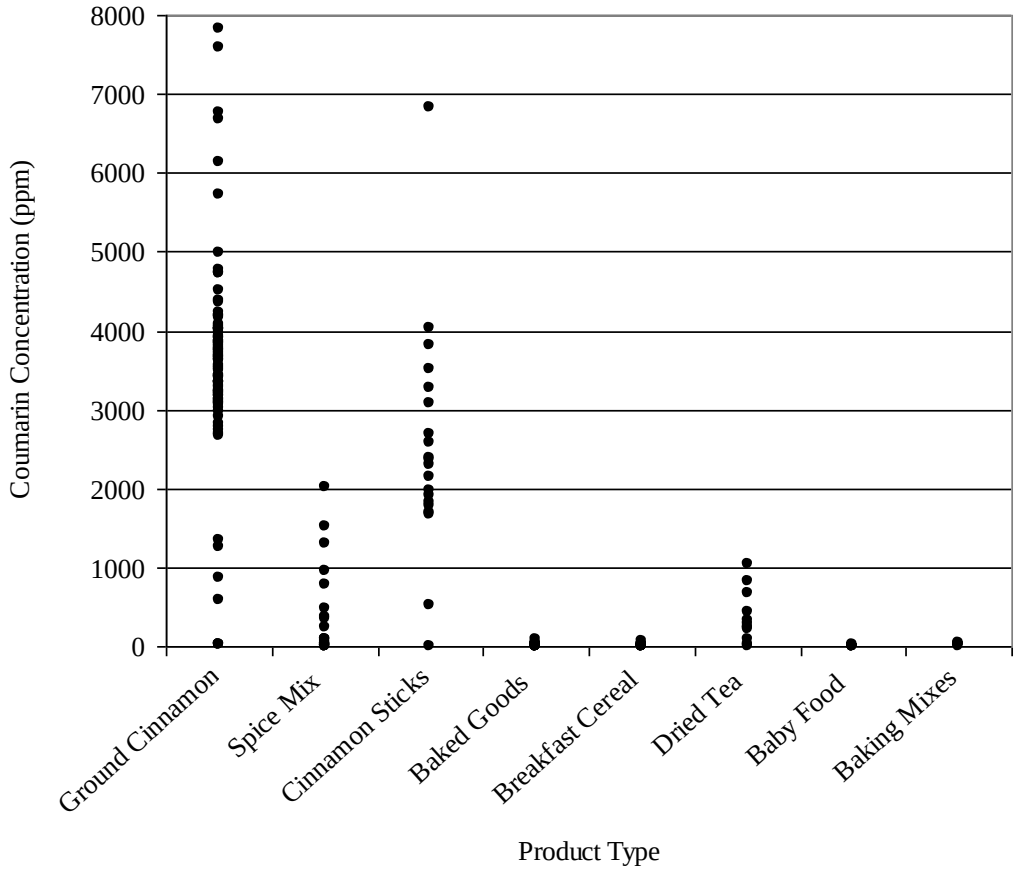

Figure 1. Concentration of coumarin in cinnamon and cinnamon-containing samples by product type (arranged by decreasing number of samples)

Overall, ground cinnamon and cinnamon sticks had the highest levels of coumarin detected. For cinnamon-containing products, spice mixes and tea had the highest levels of coumarin detected. Baked goods, cereal, baby food, and baking mixes all contained considerably lower coumarin concentrations than the previously mentioned products.

More detailed results by product type are presented in the following sections. Where feasible, Section 3.3. provides comparison of the survey results to ranges of coumarin levels reported in the scientific literature.

3.2. Coumarin Results by Product Type

All results were evaluated and shared with Health Canada, who determined they did not pose an unacceptable concern to human health. No follow up actions were necessary. It should be noted that the average coumarin results discussed below were calculated using only those samples for which coumarin was detected (i.e., average of the positive results only). The results of this survey are summarized in Table 2 below.

Table 2. Minimum, maximum and average coumarin levels (arranged in order of increasing sample size)

Product Type	Number of Samples	Minimum (ppm)	Maximum (ppm)	Average* (ppm)
Baking Mixes	7	9.50	45.80	22.91
Baby Food	9	2.30	14.90	6.34
Dried Tea	11	<LOD	1040.10	417.82
Breakfast Cereal	15	<LOD	56.70	10.65
Baked Goods	20	<LOD	95.30	16.60
Cinnamon Sticks	20	6.20	6823.20	2516.20
Spice Mix	24	<LOD	2013.80	367.22
Ground Cinnamon	87	16.20	7816.30	3593.99
Grand Total	**193**	<LOD	7816.30	1991.04

*Average of positive results
Limit of Detection = LOD = 0.29 ppm

3.2.1. Ground Cinnamon

Eighty-seven ground cinnamon samples were analyzed in this survey. Samples spanned a wide range of varieties and included generic brands, organic, bulk, and specialty items (i.e., fair trade, Saigon cinnamon). Some products specifically identified the type of cinnamon utilized (i.e., True cinnamon, Ceylon cinnamon, or cassia), while others gave no indication as to the cinnamon species. The average coumarin concentration in ground cinnamon was 3594 ppm and coumarin concentrations ranged from 16.2 ppm to 7816 ppm. The three highest values reported (7816 ppm, 7597 ppm and 6673 ppm, respectively) were detected in samples labelled as “Saigon cinnamon”. Three of the five lowest coumarin concentrations (16.2 ppm - 859.7 ppm) were detected in samples

labelled as Ceylon cinnamon. There was no apparent trend relating coumarin concentration to the country of origin.

3.2.2. Spice Mixes

Twenty-four samples of spice mixes were analyzed in this survey. Spice mixes included curry powder, Chinese five spice mix, cinnamon sugar, mulling spices, masala, pumpkin pie spice, pickling spice, and other dried pre-mixed food preparations (i.e., Indian curry mix). The average coumarin concentration in the spice mixes was 367.2 ppm. Based on the fact that spice mixes contain variable amounts of cinnamon, a wider range of concentrations was observed in this commodity than in the other cinnamon-containing commodities, ranging from < LOD to 2014 ppm. There did not appear to be any trend relating coumarin concentration to type of spice mix.

3.2.3. Cinnamon Sticks

Twenty samples of cinnamon sticks were analyzed in this survey. Samples included bulk/loose cinnamon sticks, specialty (i.e., cinnamon bark, quills, true cinnamon), organic, and generic brands. The average coumarin concentration in cinnamon stick samples was 2516 ppm, lower than the average concentration detected in ground cinnamon samples in this survey. Coumarin concentrations ranged from 1670 ppm to 6823 ppm, with the exception of two samples that had significantly lower coumarin levels (6.2 ppm and 528 ppm). The sample that contained 6.2 ppm coumarin was labelled as being “true cinnamon”. Similarly, the sample with 528 ppm appeared to be shards of bark as opposed to the traditional whole cinnamon stick.

3.2.4. Baked Goods

Twenty samples of baked goods were collected and analyzed for coumarin in this survey. Samples included cookies, granola bars, and breakfast bars. The average coumarin concentration in baked goods was 16.6 ppm, and levels ranged from < LOD to 95.3 ppm. The average coumarin concentration was slightly higher in cookies (24.9 ppm) than in bars (8.3 ppm), possibly due to the fact that there were a number of cookies specifically flavoured as cinnamon, whereas bars generally had cinnamon included as additional flavouring (i.e., apple cinnamon flavour).

3.2.5. Breakfast Cereals

A total of 15 samples of cinnamon-containing breakfast cereal were tested in this survey. Samples included specialty, organic cereals and brand name cereals. The average coumarin concentration was 10.7 ppm, and values ranged from < LOD to 56.7 ppm.

3.2.6. Dried Tea

Eleven samples of dried tea were analyzed for coumarin in this survey. Teas were selected that listed cinnamon in the ingredients. Tea types included chai, mulled apple, spiced, and Christmas flavoured tea. Tea samples were analyzed as sold, not as they would be consumed (i.e., not brewed/prepared as per the package instructions). Of all the cinnamon-containing products analyzed in this survey, tea samples contained the highest concentrations of coumarin. The average coumarin concentration was 417.8 ppm, and

levels ranged from < LOD to 1040 ppm. There did not appear to be any relationship between tea type/brand and the level of coumarin detected.

3.2.7. Baby Food

Nine samples of baby food were analyzed in this survey. Samples were jarred baby food purées and powdered baby cereal. Powdered baby cereal was tested as sold, not as they would be consumed (i.e., not prepared as per the package instructions). The average coumarin concentration in all baby food samples was 6.3 ppm, and the levels of coumarin ranged from 2.3 ppm to 14.9 ppm. The average coumarin concentration was somewhat higher in baby cereal samples (9.4 ppm) than purées (3.9 ppm). Baby foods had the lowest coumarin concentrations observed in the survey overall.

3.2.8. Baking Mixes

Seven baking mixes were tested in this survey, and included muffin and cake mixes. Baking mix samples were analyzed as sold. The average coumarin concentration was 22.9 ppm, and values ranged from 9.5 ppm to 45.8 ppm.

3.3. Coumarin Results Compared to Literature

There is little data available examining coumarin concentrations in cinnamon and cinnamon-containing products available at the Canadian retail level. A number of studies have been published that examine the levels of coumarin in cinnamon and cinnamon-containing products in the European marketplace. The results of the CFIA coumarin survey are consistent with the literature summarized in Table 3.

Table 3. Summary of CFIA coumarin survey results and literature examining coumarin concentrations in selected food products

Study Author	Year	Description	Number of Samples	Minimum (ppm)	Maximum (ppm)	Average (ppm)
Ground Cinnamon						
CFIA Survey	2012	Ground cinnamon	87	16.2	7816.3	3594.0
Lungarini	2008	Cinnamon powder	20	5	3094	1456
Blahová	2012	Ground cinnamon	60	2650	7017	3856
Sproll	2008	Cinnamon (ceylon)	5	<0.1	<0.1	<0.1
Sproll	2008	Cinnamon cassia	5	2880	4820	3612
Sproll	2008	Cinnamon (unknown origin)	20	<0.1	8790	2419
Vierikova	2009	Cinnamon (contained both whole and ground)	11	n/a	2363	1180
Cinnamon Stick						
CFIA Survey	2012	Cinnamon sticks	20	6.2	6823.2	2516.2
Lungarini	2008	Cinnamon stick	14	3	4445	648.1
Spice Mixes						
CFIA Survey	2012	Spice mix	24	<0.29	2013.8	351.9
Raters	2008	Cinnamon spices/sipce mixtures	172	<0.03	4309	173.7
Baked Goods						
CFIA Survey	2012	Baked goods	20	1.7	95.3	16.6
Raters	2008	Gingerbread	260	<0.03	33.2	5.3
Sproll	2008	Cinnamon star cookies	47	<0.1	88	25
Sproll	2008	Other bakery items	13	<0.1	32	9
Lungarini	2008	Biscuit	10	1	23	12
Lungarini	2008	Cake	10	2	18	9
Vierikova	2009	Pastry	13	n/a	18.5	6.6
Vierikova	2009	Biscuit	16	n/a	11.4	2.8
Dried Tea						
CFIA Survey	2012	Tea	11	<0.29	1040.1	379.8
Vierikova	2009	Tea with cinnamon	6	n/a	11.5	4.7
Lungarini	2008	Tea	5	30	192	81

Many of the studies note the varied coumarin concentrations detected not only between samples, but even within samples of cinnamon[13,14]. In the literature, this is speculated to be due to the mixing of cinnamon species within cinnamon products[13].

Differences in the average concentrations may be due to a variety of factors, including mixing of cinnamon species, differences in product composition (especially in cinnamon-containing products) as well as differences in data manipulation (i.e. methods of calculating average concentrations varied in the referenced studies).

4. Conclusions

The 2011-2012 Coumarin targeted survey generated baseline surveillance data on the concentrations of coumarin in domestic and imported cinnamon and cinnamon-containing products.

One hundred and ninety three products were sampled for this survey, including ground cinnamon, cinnamon sticks, spice mixes, baked goods, breakfast cereal, dried tea, baby foods, and baking mixes. Coumarin was detected in 98% of the survey samples. The highest average and maximum concentrations of coumarin detected were found in ground cinnamon and cinnamon sticks. Samples identified as Saigon cinnamon had notably high levels of coumarin, and samples labelled as Ceylon cinnamon had low levels of coumarin. Of the cinnamon-containing products, spice mixes and dried tea had the highest average coumarin levels, which may be due to the higher proportion of cinnamon contained within these products.

Comparison of the survey results with data available in the scientific literature showed that the levels of coumarin detected in Canadian retail products is similar to those reported in a variety of European studies.

Based on the absence of regulatory limits for naturally occurring coumarin in foods in Canada, survey data produced herein was provided to Health Canada. Health Canada determined that the levels of coumarin in food observed in the current Coumarin survey are not expected to pose an unacceptable health concern, and therefore no follow-up actions were needed.

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