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Inspection Agency

Agence canadienne
d'inspection des aliments

FOOD SAFETY ACTION PLAN

REPORT

2013-2014

TARGETED SURVEYS - CHEMISTRY

**Coumarin in Dried Beverage Mixes, Breads, Baking Mixes,
Spice Mixes, Dried Tea, Baked Goods, and Breakfast Foods**

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**Special Surveys
Chemical Evaluation
Food Safety Division
Canadian Food Inspection Agency
1400 Merivale Road
Ottawa Ontario Canada
K1A 0Y9**

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Executive Summary

Targeted surveys are a means used by the Canadian Food Inspection Agency (CFIA) to focus its surveillance activities on areas of highest risk. Targeted surveys have been incorporated into the CFIA's regular surveillance activities as a valuable tool for generating baseline information on foods and/or hazards that are not addressed by other Agency activities.

The main objectives of this targeted survey were to:

- generate baseline surveillance data on the levels of coumarin in selected domestic and imported cinnamon-containing products available on the Canadian retail market,
- compare, where feasible, the prevalence of coumarin in foods targeted in this survey with that of similar products in previous surveys on coumarin and the scientific literature.

Coumarin is a natural, fragrant compound found in plants such as cinnamon, tonka beans, and sweet clover. Coumarin was utilized as a flavouring agent in the food and perfume industry for many years until evidence related to its toxicological properties and potential adverse effects to the liver led to its use in food being discontinued or banned in a number of countries, such as Canada and the United States. 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 concern.

The 2013-2014 CFIA Coumarin survey targeted domestic and imported products containing cinnamon. A total of 749 samples were collected from retail stores in 6 Canadian cities between May 2013 and February 2014. The samples collected included dried beverage mixes, breads, baking mixes, spice mixes, dried tea, baked goods, oatmeal, and adult, children and infant breakfast cereals. All products sampled contained cinnamon in their list of ingredients.

Coumarin was detected in 95% of the survey samples. This is expected, as all products were known to contain cinnamon, and cinnamon is known to naturally contain low concentrations of coumarin. The detected coumarin levels ranged from 0.1 mg/kg to 2510 mg/kg (reported as parts per million in previous reports). The highest concentration of coumarin was observed in a pumpkin pie spice mix sample (2510 mg/kg).

The prevalence and levels of coumarin in product types sampled in the current survey were compared with results in the previous coumarin targeted surveys. The detected coumarin levels in spice mixes, dried tea, and baked goods were comparable to levels reported in previous surveys and scientific literature.

The current as well as the 2011-2012 FSAP survey results were provided to Health Canada. Health Canada determined that the levels of coumarin observed are not expected to pose a concern to human health, therefore no product recalls were carried out.

1. Introduction

1.1 Targeted Surveys

The Canadian Food Inspection Agency (CFIA) monitors both domestic and imported foods for the presence of allergenic, microbiological, chemical, and physical hazards. One of the tools used to maintain this oversight are targeted surveys, which are a means to establish baseline information on specific hazards and to investigate emerging risks. Targeted surveys are part of the Agency's core activities along with other surveillance strategies, which include the National Chemical Residue Monitoring Program (NCRMP), the National Microbiological Monitoring Program (NMMP), and the Children's Food Project (CFP). The surveys are complementary to other CFIA surveillance activities in that they examine hazards and/or foods that are not routinely included in those monitoring programs.

Targeted surveys are used to gather information regarding the possible occurrence or prevalence of hazards in defined food commodities. These surveys generate essential information on certain hazards in foods, identify or characterize new and emerging hazards, inform trend analysis, prompt or refine human health risk assessments, assess compliance with Canadian regulations, highlight potential contamination issues, and/or influence the development of risk management strategies as appropriate.

Due to the vast number of hazard 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, the media, and/or a risk-based model developed by the Food Safety Science Committee, a group of federal, provincial and territorial subject matter experts in the area of food safety.

Monitoring studies in Europe^{1,2} have reported that coumarin levels in some cinnamon-containing products could result in exceedance of the tolerable daily intake established³ and recently re-evaluated by the European Food Safety Authority (EFSA)⁴. 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 further baseline data in cinnamon and cinnamon-containing products of domestic and imported origin available on the Canadian retail market.

1.2 Acts, Regulations, and the Codes of Practice

The specific acts and regulations applicable to this survey are described below.

The *Food and Drugs Act* (FDA) is the legal authority that governs the sale of food in Canada. 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 *Food and Drug Regulations* (FDA and FDR).

Health Canada establishes health-based maximum levels for chemical residues, contaminants, and natural toxins in food sold in Canada. Certain maximum levels for chemical contaminants in food appear in the Canadian *Food and Drug Regulations* (FDR), where they are referred to as tolerances. There are also a number of maximum levels that do not appear in the regulations and are referred to as standards.

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 to thereto: ... (b) coumarin, an extract of tonka beans, the seed of *Dipteryx odorata* Willd. or *Dipteryx 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 concentrations. 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 such as the United States, which has prohibited the direct addition of coumarin to food since 1954⁵.

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 notification of the producer or importer, follow-up inspections, additional directed sampling, and recall of products. No elevated levels 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 (*Cinnamomum verum/zeylanicum* species). True cinnamon is known to be primarily cultivated in Sri Lanka⁶. Cassia cinnamon is primarily cultivated in Indonesia,

China, India, and to a lesser extent, Vietnam⁶. 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^{7,8}. 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^{8,9}. The vast majority of people can consume foods that naturally contain coumarin daily without any adverse health effects; however, there is a small subpopulation of individuals who are sensitive to coumarin exposure. For this sensitive subpopulation, intakes of coumarin at levels that are significantly higher than levels normally found in food can lead to elevation of liver enzymes, and in severe cases to inflammation of the liver⁷. These effects have been observed to be reversible.

In 2004, the European Food Safety Authority (EFSA) established a Tolerable Daily Intake (TDI) of 0.1 mg per kilogram of body weight for coumarin³. 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 excessive amounts of cassia cinnamon due to its relatively high content of coumarin¹⁰. 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 coumarin¹¹. That study also indicated that consumption of cinnamon-based tea may result in a coumarin intake in excess of the TDI¹¹. 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 three times higher than the TDI for 1-2 weeks was not a safety concern⁴.

2.2 Rationale

The main objectives of this targeted survey were to generate further baseline surveillance data on the level of coumarin in cinnamon-containing products available on the Canadian retail market, and to compare the prevalence and levels of coumarin to previous targeted surveys and scientific literature.

Limited data is available on the occurrence of coumarin in foods containing cinnamon. Cinnamon is a frequently used spice, and is often included in foods intended for consumption by

children, such as cereals. Cinnamon is widely used in breads, cookies, cakes, tea, and other beverages for its unique flavour¹. 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 2013-2014 Coumarin survey targeted domestic and imported dried beverage mixes, breads, baking mixes, spice mixes, dried tea, baked goods and breakfast foods. Table 1 presents the distribution of survey samples. Specific brands were not targeted. A total of 749 samples were collected from Canadian retail stores in 6 cities between May 2013 and February 2014. The 749 samples collected included 32 dried beverage mixes, 61 breads, 99 baking mixes, 103 spice mixes, 115 dried teas, 139 baked goods, and 200 breakfast foods. All products sampled contained cinnamon in their list of ingredients.

The 749 survey samples included 128 domestic products, 322 imported products, and 299 products of unspecified origin. An unspecified country of origin refers to those samples for which the origin is not indicated on the product label. It is important to note that the products sampled often contained the statement “packaged 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.

Table 1. Distribution of survey samples by commodity (in order of increasing number of total samples)

Commodity	Sub-Category (# of samples)	Total number of samples
Dried Beverage Mixes	Cappuccino Mix (2)	32
	Chai Latte Mix (19)	
	Cider Mix (1)	
	Hot Chocolate Mix (8)	
	Powdered Tea Mix (2)	
Breads	Bread (8)	61
	Bagel (25)	
	English Muffin (1)	
	Other Bread (27)	
Baking Mixes	Bread Mix (16)	99
	Cake Mix (6)	
	Cookie Mix (5)	
	Misc Baking Mixes (10)	
	Muffin Mix (62)	
Spice Mixes	Cinnamon Sugar (2)	103
	Curry (28)	
	Five Spice Mix (17)	
	Masala mix (12)	
	Misc Spice Mix (15)	
	Pickling Spice (12)	
	Pie Spice (15)	
Tea Spice (2)		
Dried Tea*	Black Tea (38)	115
	Green Tea (3)	
	Herbal Tea (72)	
	White Tea (2)	
Baked Goods	Baked Dessert (68)	139
	Cookies (31)	
	Granola/Cereal Bar (40)	
Breakfast Foods	Adult Cereal (71)	200
	Children Cereal (65)	
	Infant Cereal (52)	
	Oatmeal (12)	

* All products marketed in the Canadian marketplace as tea are included. CFIA does not provide any assurances that these products meet the botanical definition of tea and hence these products may also be considered as infusions or flavored teas

2.4 Limitations

This targeted survey was designed to provide a snapshot of coumarin levels in cinnamon-containing foods available to Canadian consumers, and highlight commodities that warrant further investigation. The limited number of samples analyzed represents a small fraction of the products available to consumers. Therefore, care must be taken when interpreting and extrapolating these results. Few inferences or conclusions were made regarding the data with respect to country of origin (refer to Section 2.3).

Analysis was completed on products as available on the Canadian retail market. Some of the products sampled in this survey are considered ingredients and/or require preparation prior to consumption (i.e., mixing with liquid). However, the results herein represent finished food products as sold and not as they would be consumed.

3. Results and Discussion

3.1 Overview of Coumarin Results

The 2013-2014 Coumarin in Cinnamon-Containing Products survey consisted of analyzing 749 samples obtained at the Canadian retail level. All products sampled contained cinnamon in their list of ingredients.

Coumarin was detected in 95% samples. This was expected, as all of the products sampled contained cinnamon, which is known to be a natural source of coumarin. Detected Coumarin concentrations ranged from 0.1 to 2510 mg/kg. Figure 1 illustrates the range of coumarin concentration detected in the survey samples. Overall, spice mixes and dried tea contained the highest levels of coumarin.

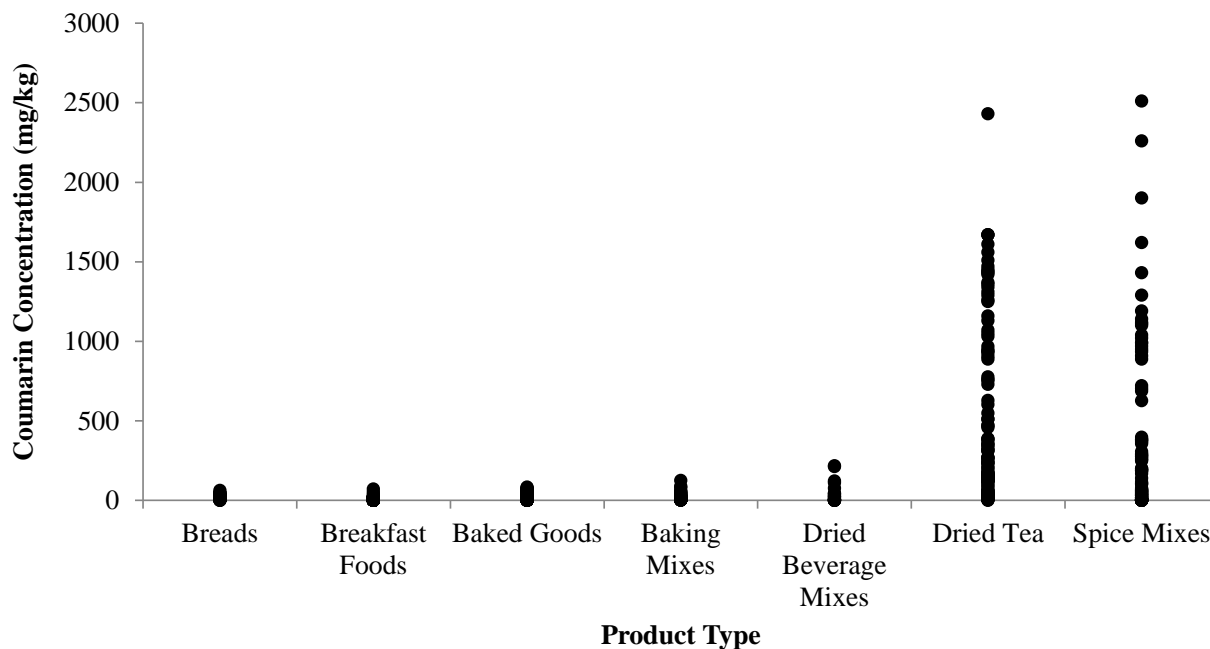


Figure 1. Concentration of coumarin in cinnamon-containing samples by product type (arranged in increasing coumarin levels)

Note: Only levels of coumarin above the limit of detection are depicted in the graph

The results of this survey are summarized in Table 2 below. More detailed results by product type are presented in the following sections, with comparison to the results from previous targeted surveys, as well as to the scientific literature, where feasible. Many studies have noted that the coumarin concentrations detected were highly varied, not only between samples but even within the same sample package^{12,15}.

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

Product Type	Number of Samples	Number (%) of Samples with Detected Coumarin Levels	Minimum (mg/kg)	Maximum (mg/kg)	Average* (mg/kg)
Dried Beverage Mixes	32	21 (66)	0.2	217	45.4
Breads	61	60 (98)	0.2	63.4	19.7
Baking Mixes	99	99 (100)	0.9	125	14.8
Spice Mixes	103	90 (87)	0.2	2510	390
Dried Tea	115	114 (99)	0.3	2430	500
Baked Goods	139	138 (99)	0.1	83.3	15.5
Breakfast Foods	200	188 (94)	0.1	70.7	5.5

* Average is calculated using only the results of the samples testing positive for coumarin

3.2 Coumarin Results by Product Type

3.2.1 Dried Beverage Mixes

The average coumarin concentration in dried beverage mixes was 45.4 mg/kg, and the levels observed ranged from 0.2 to 217 mg/kg. Chai latte mixes had the widest range of coumarin levels detected compared to other beverage mixes. Figure 2 depicts the distribution of coumarin results by type of dried beverage mix.

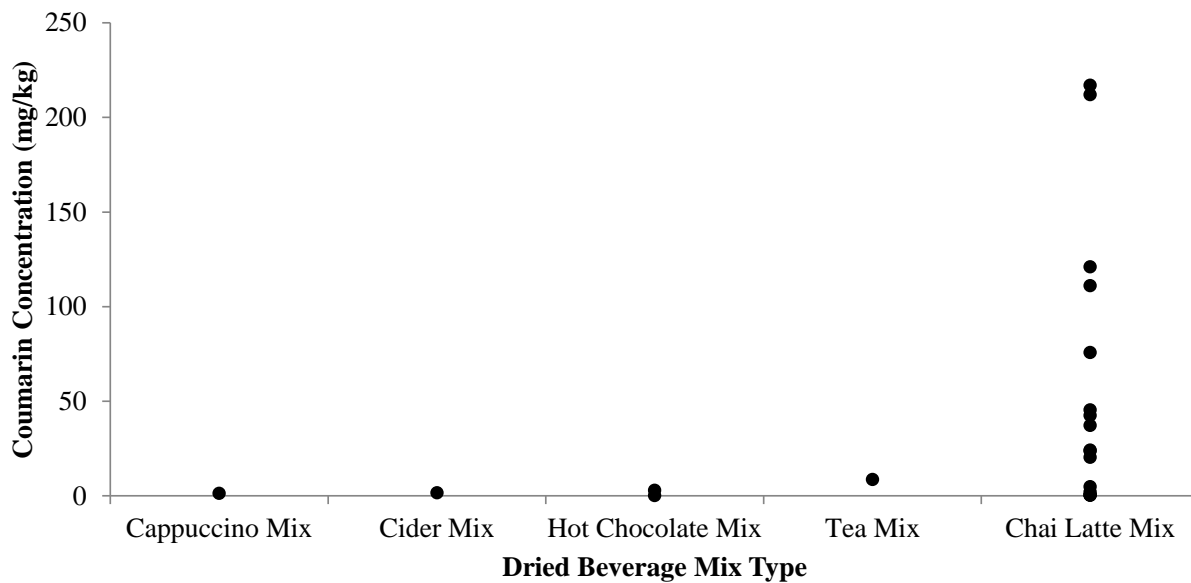


Figure 2. Concentration of coumarin in dried beverage mixes by sample types

Note: Only levels of coumarin above the limit of detection are depicted in the graph

Dried beverage mixes have not been previously examined in targeted surveys or to our knowledge, in the scientific literature. Therefore, no comparisons could be made.

3.2.2 Breads

The average coumarin concentration was 20 mg/kg, with levels ranging from 0.2 to 63.4 mg/kg. Overall, breads, bagels, and other breads sampled had a wide distribution of coumarin levels, with the exception of English muffins as only one sample was taken. The highest coumarin level was detected in a sample of cinnamon scones (63.4 mg/kg). Figure 3 depicts the distribution of coumarin results by type of bread.

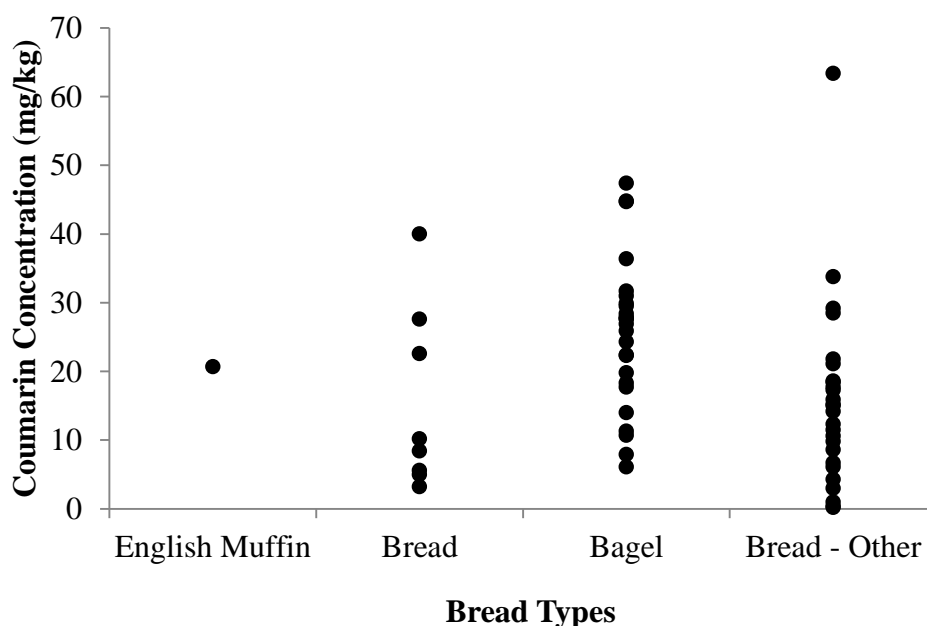


Figure 3. Concentration of coumarin in breads by sample types

Note: Only levels of coumarin above the limit of detection are depicted in the graph

Breads have not been previously examined in targeted surveys or to our knowledge, in the scientific literature. Therefore, no comparisons could be made.

3.2.3 Baking Mixes

Baking mix samples were analyzed as sold, and not as they would be consumed. The average coumarin concentration was 14.8 mg/kg, and levels ranged from 0.9 to 125 mg/kg. Cookie mix and bread mix had lower levels of coumarin compared to muffin mix, cake mix and miscellaneous baking mix. One sample of cake mix contained a higher level of coumarin compared to the rest of the samples. Figure 4 depicts the distribution of coumarin results by type of baking mix.

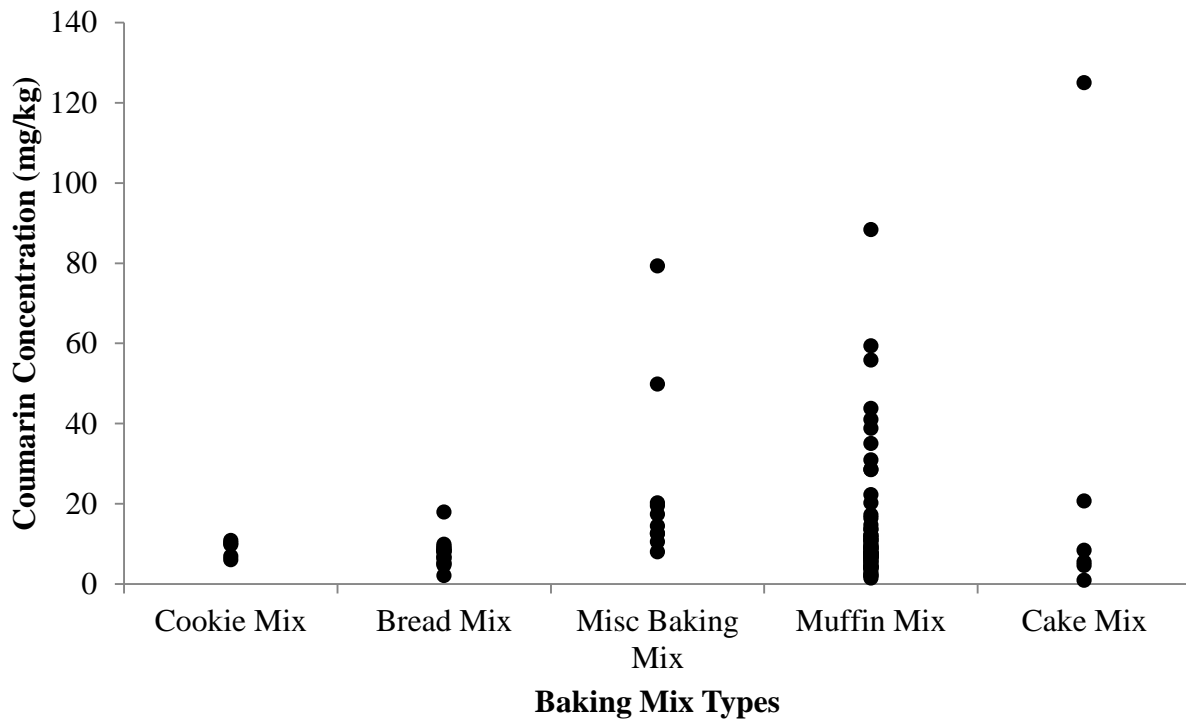


Figure 4. Concentration of coumarin in baking mixes by sample types
 Note: Only levels of coumarin above the limit of detection are depicted in the graph

Baking mixes have not been previously examined in targeted surveys or to our knowledge, in the scientific literature. Therefore, no comparisons could be made.

3.2.4 Spice Mixes

The average coumarin concentration in the spice mixes was 390 mg/kg, with levels ranging from 0.2 to 2510 mg/kg. Curry powder contained the lowest levels of coumarin compared to the other commodities sampled. Spice mixes for pies contained the highest levels of coumarin. Figure 5 depicts the distribution of coumarin results by type of spice mix.

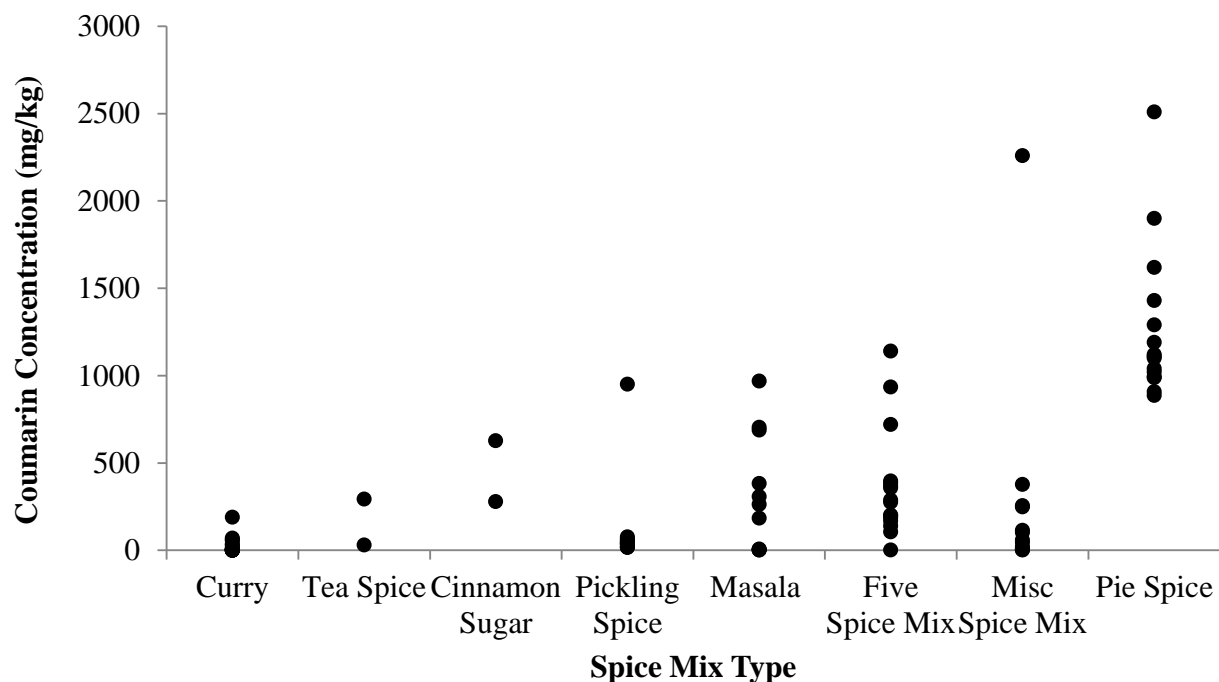


Figure 5. Concentration of coumarin in spice mix by sample types

Note: Only levels of coumarin above the limit of detection are depicted in the graph

Table 3 summarizes the current and previous targeted survey results on spice mixes and makes comparisons to scientific literature. For spice mixes, the average coumarin levels in the current survey are lower than the levels detected in the 2012-2013 survey¹³, but are very similar to the 2011-2012 survey¹⁴. Coumarin levels were also comparable to a study conducted by Raters¹⁵.

Table 3. Summary of targeted survey and scientific literature results on coumarin levels in spice mixes

Study Author	Year	Description	Number of Samples	Minimum (mg/kg)	Maximum (mg/kg)	Average (mg/kg)
Spice Mixes						
CFIA Survey	2013 - 2014	Spice mix	103	0.2	2510	390*
CFIA Survey ¹³	2012 - 2013	Spice mix	53	30	3078	568*
CFIA Survey ¹⁴	2011 - 2012	Spice mix	24	<0.29	2014	352*
Raters ¹⁵	2008	Cinnamon spices / spice mix	172	<0.03	4309	174

* Average is calculated using only the results of the samples testing positive for coumarin

3.2.5 Dried Tea

There is a wide selection of products currently marketed as “tea”. These products include infusions, blends as well as mixtures that are often more than what is accepted in the botanical

definition of tea. As Canadians consume this wide array of products, they are included as part of this survey.

Tea samples were analyzed as sold, not as they would be consumed (i.e. not brewed as per the package instructions). Cinnamon is sometimes added to dried tea leaves for flavor and may contain elevated levels of coumarin¹. The average coumarin concentration in the dried tea samples was 500 mg/kg, and levels ranged from 0.3 mg/kg to 2430 mg/kg. Herbal tea contained the highest levels of coumarin in comparison to other dried teas. Figure 6 depicts the distribution of coumarin results by type of dried tea.

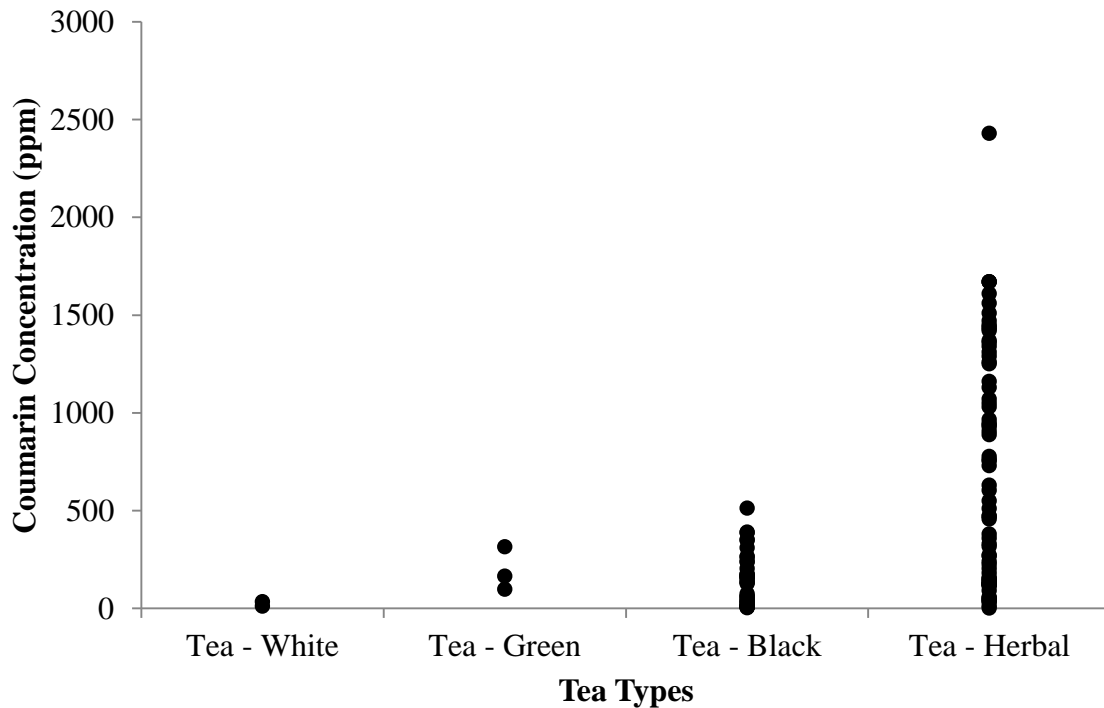


Figure 6. Concentration of coumarin in dried tea by sample types

Note: Only levels of coumarin above the limit of detection are depicted in the graph

Table 4 summarizes the current and previous targeted survey results on dried tea and makes comparisons to scientific literature.. The average and maximum concentrations measured in this survey are higher than the 2011-2012 survey¹⁴ and a survey conducted by Lungarini¹.

Table 4. Summary of targeted survey and scientific literature results on coumarin levels in dried tea

Study Author	Year	Description	Number of Samples	Minimum (mg/kg)	Maximum (mg/kg)	Average (mg/kg)
Dried Tea						
CFIA Survey	2013 - 2014	Tea	115	0.3	2430	500*
CFIA Survey ¹⁴	2011 - 2012	Tea	11	<0.29	1040	380*
Lungarini ¹	2008	Tea	5	30	192	81

* Average is calculated using only the results of the samples testing positive for coumarin

3.2.6 Baked Goods

The average coumarin concentration in baked goods was 16 mg/kg, and levels ranged from 0.1 mg/kg to 83 mg/kg. Baked desserts contained the highest levels of coumarin in comparison to granola bars and cookies. Figure 7 depicts the distribution of coumarin results by type of baked goods.

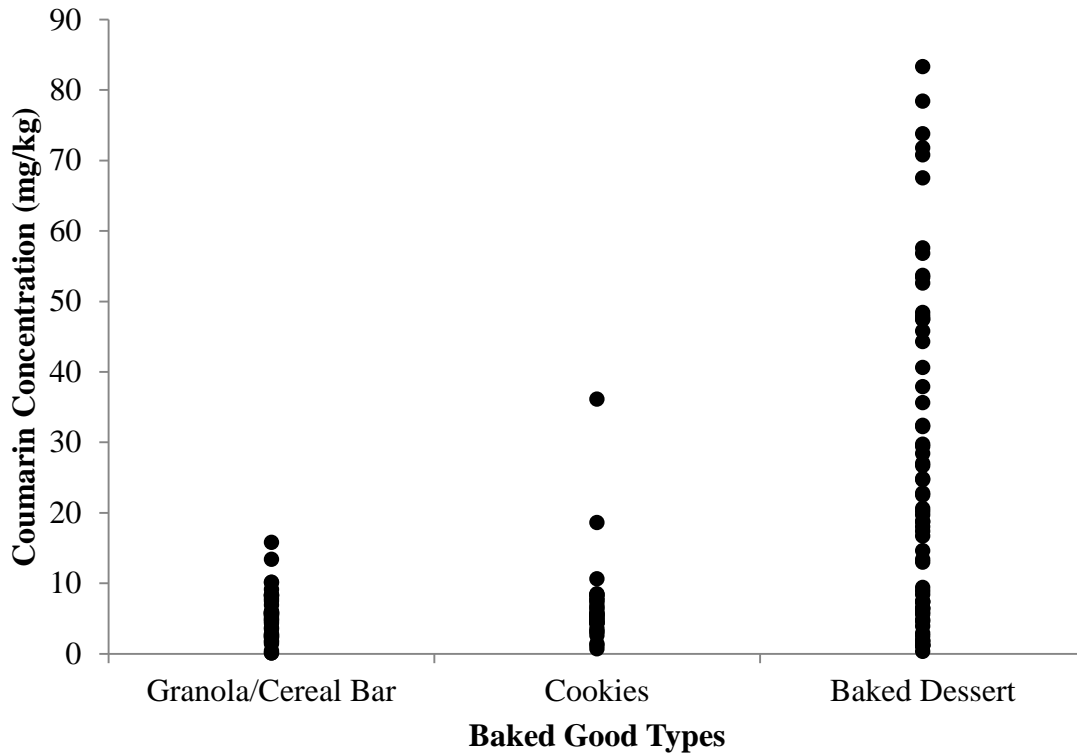


Figure 7. Concentration of coumarin in baked goods by sample types
 Note: Only levels of coumarin above the limit of detection are depicted in the graph

Table 5 summarizes the current and previous targeted survey results on baked goods and makes comparisons to scientific literature. Overall, the coumarin levels in baked goods from the current survey are consistent with the results obtained in the previous surveys^{13,14}, and with scientific literature.

Table 5. Summary of targeted survey and scientific literature results on coumarin levels in baked goods

Study Author	Year	Description	Number of Samples	Minimum (mg/kg)	Maximum (mg/kg)	Average (mg/kg)
Baked Goods						
CFIA Survey	2013 - 2014	Baked goods	139	0.1	83.3	15.5*
CFIA Survey ¹³	2012 - 2013	Baked goods	20	1.7	95	17*
Ballin ¹⁶	2013	Traditional and fine bakery ware	53	0.4	53	18
Raters ¹⁵	2008	Gingerbread	260	<0.03	33	5
Raters ¹⁵	2008	Cinnamon cookies	47	<0.03	103	22
Sproll ²	2008	Cinnamon cookies	47	<0.1	88	25
Lungarini ¹	2008	Biscuit	10	1	23	12
Lungarini ¹	2008	Cake	10	2	18	9

* Average is calculated using only the results of the samples testing positive for coumarin

3.2.7 Breakfast Foods

The average coumarin concentration was 5 mg/kg, with levels ranging from 0.1 mg/kg to 71 mg/kg. One sample of adult cereal tested higher level of coumarin compared to the rest of the breakfast food samples. Figure 8 depicts the distribution of coumarin results by type of breakfast food.

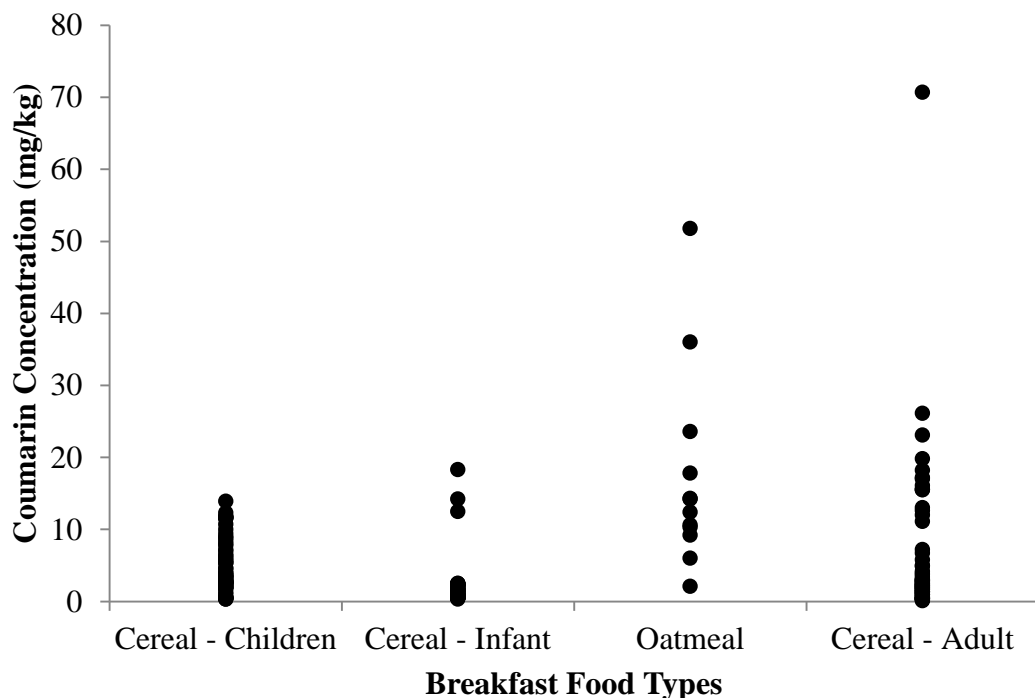


Figure 8. Concentration of coumarin in breakfast foods by sample types

Note: Only levels of coumarin above the limit of detection are depicted in the graph

Table 6 summarizes the current targeted survey results on breakfast foods and makes comparisons to scientific literature. In the current survey, the average concentration of coumarin in breakfast foods is comparable to levels reported in scientific literature^{17,16}. The maximum concentration measured in the current survey is higher than that reported in literature.

Table 6. Summary of targeted survey and scientific literature results on coumarin levels in breakfast foods

Study Author	Year	Description	Number of Samples	Minimum (mg/kg)	Maximum (mg/kg)	Average (mg/kg)
Breakfast Foods						
CFIA Survey	2013 - 2014	Breakfast cereal and oatmeal	200	0.1	71	5*
Ballin ¹⁶	2013	Breakfast cereal	4	0.9	10	3
Vierikova ¹⁷	2009	Breakfast cereal	23	N/A	9	2

* Average is calculated using only the results of the samples testing positive for coumarin

4. Conclusions

The 2013-2014 coumarin targeted survey generated baseline surveillance data on the concentrations of coumarin in domestic and imported cinnamon-containing products. Seven hundred and forty-nine products were sampled and analyzed in this survey, including 200 breakfast foods, 139 baked goods, 115 dried tea, 103 spice mixes, 99 baking mixes, 61 breads, and 32 dried beverage mixes. Coumarin was detected in 95% of the samples, with levels ranging from 0.1 mg/kg to 2510 mg/kg. The highest levels of coumarin were detected in spice mixes and dried tea samples.

The average and maximum coumarin concentration in spice mixes, dried tea, and baked goods were comparable to previous FSAP targeted surveys. In addition, comparison of the survey results to scientific literature showed that the levels of coumarin detected in Canadian retail products are similar to those reported in a variety of European studies.

Based on the opinion received from Health Canada on the combined 2011-2012 and 2012-2013 coumarin surveys, the levels of coumarin in food observed in the current survey are not expected to pose a concern to human health, therefore no product recalls were carried out.

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