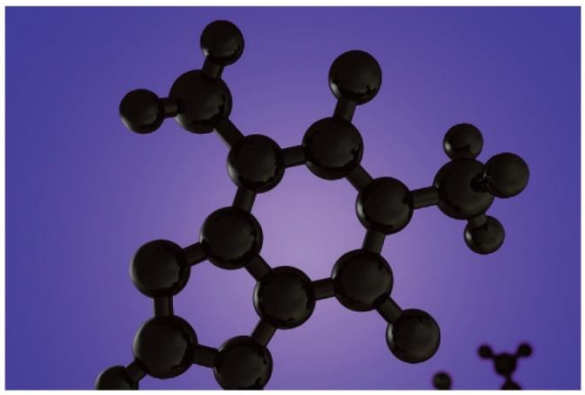
Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2012-2013 Targeted Surveys

Chemistry



Coumarin in Cinnamon and Cinnamon-Containing Products

Canada

Table of Contents

Executive Summary 2
1 Introduction 3
1.1 Food Safety Action Plan 3
1.2 Targeted Surveys 3
1.3 Acts and Regulations 4
2 Survey Details 5
2.1 Coumarin 5
2.2 Rationale 6
2.3 Sample Distribution 6
2.4 Method Details 7
2.5 Limitations 7
3 Results and Discussion 7
3.2 Coumarin Results by Product Type 8
3.2.1 Ground Cinnamon 8
3.2.2 Spice Mixes 9
3.3 Coumarin Results Compared to Previous FSAP Survey and to the Scientific Literature 10
4 Conclusion 11
5 References 12

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 generate baseline data in order to evaluate various foods for specific hazards.

The main objectives of this targeted survey were to generate baseline surveillance data on the level of coumarin in cinnamon and cinnamon-containing products available on the Canadian retail market, and to compare the levels of coumarin detected with the results of the 2011-2012 FSAP Targeted Survey on coumarin.

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 (which are based on model studies carried out on rats and dogs) 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 risk.

The 2012-2013 coumarin survey targeted domestic and imported cinnamon and cinnamon-containing spice mixes. A total of 93 samples were collected from grocery and specialty stores in 11 Canadian cities between April 2012 and March 2013. All products sampled contained cinnamon in their list of ingredients. The samples collected included ground cinnamon and spice mixes.

Coumarin was detected in 100% 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. Unusually high concentrations of coumarin in a product may indicate that coumarin has been directly added to a product, and may highlight the need for more detailed follow-up. Elevated coumarin concentrations were not observed in any of the products tested in this survey. The highest concentration of coumarin was observed in a ground cinnamon sample (7621 ppm). None of the samples tested for the current survey contained levels of coumarin in excess of levels detected in samples analyzed in the 2011-2012 FSAP survey. Health Canada had indicated that the levels of coumarin observed in this previous survey would not pose an unacceptable concern to human health, therefore this opinion is applicable to the current survey results as well since lower coumarin levels were detected. 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 system for food, health, and consumer products. The FCSAP initiative unites multiple government 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. FSAP also looks to verify that the food industry is actively applying preventive measures, and that there is a rapid response when/if these measures fail.

Within 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 testing of foods from 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 the *Food and Drug Regulations*. Targeted surveys are primarily directed towards non-federally registered commodities.

1.2 Targeted Surveys

Targeted surveys are used to gather information regarding the possible 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 of a particular chemical hazard is targeted to commodity types and/or geographical areas.

Due to the vast number of chemical hazards and food commodity combinations, it is not possible, nor should it be necessary, to use targeted surveys to identify and quantify all chemical hazards in foods. To identify food-hazard combinations of greatest potential health risk, the CFIA uses a combination of scientific literature, media reports, and/or a risk-based model

developed by the Food Safety Science Committee, 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 established[3] 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.

1.3 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 *Food and Drug Regulations*.

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 Dipterym odorata Willd. Or Dipteryz oppositifolia Willd."*[5]

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 1954[6].

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 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 (*Cinnamonum verum/zeylanicum* species). True cinnamon is known to be primarily cultivated in Sri Lanka[7]. Cassia cinnamon is primarily cultivated in Indonesia, China, India, and Vietnam to a lesser extent[7]. 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[8,9]. 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[9,10]. The vast majority of people can consume foods that naturally contain coumarin daily without adverse effects from exposure to coumarin; however, there is a small subpopulation of individuals who are sensitive to coumarin. For this sensitive subpopulation, intakes of coumarin at significantly higher levels than would normally be found in food can lead to elevation of liver enzymes, and in severe cases to inflammation of the liver[8]. These effects have been observed to be reversible.

In 2004, the European Food Safety Authority (EFSA) established a Tolerable Daily Intake (TDI) for coumarin[3]. 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 coumarin[10]. 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[11]. That study also indicated that consumption of cinnamon-based tea may result in a coumarin intake in excess of the TDI[11]. 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 of safety concern[4].

2.2 Rationale

The main objectives of this targeted survey were to generate further baseline surveillance data on the level of coumarin in cinnamon and cinnamon-containing products available on the Canadian retail market, and to compare the prevalence and levels of coumarin to previous FSAP 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. 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 2012-2013 Coumarin in Cinnamon and Cinnamon-Containing Products survey targeted ground cinnamon and spice mixes containing cinnamon of both domestic and imported origin. A total of 93 samples were collected in grocery and specialty stores in 11 Canadian cities between April 2012 and March 2013. The samples collected included 40 samples of ground cinnamon and 53 spice mixes (e.g., curry mix, garam masala, Chinese five spice).

As cinnamon is not produced in Canada, all of it is imported. The distinction between imported and domestic is the origin of the finished product and not the source of cinnamon. The 93 samples collected included 33 domestic products, 55 imported products (from at least 10 different countries) and 5 products of unspecified origin. In general, an unspecified country of origin refers to those samples for which the origin could not be determined from the product label or sample information. It is important to note that the products sampled often contained the statement “imported for Company A in Country Y” or “manufactured for Company B in Country Z”, and though the labeling meets the intent of the regulatory standard, it does not specify the true origin of the product ingredients. Only those products labeled 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 ISO 17025 accredited CFIA laboratory using a method which quantitatively determines coumarin concentration in various cinnamon matrices by liquid chromatography (LC) 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.

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 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 2012-2013 Coumarin in Cinnamon and Cinnamon-Containing Products survey consisted of analyzing 93 samples obtained at the Canadian retail level.

Coumarin was detected in 100% of the samples. This was expected, as all of the products sampled contained cinnamon, which is known to be a natural source of coumarin. Coumarin concentrations ranged from 30 ppm to 7621 ppm. Figure 1 illustrates the range of coumarin concentrations detected in the survey samples. Overall, ground cinnamon had the highest levels of coumarin detected in comparison to the spice mixes.

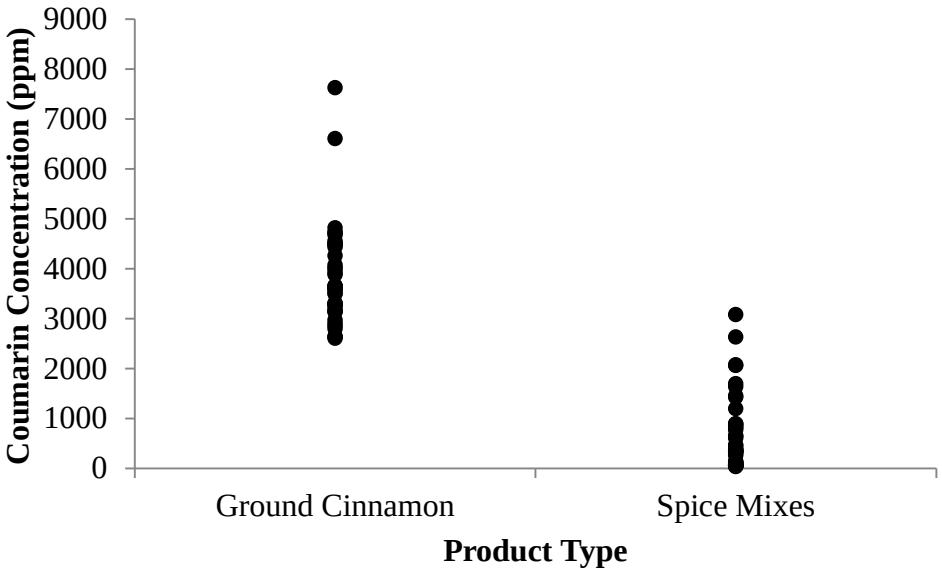


Figure 1. Concentration of coumarin in ground cinnamon and cinnamon-containing spice mixes by product types

The results of this survey are summarized in Table 1 below. More detailed results by product type are presented in the following sections, with comparison to results obtained from the 2011-2012 FSAP coumarin survey conducted by the CFIA, as well as to the scientific literature.

Table 1. Minimum, maximum, and average coumarin levels in ground cinnamon and spice mixes.

Product Type	Number of Samples	Minimum (ppm)	Maximum (ppm)	Average (ppm)
Ground Cinnamon	40	2604	7621	3844
Spice Mixes	53	30	3078	568
Grand Total	**93**	30	7621	1977

3.2 Coumarin Results by Product Type

3.2.1 Ground Cinnamon

Forty ground cinnamon samples were analyzed in this survey. Samples spanned a wide range of varieties and included generic brands, organic, and specialty items (e.g.,fair trade, Saigon

cinnamon). None of the ground cinnamon products identified the specific type of cinnamon utilized (e.g., Ceylon cinnamon or cassia). The average coumarin concentration in ground cinnamon was 3844 ppm, and the levels observed ranged from 2604 to 7621 ppm.

3.2.2 Spice Mixes

Fifty-three samples of spice mixes were analyzed in the current survey. Spice mixes included curry powder, Chinese five spice mix, cinnamon sugar, pumpkin pie spice, masala, and other dried pre-mixed spice preparations (e.g., stewing or barbeque spice mix). The average coumarin concentration in the spice mixes was 568 ppm. Based on the fact that spice mixes contain variable amounts of cinnamon, a wider range of concentrations and a lower maximum concentration was observed in this commodity in comparison to ground cinnamon, ranging from 30 ppm to 3078 ppm. See Figure 2 for an illustration of the range of coumarin concentrations detected in spice mix samples.

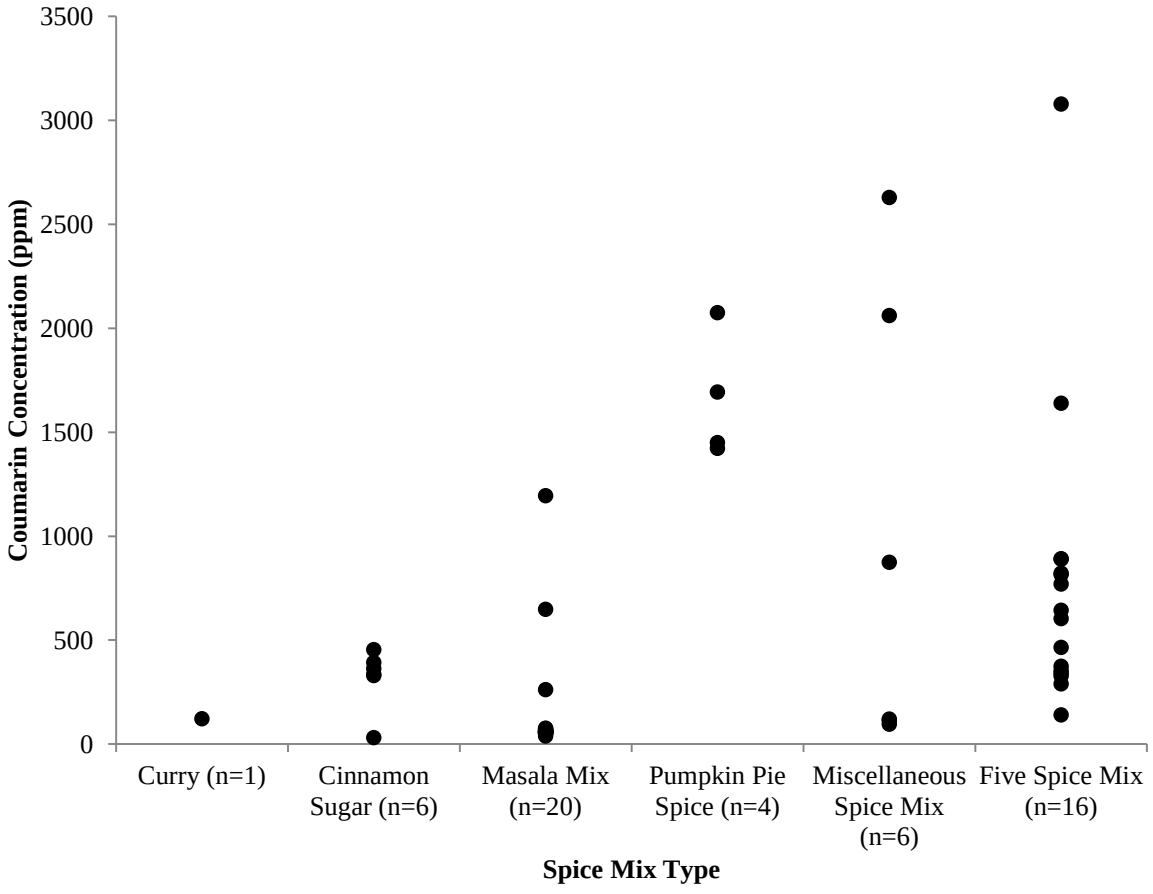


Figure 2. Concentration of coumarin in spice mixes by sample types.

3.3 Coumarin Results Compared to Previous FSAP Survey and to the Scientific Literature

The previous 2011-2012 FSAP survey examined coumarin levels in 87 cinnamon samples and 24 spice mixes. Similar to the current survey, all but one of the samples contained detectable levels of coumarin. See Figure 3 for a visual representation of the similarities between the current and previous survey results.

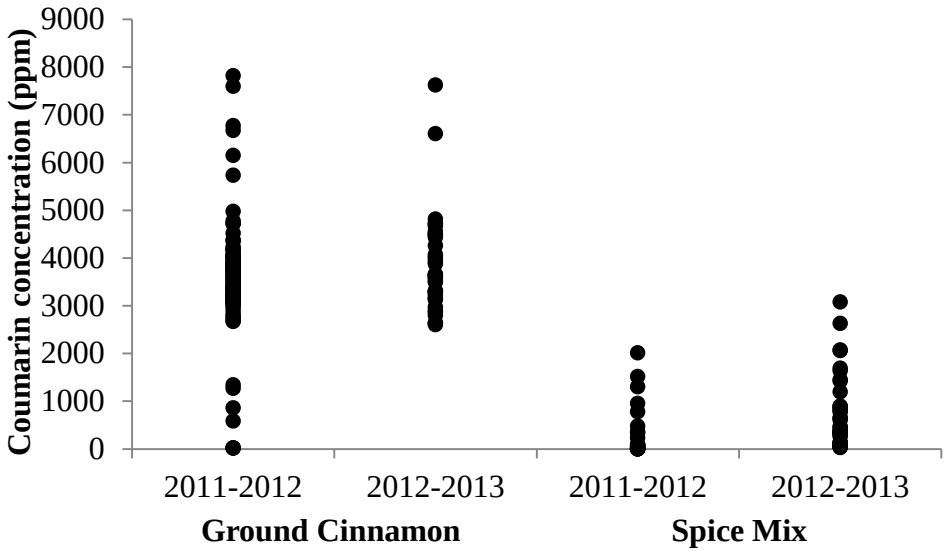


Figure 3. Distribution of coumarin concentration for each product type in 2011-2012 and 2012-2013

Table 2 outlines the ranges and average concentrations detected in the current and previous CFIA survey, as well as the academic literature. The average and maximum coumarin levels for cinnamon were comparable between the two survey years. For spice mixes, the average and maximum coumarin levels were lower in the previous survey. There is little scientific data available examining coumarin concentrations in cinnamon and cinnamon-containing products available in Canada. A number of academic studies have been published that examine the levels of coumarin in cinnamon and cinnamon-containing products in the European marketplace. It is apparent that the ranges and averages reported are highly variable for both ground cinnamon and spice mixes.

Table 2. Summary of CFIA coumarin survey results and literature examining coumarin concentrations in cinnamon and spice mixes.

Study Author	Year	Description	Number of Samples	Minimum (ppm)	Maximum (ppm)	Average (ppm)
Ground Cinnamon						
CFIA Survey	**2012-2013**	**Ground cinnamon**	**40**	**2604**	**7621**	**3844**
CFIA Survey	2011-2012[12]	Ground cinnamon	87	16	7816	3594
Lungarini	2008[1]	Cinnamon powder	20	5	3094	1456
Blahová	2012[7]	Ground cinnamon	60	2650	7017	3856
Sproll	2008[2]	Cinnamon (ceylon)	5	<0.1	<0.1	<0.1
Sproll	2008[2]	Cinnamon (cassia)	5	2880	4820	3612
Sproll	2008[2]	Cinnamon (unknown origin)	20	<0.1	8790	2419
Spice Mixes						
CFIA survey	**2012-2013**	**Spice Mix**	**53**	**30**	**3078**	**568**
CFIA Survey	2011-2012[12]	Spice mix	24	<0.29	2013	351
Raters	2008[13]	Cinnamon spices/spice mixtures	172	<0.03	4309	173

Many of the studies note that the coumarin concentrations detected were highly varied, not only between samples but even within the same sample package[13,14].

4 Conclusion

The 2012-2013 coumarin targeted survey generated baseline surveillance data on the concentrations of coumarin in domestic and imported ground cinnamon and cinnamon-containing spice mixes. Ninety-three products were sampled and analyzed for this survey. Coumarin was detected in 100% of the samples. Coumarin concentrations ranged from 30 ppm to 7621 ppm. Comparison of the survey results with data available in the scientific literature showed that the levels of coumarin detected in Canadian retails products is similar to those reported in a variety of European studies. The current survey results were also consistent with the data from the 2011-2012 coumarin FSAP survey.

Based on the opinion received from Health Canada for the 2011-2012 coumarin survey, the levels of coumarin in food observed in the current survey are not expected to pose an unacceptable health concern, and therefore no follow-up actions were needed.

5 References

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