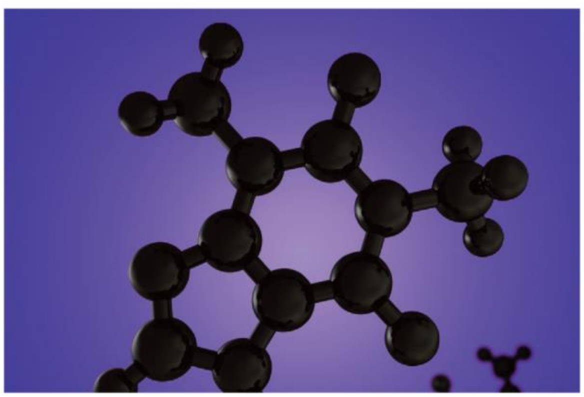
Canadian Food Inspection Agency   Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2011-2012 Targeted Surveys

Chemistry



Microcystins and Nodularin in Bottled Water

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 a 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 microcystin and nodularin levels in bottled water available on the Canadian retail market.

Cyanobacteria, also known as blue-green algae, are commonly found in surface water algae blooms or blue-green scums[1]. Cyanobacteria can produce hepatotoxins, of which microcystins and nodularin are the most common cyanobacterial toxins found in water[2]. The presence of microcystins and/or nodularin in water may result in an unpleasant taste and odour, and may cause illness in people consuming these toxins. It is also possible that extended exposure to low levels of these cyanobacterial hepatotoxins may have long-term or chronic effects in humans[3]. Microcystins in particular have been identified as a significant threat to freshwater supplies by the World Health Organization (WHO)[4]. Microcystins/nodularin may be present in bottled waters available at retail if they are present in the water source used to manufacture the final bottled product and if the water is inadequately treated.

The Federal-Provincial-Territorial Committee on Drinking Water (CDW) has established the Guidelines for Canadian Drinking Water Quality, which are published by Health Canada. The guideline for the maximum acceptable concentration of total microcystins in drinking water is 1.5 micrograms per litre (µg/L)[5]. There are currently no guidelines for nodularin in drinking water in Canada.

The 2011-2012 Microcystins and Nodularin in Bottled Water survey targeted domestic and imported bottled water (unflavoured, carbonated and non-carbonated) packaged in plastic and glass bottles. A total of 301 samples were collected from retail stores in 11 Canadian cities between May 2011 and March 2012. Each sample was analyzed for the most commonly-occurring hepatotoxins, specifically, four forms of microcystin and nodularin.

All 301 samples tested did not contain a detectable level of microcystins or nodularin. Thus, 100% of the samples tested were below the Canadian guideline for the maximum acceptable concentration of total microcystins in drinking water. Given that none of the samples in this survey were positive for microcystins, follow-up actions were not 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 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 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. Targeted surveys are largely directed towards 70% of domestic and imported foods that are regulated solely under the *Food and Drugs Act* and *Regulations*, and are generally referred to as non-federally registered commodities.

1.2 Targeted Surveys

Targeted surveys are used to gather information regarding the potential occurrence of contaminants (hazards) in defined food commodities. The surveys are designed to answer specific questions. Therefore, unlike monitoring activities, testing for a particular hazard is targeted to commodity types and/or geographical areas.

Due to the vast number of hazard/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, a group of Canadian federal, provincial and territorial subject matter experts in the area of food safety.

Microcystins and nodularin are potent liver toxins, and can cause unpleasant tastes and odours in drinking water. The major route for human exposure is through the ingestion of contaminated drinking water[6]. Microcystins and/or nodularin may be present in bottled waters available at retail if they are present in the water source used to manufacture the final bottled product, and if the water has not undergone adequate treatment to remove these microcystins/nodularin prior to use.

Bottled water is a widely-consumed beverage for Canadians, comprising 10.6% of Canada's commercial non-alcoholic beverage market share in 2009[7]. Various drinking water sources are used in the manufacture of bottled water, including natural artesian springs, glacial run-off, and municipal water supplies. Conventional water treatment processes (e.g., filtration/flocculation) are ineffective in eliminating microcystins and nodularin[4,8,9]. Advanced water treatment options (e.g., ozonation, UV photolysis) show various degrees of success in removing microcystins and nodularin[10].These treatments are more complex (often requiring more time and/or more steps in the process), expensive, and are less common in water treatment facilities.

Currently, little to no literature or studies have been published that examine bottled water for microcystins or nodularins. A previous 2010-2011 FSAP Targeted Survey, Microcystins in Bottled Water, has been published on CFIA's website[11]. The purpose of this targeted survey was to add to existing baseline data on the levels of microcystins and nodularin in bottled water available to Canadian consumers.

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*, 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 are not set out in the regulations but appear instead on Health Canada's website, referred to as standards. Both tolerances and standards are established by Health Canada and enforced by the CFIA. Pre-packaged (bottled) waters are regulated as a food, and therefore are subject to all the provisions of the *Food and Drugs Act* and *Regulations*.

The Federal-Provincial-Territorial Committee on Drinking Water (CDW) has established Guidelines for Canadian Drinking Water Quality, which are published by Health Canada. The guideline for the maximum acceptable concentration of total microcystins in drinking water is 1.5 micrograms per litre (µg/L)[5]. This Canadian guideline is similar to existing guidelines for microcystins in drinking water in Australia, New Zealand, and France, and those published by the World Health Organization (WHO). Some of these guidelines are provisional or proposed due to the limited amount of toxicological data available. Microcystin-LR (the form of microcystins first isolated and most studied) is often used as an indicator for other forms of microcystins in water[17].

Relative to microcystins, nodularin has similar toxicity but occurs infrequently, and is usually seen in brackish waters or seawater[12]. There are currently no guidelines for nodularin in drinking water or recreational water in Canada given that there have been no recorded occurrences of nodularin in North American waters to date[12]. Please refer to Table 1 below for a summary of Canadian and international guidelines for microcystins and nodularin in drinking water.

Table 1. Summary of Canadian and selected international guidelines for maximum acceptable microcystin and/or nodularin concentration in drinking water

Country/Organization	Proposed or Established Microcystin or Nodularin Guideline[13]	Notes
Canada	1.5 µg/L	Guideline -Total microcystins in drinking water (based on the toxicity of microcystin-LR)
United States	No current federal guidelines	
World Health Organization (WHO)[†]	1 µg/L	Provisional Guideline - Microcystin-LR
Australia	1.3 µg/L	Total microcystins expressed as microcystin-LR toxicity equivalents
New Zealand	1 ug/L for each Total Microcystins and Nodularin	Total microcystins expressed as microcystin-LR toxicity equivalents

Elevated levels of microcystins or nodularin in bottled water 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 Microcystins and Nodularin

Cyanobacteria are commonly found in surface water algae blooms or scums[1]. Cyanobacteria can produce hepatotoxins, of which microcystins and nodularin are the most common cyanobacterial toxins found in water[2]. Microcystins in particular have been identified as a significant threat to freshwater supplies[4]. Microcystins and nodularin may impart an unpleasant taste and odour to water. Not all blue-green algae produce toxins[14] and some cyanobacteria produce different toxins altogether (i.e., neurotoxins)[15].

[†] Many countries have adopted the WHO Provisional Guideline directly or indirectly, including France, Japan, Brazil, Spain, Poland, and Germany.

Microcystins have more than 60 congeners (variant forms)[16], which differ based on the combination of amino acids found in the toxin. Microcystin-LR is the most common and the most studied form of the toxin[17]. Other microcystin forms include microcystin-RR, -YR, -LY, and –LA. Nodularin hepatotoxins are structurally similar to microcystins (and also have variant forms) but contain fewer amino acids[4].

Microcystin and nodularin formation is difficult to predict, as the occurrence of algal blooms is highly variable from year-to-year, and the mechanisms that promote algal growth are complex[18]. Additionally, it is difficult to predict whether these blooms will be harmful[14]. The greatest release of toxins from cyanobacteria cells comes from cell death rather than excretion[6]. In Canada, cyanobacterial blooms tend to appear in summer months and are prevalent in the prairies. The degree to which these blooms occur across Canada is unknown, although it is presumed that the duration of exposure to the blooms and their associated cyanobacterial toxins would be shorter in Canada than in countries with milder climates[3]. Several collaborative studies (involving Canadian government and industry or foreign government) in multiple provinces in the 1990s showed frequent detection of microcystins in raw water supplies, municipal water supplies, dugouts used for domestic and/or livestock water consumption, and recreational use sites, although these levels were well below the Canadian drinking water quality guidelines[19]. The relationship between these occurrences and the residual presence of microcystins in bottled water is unknown.

Human exposure to microcystins and nodularin primarily occurs through consumption of contaminated drinking water[4]. People can be exposed to these cyanobacterial toxins by accidental ingestion of contaminated water used for recreational activities. Exposure may also be through consumption of algal health products or by eating the liver of fish taken from water with blue-green algae blooms, although these routes are less likely[3]. Acute exposure to high levels of microcystins or nodularin may result in stomach cramps, vomiting, diarrhoea, fever, headache, joint and muscle pain, weakness, and skin, eye, and throat irritation[20]. Long-term exposure to microcystins or nodularin may cause liver damage[3].

Eliminating microcystins and nodularin from contaminated water is difficult. These cyanobacterial toxins are typically stable at high temperatures and at extreme pH[8,9]. They are not degraded by boiling, sedimentation, sand filtration, chlorination, or other conventional water treatments. Extreme treatment conditions are necessary to degrade microcystins over a period of weeks[4]. Applying a high level of chlorine or ozonation is the best way to treat drinking water contaminated with microcystins or nodularin[21], but this extensive level of water treatment is not often undertaken. While treating surface waters exhibiting blue-green algae blooms with ozone or chlorination will kill the cyanobacteria, it will also release cyanobacterial toxins into the water[6].

2.2 Rationale

Both domestic and imported bottled water can come from a variety of sources, including natural aquifers, springs, glacier run-off, and municipal water supplies[22]. These sources could potentially be contaminated with microcystins and/or nodularin. As normal water treatment techniques do not readily degrade microcystins or nodularin, these toxins, if present in the source water, could remain in the finished bottled water product.

In 2007, 24% of Canadian households drank primarily bottled water as opposed to tap water[23]. The per capita consumption of bottled water in Canada was 66 L, and that volume had been steadily increasing over the previous decade[7]. Bottled water, of both domestic and imported origin, is consumed in large quantities by Canadians and is a significant trade commodity.

To our knowledge, only one study on levels of microcystins and nodularin in bottled water has been published. This single Italian study analysed two domestic bottled spring water samples for the presence of various microcystins and nodularin, and did not detect these cyanotoxins[24].

A previous FSAP Targeted Survey conducted in 2010-2011 generated initial baseline data on the levels of microcystins and nodularin in bottled waters available in Canada[25]. The purpose of the current targeted survey was to generate additional baseline data on the levels of microcystins and nodularin in bottled water available to Canadian consumers.

2.3 Sample Distribution

The 2011-2012 Microcystins and Nodularin in Bottled Water survey targeted imported and domestic bottled waters (packaged in glass or plastic). A total of 301 samples were collected from retail stores in 11 Canadian cities between May 2011 and March 2012.

The 301 samples collected included 150 domestic products, 137 imported products (from at least 15 countries), and 14 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 specify the true origin of the product. 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 157 spring waters, 72 treated waters, 69 mineral waters, and 3 “other” waters (e.g., iceberg water). Bottled waters with added flavour or those supplemented with vitamins were not sampled. Spring/mineral water is defined in the *Food and Drug Regulations* (Division 12, B.12.001.[S]) as potable water obtained from an underground source, and may have added fluoride, ozone, and carbon dioxide. For the purpose of this survey, treated waters are bottled waters not labelled as spring or mineral water that may be sourced from municipal water supplies and further treated/purified before bottling[22]. Other waters were those labelled/sourced from glaciers/icebergs and those not clearly labelled/identified as mineral, spring, or treated water. Table 2 illustrates the distribution of samples by country of origin and category.

Table 2. Distribution of survey samples by category and by country of origin (in order of decreasing number of samples)

Country of Origin	Number of Spring Water Samples	Number of Treated Water Samples	Number of Mineral Water Samples	Number of Other Water Samples	Total Number of Samples
Canada	81	58	9	2	**150**
Italy	11		28		**39**
France	32		3		**35**
Germany			20		**20**
Fiji	18				**18**
Unverifiable*		14			**14**
United States	4			1	**5**
Portugal	4				**4**
Slovenia			4		**4**
Norway	3				**3**
Poland			2		**2**
United Kingdom	2				**2**
Argentina			1		**1**
Belgium			1		**1**
Greece			1		**1**
Iceland	1				**1**
Republic of Korea	1				**1**
Overall	**157**	**72**	**69**	**3**	**301**

*****Unverifiable refers to samples for which country of origin could not be determined based on the available information or product label.

2.4 Method Details

Survey samples were analyzed by a CFIA laboratory using a liquid chromatography tandem mass spectrometry (LC-MS/MS) method for the analysis of microcystins and nodularin in commercially bottled water. The method analyzed for microcystin-LR, -YR, -RR, -LA, and nodularin. The limits of detection (LOD) for the four microcystin forms and nodularin ranged from 0.02 to 0.1 µg/L, and the limits of quantitation (LOQ) ranged from 0.05 to 0.5 µg/L.

2.5 Limitations

The current targeted survey was designed to provide a snapshot of the levels of microcystins and nodularin in bottled waters available to Canadian consumers, and to highlight commodities that warrant further investigation. The limited sample size analyzed represents a small fraction of the products available to Canadian consumers. Therefore, care must be taken when interpreting and extrapolating these results. A country of origin was assigned for all but fourteen samples (all treated waters) based on information provided by the sampler or as indicated on the product label. Regional differences, impact of product shelf-life, storage conditions, or cost of the commodity on the open market were not examined in this survey.

3 Results and Discussion

The 2011-2012 Microcystins and Nodularin in Bottled Water Targeted Survey consisted of testing 301 samples obtained at the Canadian retail level. The samples were both domestic and imported products (in glass and plastic packaging), and included 157 spring waters, 72 treated waters, 69 mineral waters, and 3 “other” waters (e.g., iceberg water). Some of the samples were carbonated. None of the samples were flavoured. Microcystins and nodularin were not detected in any of the samples in the survey. Given that none of the samples in this survey were positive for microcystins and/or nodularin, follow-up actions were not deemed necessary.

Depending on the label statement of the underground source of the water, spring waters were further classified as artesian, oxygenated, glacial, carbonated/sparkling, or just as “spring water”. Refer to Figure 1 for the number of samples of each type of spring water analyzed.

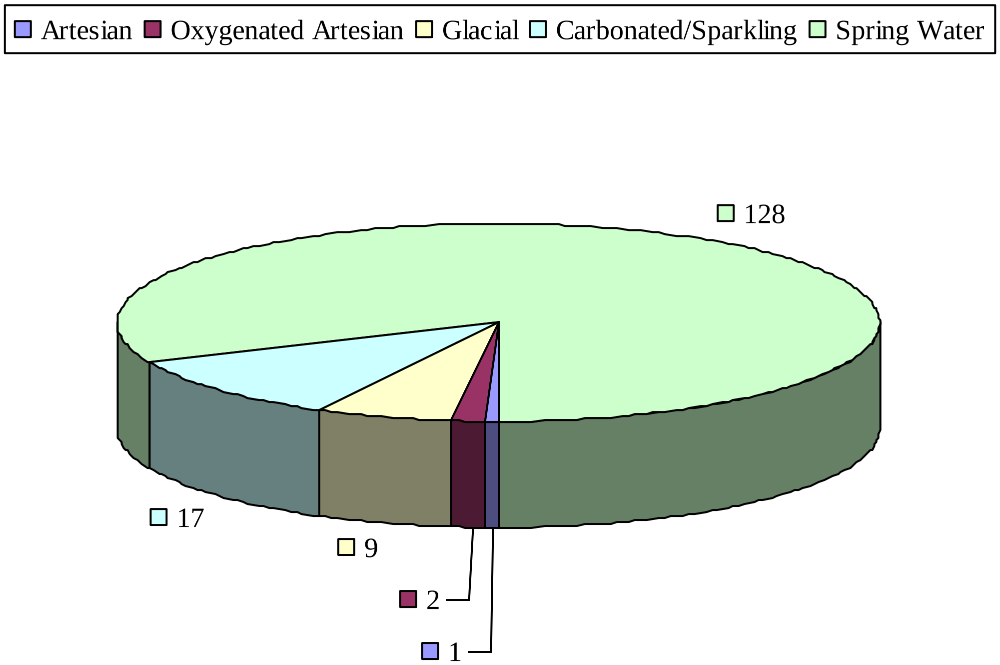

Figure 1. Distribution of spring water samples by type

In this survey, treated waters were defined as bottled waters not labelled as spring or mineral water that have been mineralized/re-mineralized, demineralised, and/or oxygenated. Treated waters may be sourced from municipal water supplies and further treated/purified (e.g., by reverse osmosis, vapour distillation, ozonation, or oxygenation) before bottling[22]. Refer to Figure 2 for the number of samples of each type of treated water analyzed.

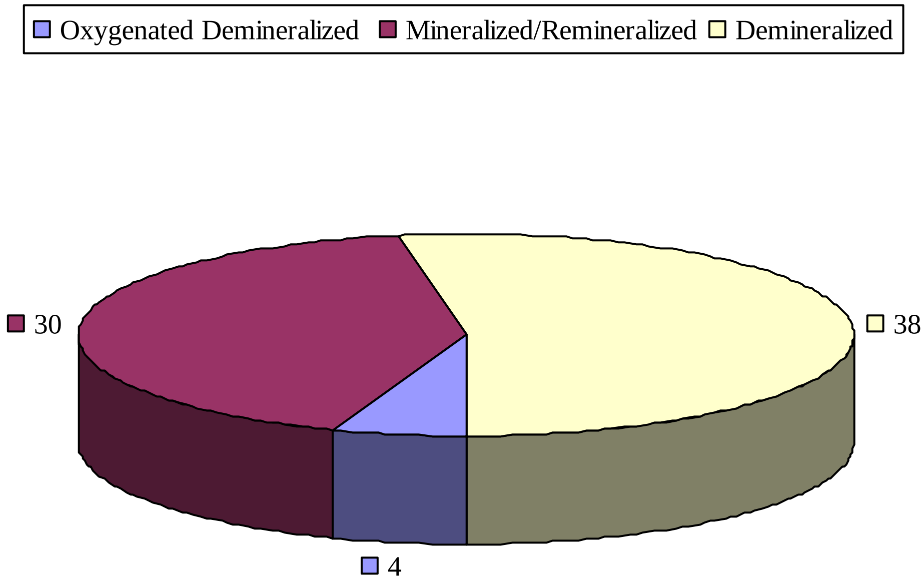

Figure 2. Distribution of treated water samples by type

Mineral waters were classified as carbonated/sparkling (58 samples), or just as “mineral water” (11 samples). Other waters consisted of one carbonated/sparkling sample not clearly labelled/identified as mineral, spring, or treated water, and two samples of water sourced from icebergs.

All samples analyzed in this survey were negative for microcystins and nodularin, and thus were below the Canadian drinking water guideline of 1.5 µg/L total microcystins in drinking water. The lack of positive results may be due to the water sources used for these products. These sources could be cold, fast-moving, pre-treated, or low in nutrients that would support the growth of algae (e.g., glacial run-off). Algae tend to thrive in waters that are nutrient-rich, shallow, slow-moving or still, and relatively warm. They generally do not persist through the winter months in temperate climates (like Canada), however, the hepatotoxins may remain[3]. Also, if there were few algal blooms in the source water, it is less likely that microcystins or nodularin will be present in the final bottled product.

The results of this survey are similar to the results of the previous 2010-2011 FSAP Targeted Survey on Microcystins in Bottled Water[11]. The Microcystins in Bottled Water survey conducted in 2010-2011 targeted 300 imported and domestic bottled waters (unflavoured, carbonated and non-carbonated) packaged in plastic and glass bottles. None of those samples were positive for microcystins or nodularin, and thus were below the Canadian drinking water guideline for total microcystins in drinking water.

4 Conclusions

The 2011-2012 Microcystins and Nodularin in Bottled Water Targeted Survey generated baseline surveillance data on the microcystin and nodularin levels in bottled water available on the Canadian retail market. All 301 samples collected and tested did not contain a detectable level of microcystins or nodularin. Thus, 100% of the samples tested were below the guideline for the maximum acceptable concentration of total microcystins in drinking water. Given that none of the samples in this survey were positive for microcystins or nodularin, follow-up actions were not deemed necessary.

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