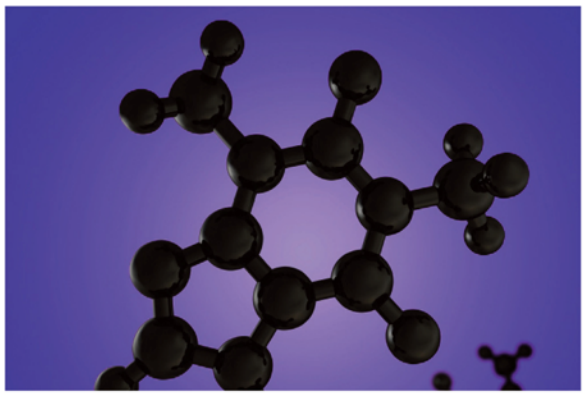
Food Safety Action Plan

REPORT

2010-2011 Targeted Surveys

Chemistry



Bromate in Bottled Water

TS-CHEM-10/11-06

Canada

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Executive Summary

The Food Safety Action Plan 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 hazards.

The main objectives of the bromate in bottled water targeted survey were to:

- Provide baseline surveillance data for bromate levels in bottled waters
- Examine whether elevated bromate levels in bottled waters can be linked to products that have undergone ozonation

Bromate is a residual chemical compound that can be formed in bottled waters when sufficient levels of bromide are present in waters during disinfection via ozonation. Bromide ions are naturally occurring compounds in water resulting from runoff, leaching or seawater intrusion. Bromate is considered to be possibly carcinogenic to humans. In the 2010-11 bromate targeted survey, a total of 288 samples were collected across Canada. Samples consisted of spring waters, mineral waters and purified waters from both domestic and imported origins.

Of the 288 samples analyzed for bromate, 250 samples (87%) did not contain any detectable residues of bromate. The remaining 38 samples (13%) had bromate levels ranging from 1.7-21 ppb. Six samples (2%) contained bromate levels in excess of the Canadian drinking water standard of 10 ppb.

When the resulting levels of bromate were compared with the declared use of ozone on a product, the results were varied. The average levels of bromate in non-ozonated products were lower than ozonated products. However, the highest bromate levels observed were in products that did not indicate ozonation had been utilized.

Health Canada was asked to provide an opinion on the dataset generated for this survey. Based on their evaluation of the data, Health Canada determined that overall levels of bromate in bottled water are not expected to pose an unacceptable health risk. The majority of bromate levels in bottled water are well below the Canadian Guidelines for Drinking Water Quality and therefore exposure exceeding the guideline is not expected to occur on a long-term basis.

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 the food safety regulatory system. The FCSAP initiative unites multiple partners in ensuring safe food for Canadians.

The CFIA's Food Safety Action Plan (FSAP) is one element of the Government's broader FSCAP initiative. The goal of FSAP is to identify risks in the food supply, limit the possibility that these risks happen, improve import and domestic food controls and identify importers and manufacturers. FSAP also looks to verify that industry is actively applying preventative measures and that there is a rapid response in the case that these measures fail.

Within 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 testing food from the Canadian marketplace. Targeted surveys are a tool used to test for the presence and level of a particular hazard in specific foods. Targeted surveys are largely directed towards the 70% of domestic and imported foods that are covered exclusively by the *Food and Drugs Act,* and are generally referred to as non-federally registered commodities.

1.2 Targeted Surveys

Targeted surveys are pilot surveys used to gather information regarding the potential occurrence of specific contaminants in defined commodities. The surveys are designed to answer specific questions. Therefore, unlike monitoring activities, testing of a particular chemical hazard is targeted to specific 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. Instead, the CFIA uses a combination of media reports, scientific literature and/or a risk-based model developed by the Food Safety Science Committee (FSSC) to identify food-hazard combinations of greatest potential health risk.

The bottled water industry has shown rapid growth and greater consumer acceptance over the past decade. There are a variety of reasons for the increased popularity of bottled water, ranging from increased convenience to a shift to desired healthier consumption habits, as well as the perception that bottled water tastes better than tap water[1]. This increase in bottled water popularity has created a need to regulate the quality of bottled water to ensure that it complies with the national standards established in the *Food and Drug Act and Regulations*. A number of media reports and academic articles have been

published recently, that have examined the issue of bromate in bottled water. Bromate is a possible human carcinogen that may be formed in drinking water as a by-product of the ozone disinfection process. The purpose of this survey was to carry out a national survey of a variety of types of bottled waters available at the retail level to examine the presence/levels of bromate in this commodity.

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* (FDAR).

Health Canada (HC) determines the maximum levels of contaminants in food. Maximum levels are established as a risk management tool and generally only for foods that significantly contribute to the total dietary exposure. Pre-packaged waters are regulated as a food and therefore are subject to all the provisions of the FDAR. Currently, HC has established an interim maximum acceptable concentration (IMAC) for bromate in drinking water of 10 ppb, and has proposed that this maximum limit for bromate also apply to bottled water and packaged ice.

The aforementioned Canadian maximum levels are in alignment with other international regulations relating to bromate.

Table 1. Worldwide Regulations related to Bromate in Water

Country	Regulation	Level (ppb)	Commodity
Canada[2,3]	IMAC	10	Drinking water
	Proposed Guideline[2]	10	Bottled water
USA[4]	Max allowable level	10	Bottled water
UK[5]	Maximum limit	3	Bottled water
WHO	Provisional guideline	10	Drinking water
EU[6]	Guideline	3	Drinking water

2 Bromate in Bottled Water

2.1 Bromate Overview

Different forms of bromate, such as sodium bromate and potassium bromate, are strong oxidizers with a variety of industrial applications. Potassium bromate has been used in flours to strengthen the dough and allow for higher rising, and in the production of malt barley. When used appropriately, once the processing/cooking of a product containing potassium bromate is complete, no residual bromate should remain. However, if too much is used, or if the bread is not baked long enough, residual amounts could linger, which may be harmful if consumed. In 1995, the Joint FAO/WHO Expert Committee of Food Additives (JECFA) concluded that the use of potassium bromate in food processing was not appropriate and that bromate should not be present in food as consumed.

Bromate is considered by the International Agency for Research on Cancer (IARC) to be a category 2B carcinogen (possibly carcinogenic to humans), based on the incidence of renal tumours in rats. No mode of carcinogenic action of bromate has been determined in humans[7].

Given the findings by JECFA and the IARC, the use of potassium bromate has either been banned from use in a number of countries, including Canada, or voluntarily withdrawn from use by food producers in countries where it has not been banned.

In the case of water, bromate can be formed if sufficient levels of bromide are present in water during disinfection via ozonation. Bromide is a negatively charged bromine ion and is naturally present in groundwater and seawater. Ozonation is a water treatment process by which micro-organisms are destroyed through the infusion of water with ozone gas. The application of ozone in drinking water treatment is widespread throughout the world.

In Canada the declaration of the addition of ozone to bottled waters is regulated in the FDAR, under Division B.12.002(d), where it states:

> *"The principal display panel of the label on a container of water represented as a mineral water or spring water shall carry a statement … of any addition of fluoride or ozone thereto".*

2.2 Bromate in Bottled Water

Bromide levels in water prior to treatment can vary widely, and are dependent on both the natural processes (such as geologic formations) and anthropogenic activities (such as mining and chemical production). The formation of bromate is caused by the combination of bromide with ozone in an extremely complicated chemical reaction[8]. Strategies for minimizing the formation of bromate in drinking water have been examined, and it has been found that the addition of ammonia and/or lowering the pH during water treatment may reduce the formation of bromate by up to 50% in waters that contain bromide levels of 50-150 ppb[8].

The issue of bromate in both drinking water and bottled waters has been examined by Health Canada in the recent past. In 1996, a survey of 18 different brands of bottled spring water, all bottled in Canada, was carried out[3]. Eleven of these samples were ozonated, and the results showed that most samples had bromate levels that were much higher than in non-ozonated samples. The average bromate concentration in the non-ozonated bottled waters was 3.72 ppb, with a range of <0.20-12.90 ppb, whereas the average concentration for the ozonated bottled waters was 18.14 ppb, with a range of 4.28-37.30 ppb. Another bottled water survey was carried out in 1998 by the Food Directorate of Health Canada. In this survey, bromate levels of 206 bottled waters were tested, with bromate concentrations ranging from below the limit of detection (0.5 ppb) to 144 ppb. An overall average of 6.88 ppb was found. There was no apparent connection between bromate levels and bromide, or use of ozone[9].

2.3 Rationale

In Canada, bottled water consumption was estimated at 24.4 litres per person in 1999[10]. By 2005, that had increased to about 60 litres per person[1]. Statistics Canada reported that 24% of Canadian households used bottled water as their main source of drinking water in 2009[11]. As the consumption of bottled water has increased in Canada, there is a need for additional surveillance of bottled water, for continued assessment of compliance, and establishment of baseline levels of certain contaminants.

2.4 Sample Distribution

The 2010-11 Bromate survey targeted bottled waters. A total of 288 samples were collected from 11 different cities across Canada. A total of 136 samples originated from Canada, while the remaining 152 samples were imported products originating from 12 different countries. The distribution of samples with respect to country of origin is depicted in Figure 1. A variety of spring waters, mineral waters, and purified waters were selected for this survey.

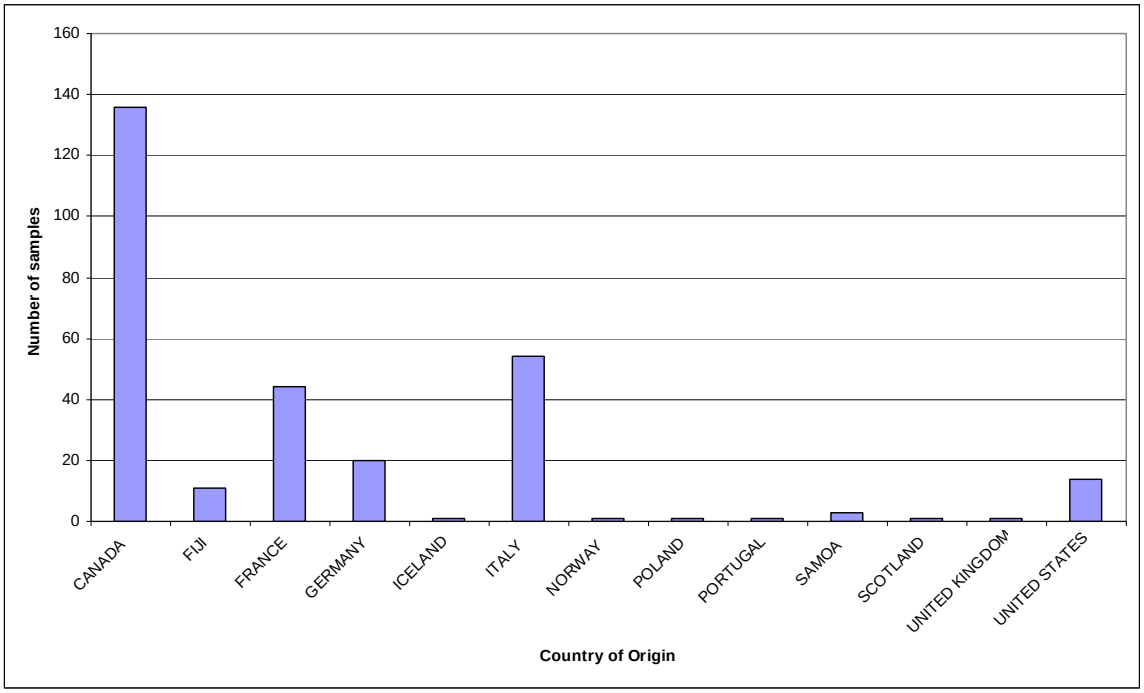

Figure 1. Distribution of samples by country of origin

2.5 Method Details

Samples from the bromate targeted survey were analyzed by the CFIA's Dartmouth laboratory using the method "Determination of bromate in flour and bottled water". This method quantitatively determined bromate by means of ion chromatography using inductively coupled plasma mass spectroscopy (ICP-MS) and liquid chromatography (LC) for detection and confirmation. The limit of detection (LOD) for bromate in water is 1.5 ppb and the limit of quantitation (LOQ) is 4.5 ppb.

2.6 Limitations

The bromate survey was designed to provide a snapshot of the levels of bromate in bottled waters available to Canadian consumers. In comparison to the total number of bottled water products in the Canadian market, 288 samples represent a small fraction of products available to consumers. Therefore, care must be taken with interpretation and extrapolation using these results. This survey does not examine year-to-year trends or the impact of product shelf-life.

3 Results & Discussion

A total of 288 samples were analyzed for bromate of which 250 (87%) did not contain any detectable residues of bromate (<1.5ppb). The remaining 38 samples had detectable residues of bromate ranging from 1.7 to 21ppb (see Table 2). Six of the samples tested contained residues in excess of the proposed Canadian guideline for bottled water of 10 ppb. The overall compliance rate was 98% (see Figure 2).

Table 2. Summary of bromate concentrations in bottled waters

Product	# of Samples	Min (ppb)	Max (ppb)	Average (ppb)	Standard Deviation
All bottled water: (Non detect, Compliant positive and Non-compliant)	288	<LOD	21	0.81	2.71
Bottled waters with detectable residues: (Compliant positive and Non-compliant)	38	1.7	21	6.11	4.87

Non Detect = <LOD
Compliant positive = <proposed Canadian Maximum Limit of 10 ppb
Non-compliant = >proposed Canadian Maximum Limit of 10 ppb

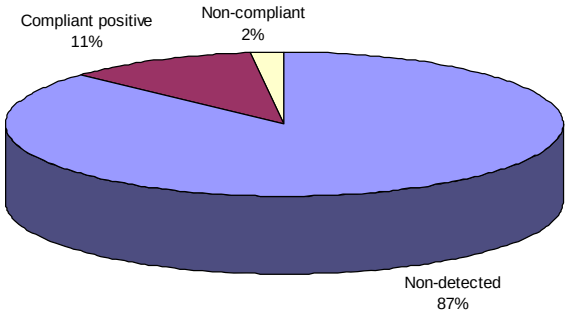

Figure 2. Distribution of samples for the 2010-11 bromate targeted survey.

With regards to the distribution of samples with detectable residues compared to their country of origin, care must be taken to not infer too much, as the number and variety of samples selected cannot be considered statistically significant. That being said, the following table presents some of the findings of this survey related to the countries from which products originate. Samples with detectable residues of bromate originated from 5 different countries.

Table 3. Distribution of positive results with respect to country of origin

Country	# of Samples	# of samples with Detectable Residues*	# of samples with residues higher than CDN IMAC
Canada	136	27 (20%)	3(2%)
Italy	54	5 (9%)	0
Samoa	3	3 (100%)	3 (100%)
France	44	2 (5%)	0
Germany	20	1 (5%)	0

* Percentages represent the % of the total number of samples from that country

Information on ozonation was primarily derived from the product label. As mentioned previously, the *Canadian Food and Drug Regulations* require that products having undergone the addition of ozone must declare the addition of ozone to mineral or spring water. Table 4 describes the bromate concentrations related to the declaration of ozonation on the product label. The resulting information indicates that non-ozonated products were less likely to contain detectable levels of ozone; however the highest bromate result observed was detected in a product for which there was no declaration of the addition of ozone on the label.

Table 4. Bromate Concentrations (in ppb) in Ozonated and Non-ozonated Products

Category	# of Samples	Min	Max	Average**	# samples <LOD (%)
Non-ozonated*	182	<LOD	21	1.92	167 (92)
Ozonated	106	<LOD	14	2.42	83 (78)
Total	288	--	--	2.11	250 (87)

* non-ozonated refers to the lack of designation on the product label
** Average was calculated using complete datasets, where values below the LOD were included at the LOD (1.5 ppb)

4 Conclusions

Previous work examining levels of bromate in Canadian bottled water found that bromate levels were highly variable, with no clear indication that ozonation resulted in elevated levels of bromate. Results from the current survey are varied as well.

The majority of samples tested (87%) did not contain detectable residues of bromate. Of the 38 samples that did contain detectable residues, six samples (2%) were found to contain bromate levels in excess of the proposed Canadian guideline for bromate in bottled water (10 ppb). Of these six samples, three were the same product brand and two of the others were also identical brands indicating that a limited number of brands had water that exceeded the proposed limit. Health Canada provided an opinion on the complete bromate dataset resulting from this survey. They concluded that overall, bromate levels in bottled water sold in Canada are not of concern as the majority of results were far below the drinking water guideline. Therefore, the 10 ug/L guideline is readily achievable and exposure to levels of bromate exceeding the guideline is not expected to occur on a long-term basis. Follow-up on the products which exceeded the Canadian drinking water guidelines is ongoing.

When the results are compared with the declared use of ozonation of a product, the results are also varied. The incidence of ozonated products containing measurable residues of bromate was higher than in products which have not undergone ozonation (22% vs. 8%), however the three maximum residue detected (18, 19 and 21 ppb) were found in the same brand of product, in which ozonation was not declared.

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