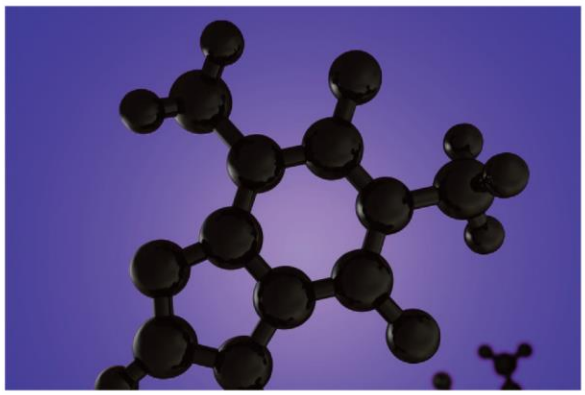
Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2012-2013 Targeted Surveys

Allergens



Undeclared Sulphites in Children's Food

RDIMS 4676729

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 evaluate various foods for specific hazards.

The main objectives of this targeted survey were to obtain baseline information regarding the presence and levels of undeclared sulphites in foods that are commonly consumed by children and to identify potential food safety concerns relating to those undeclared sulphites in foods.

Sulphites are used as additives in food products, both as preservatives and to maintain colour. These additives may also be present due to cross-contamination during manufacturing (e.g., a product containing sulphites may contaminate a product that does not contain the compound if both are produced using the same processing equipment). In the past, product recalls have been initiated due to the health risk to sensitive individuals associated with the presence of undeclared sulphites in food. Children represent a susceptible sub-population that may consume food products containing this commonly used food additive. This survey was designed to complement other allergen related targeted surveys that have focussed on foods consumed by children.

A total of 527 baking mixes, baked goods, canned fruit, cereals, cookies, desserts, infant foods, and juice were analyzed for the presence of undeclared sulphites. Of the 11 samples found positive for undeclared sulphites, 10 were cereals and 1 was a baking mix.

All positive samples were followed up by CFIA. Follow-up actions are initiated in a manner that reflects the magnitude of the health concern. Actions may include further analysis, notification to the producer or importer, follow-up inspections, additional directed sampling, a food safety investigation (including a health risk assessment conducted by Health Canada), and recall of products.

1 Introduction

1.1 The 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) 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 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 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 *Food and Drugs 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 specific hazards in various foods, and are meant to complement the CFIA's regular monitoring programs and inspection activities. The surveys are designed to answer specific questions. Testing is often targeted to commodity types and focused on a specific segment of the population (i.e. consumers with an allergy or intolerance).

Due to the possible number of undeclared allergens and food commodity combinations, it is not possible, nor should it be necessary, to use targeted surveys to identify and quantify all potential allergen related hazards in foods. To identify food-hazard combinations of greatest potential health risk, the CFIA uses a combination of scientific literature, media reports, environmental scanning 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.

This targeted survey focused on the presence of undeclared sulphites in foods often consumed by children, a susceptible sub-population. Products included baking mixes, baked goods, canned fruit, cereals, cookies, desserts, infant foods, and juice. Sulphites may be intentionally added to these types of products as preservatives (i.e., to prevent spoilage) and/or to maintain colour. Sulphites are used as additives in food products, both as preservatives and to maintain colour. These additives may also be present due to cross-contamination during manufacturing (e.g., a product containing sulphites may contaminate a product that does not contain the compound if both are produced using the same processing equipment).

The information gathered in this survey provides baseline information regarding the presence and levels of undeclared sulphites, which may be a potential food safety concern for individuals sensitive to sulphites, in foods commonly consumed by children.

1.3 Acts and Regulations

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).

The use of sulphites in food is regulated under the FDA and FDR. Sulphites are permitted for use in certain foods as preservatives, pH adjusters, starch modifiers, bleaching agents, and dough conditioners[1, 2].

Based on current scientific knowledge, sulphites present in a food product at a level of up to 10 parts per million (ppm) are unlikely to cause an adverse reaction in an individual sensitive to these compounds[3]. However, if the level of sulphites present in a food product is above 10 ppm, this may pose a hazard for susceptible consumers.

Health Canada has made amendments to the *Food and Drug Regulations* to enhance the labelling of priority allergens, gluten sources, and added sulphites on prepackaged food sold in Canada [3]. These amendments require added sulphites be labelled when they are present in the prepackaged food product at a total level of 10 ppm or more. To facilitate understanding food product labels, one of the terms "sulphite", "sulfite", "sulphiting agent", or "sulfiting agent" is required to appear on the label of the prepackaged product, either in the list of ingredients or in a "Contains" statement[2].

Other amendments to the FDR require that food allergen and gluten sources be declared on the labels of prepackaged foods having a list of ingredients whenever the protein, modified protein, or protein fractions of the food allergen or gluten source are added to the food product. Due to the complexity of the labelling changes required, and given the extended shelf-life of some processed foods, Health Canada provided manufacturers with 18 months from the date of registration of the regulatory amendments to implement any necessary label changes. Thus, manufacturers were required to comply with Canada's amended food allergen labelling regulations when they came into force on August 4, 2012[3]. The products analyzed in this survey were sampled both prior to and following these amended regulations coming into force.

2 Survey Details

2.1 Undeclared Sulphites in Children's Food

Typically, true allergic reactions to food occur following exposure to allergenic proteins. Sulphites, however, are chemicals, not proteins, and thus adverse reactions to these additives in foods are considered to be a non-allergic food sensitivity. Sulphite sensitivity may lead to the same life-threatening symptoms that occur during an allergic reaction[4].

It has been estimated that sulphite sensitivity affects approximately 200,000 people in Canada[3], and those individuals with asthma are most at risk. For sensitive individuals, the severity of a reaction may range from mild to very serious, and include symptoms such as a flushed face, hives, vomiting, rapid heartbeat, and loss of consciousness[3]. For individuals with this sensitivity, consumption of a food product with less than 10 ppm of sulphite is unlikely to lead to such adverse reactions[4].

Past surveys have focussed on undeclared allergens in foods commonly fed to children, such as infant formula, infant cereals, puréed first foods, as well as prepackaged foods

that could be included in older children's lunches. This survey complements previous targeted surveys and focusses on testing for sulphites in prepackaged food commonly consumed by children, a sensitive sub-population.

There is no cure for sulphite sensitivity, and the most important strategy for sensitive individuals, or people choosing food for a sensitive individual, is avoidance of sulphites. Therefore, sulphite must be appropriately labelled (i.e., declared) on finished food products to ensure consumers have complete, accurate information when choosing food.

2.2 Rationale

The presence of sulphites in food is not a health concern for the majority of Canadians. However, consumption of sulphites may represent a serious or life-threatening health risk for sensitive individuals. Sulphites are added to some processed foods to maintain colour, prolong shelf life, prevent the growth of microorganisms, and are used as anti-browning agents, for bleaching food starches, and as processing aids.

The main objective of this survey was to obtain baseline information regarding the presence and levels of undeclared sulphites in foods that are commonly consumed by children. Children represent a susceptible sub-population that may consume food products containing this commonly used food additive. This survey was designed to complement other targeted surveys that have focussed on food consumed by children. Information gathered provides an indication of potential food safety concerns relating to the lack of declaration of sulphites used in foods such as baking mixes (e.g. cake mixes, muffin mixes), baked goods (e.g. ready-to-eat cakes and muffins), canned fruit, cereals, cookies, desserts (e.g. puddings, ice cream, gelatin), infant foods (prepackaged ready-to-eat purées), and juice.

2.3 Sample Distribution

This survey targeted a variety of foods likely to be consumed by children, such as baking mixes (e.g. muffin mixes, cake mixes, cookie mixes), baked goods (e.g. ready-to-eat cakes, muffins), cookies (e.g. prepackaged cookies), desserts (e.g. fruit gelatin, pudding, ice cream), canned fruit, cereals, infant foods (e.g. prepackaged pureed fruits and vegetables, pureed mixed ingredient infant meals), and juice. This survey sampled foods that that did not declare sulphites either as an ingredient or in a precautionary statement.

Samples were collected from Canadian retail stores in 11 cities between April 2012 and January 2013. No specific brands were targeted, and a total of 527 samples were collected based on availability. The distribution of samples by product type is shown in Table 1. The imported products sampled came from at least 15 different countries, with the majority of samples originating in the United States.

Table 1: Distribution of samples by product type and origin

Product Type	Domestic	Import	Unspecified*
Baked Goods	10	15	28
Baking Mixes	1	29	14
Canned Fruit	0	1	0
Cereals	41	122	66
Cookies	3	2	8
Desserts	3	68	14
Infant Foods (non-cereal)	12	11	49
Juice	3	1	26
Total	**73**	**249**	**205**

*Unspecified refers to those samples for which the origin (i.e., imported or domestic) could not be determined from the product label or sample information

2.4 Limitations

The 527 samples taken in this survey represent a small sample size in comparison to what is available to Canadian consumers throughout the country. The samples collected in this survey do not guarantee representation of all children's foods available nationally. 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 necessarily as they would be consumed.

The data collected from this survey is intended to provide a snapshot of the targeted commodity and to potentially highlight problem areas that warrant further investigation. Few inferences or conclusions were made regarding the data with respect to country of origin of the samples.

2.5 Analytical Methods

Samples in the Undeclared Sulphites in Children's Foods targeted survey were analyzed by an ISO 17025 accredited food testing laboratory under contract to the Government of Canada. The laboratory used the internationally accepted AOAC optimized Monier-Williams method (AOAC Official Methods of Analysis 990.28). Results below 10 ppm are outside the applicable range of the method and not considered as being reliable therefore a reporting limit of 10 ppm is used and results below this value are considered not detected.

3 Results and Discussion

Of the 527 samples tested in this survey, 11 samples were found to contain a level of sulphur dioxide above 10 ppm (11.5 to 25 ppm). There were no positive results for infant foods, canned fruit, cookies, baked goods, juice, or desserts. Of the 11 positive samples, 10 were cereals (levels ranged from 11.5 to 25 ppm) and 1 was a baking mix (16 ppm). Description of the products containing more than 10 ppm of undeclared sulphites can be found in Table 2.

Samples were tested as sold, meaning that the product was not prepared as per the package instructions, if applicable (refer to Section 2.4).

Table 2: Products found positive for sulphites	
Product Type	**Amount (ppm)**
Baking Mixes - Unspecified Origin	
Banana-flavoured pudding & pie filling mix	16
Cereals - Domestic	
Apple spice muesli	12.5
Cereals - Import	
Fruit and nut muesli	12.2
Oat and flax instant oatmeal	12.2
Instant hot oatmeal	18.4
Blueberry cinnamon flax multigrain cereal	18.9
Corn-based cereal	25
Cereals - Unspecified Origin	
Oat and corn-based cereal	11.5
Wheat squares cereal	13.1
Toasted puffed rice cereal	17.1
Multigrain cereal	19.1

Of the samples analyzed, 2.0% (5/249) of imported samples, 1.4% (1/73) of domestic samples and 2.4% (5/205) of samples of unspecified origin were found to contain undeclared sulphites. Cereals had a higher percentage, 4.4% (10/229), of undeclared sulphites in comparison to the other products tested (baking mixes 2.3% (1/44)).

4 Conclusions

This survey analysed 527 samples for undeclared sulphites in foods commonly consumed by children. Eleven samples were positive for undeclared sulphites above 10 ppm. Cereals had a higher percentage of undeclared sulphites in comparison to the other products tested.

A prepackaged food product with a list of ingredients and a level of sulphites above 10 ppm must have sulphites declared on the label to inform sensitive individuals of its presence. If sulphites are not an intentionally added ingredient or ingredient

component, and their addition cannot be controlled through good manufacturing processes, the use of a precautionary statement on the label should be considered by the manufacturer.

The samples that had levels of sulphites above 10 ppm were followed up by CFIA. Follow up action may involve a food safety investigation, including a health risk assessment conducted by Health Canada and a recall or one of the following: notification of manufacturer/importer and/or additional sampling.

5 References

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2. Department of Justice Canada. *Food and Drug Regulations*. [online] 2014 July 29, 2014; Available from: http://laws.justice.gc.ca/eng/regulations/C.R.C.,_c._870/index.html.
3. Health Canada, *ARCHIVED — Regulations Amending the Food and Drug Regulations (1220 — Enhanced Labelling for Food Allergen and Gluten Sources and Added Sulphites)*, H. Canada, Editor. 2011: Canada Gazette.
4. Health Canada. *Sulphites - One of the ten priority food allergens*. [Online] 2012 2012-10-26 [cited 2014 July 29]; Available from: http://hc-sc.gc.ca/fn-an/pubs/securit/2012-allergen_sulphites-sulfites/index-eng.php.