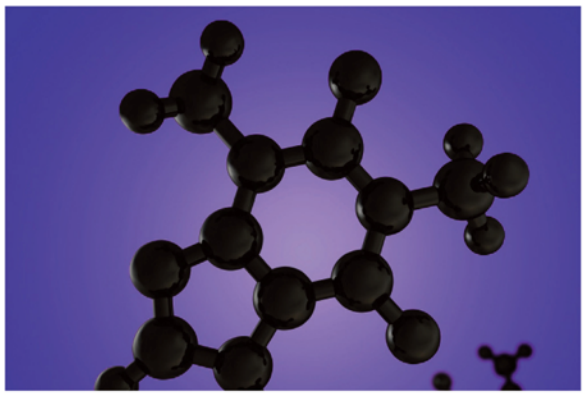
Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2009-2010 Targeted Surveys

Allergen



Undeclared Allergens in Infant Formulas and Foods

TS-ALLERGEN-09/10

Canada

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1 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 objective of the allergens in infant formulas and infant foods survey was:

- To gain an understanding of undeclared priority allergens in infant formulas and foods manufactured for infants under twelve months of age.

A total of 200 infant formulas and food products marketed for infants less than one year of age were collected and analyzed. The samples represented a range of products often included in an infant's diet. These included milk-based, soy-based and non-milk/non-soy formulas, cereals, and foods containing fruit(s), vegetable(s), milk and meat. The samples were analyzed to determine if they contained quantifiable levels of four allergens: peanut, soy, egg, milk (casein and beta-lactoglobulin), as well as gluten.

The samples were compliant with current legislation. Three of the rice cereal samples contained low levels of quantifiable gluten likely from cross contamination; the levels were determined by Health Canada as unlikely to cause an adverse health effect. One sample, a fruit based dessert, contained a low level of quantifiable milk protein. This product was assessed by Health Canada as unlikely to cause an adverse health effect. All positive samples were referred for follow up with the company so they could address the issue.

2 Introduction

2.1 The Food Safety Action Plan

The Food Safety Action Plan (FSAP) is a five-year project (2008-2013) led by the Canadian Food Inspection Agency (CFIA) and is a part of the Food and Consumer Safety Action Plan (FCSAP), a joint federal initiative with Health Canada, the Public Health Agency of Canada and the Canadian Institutes of Health Research. The FCSAP encompasses a series of initiatives to modernize and strengthen Canada's safety system for food, health and consumer products and to better support the collective responsibilities that government, industry and consumers have for product safety. The four main priorities identified for the FSAP were imported food ingredients, fresh produce, mycotoxins in cereals and undeclared allergens.

Within FSAP, the Canadian Food Inspection Agency (CFIA) gained increased ability to monitor potential food risks and to prevent unsafe food products from entering the Canadian marketplace. The CFIA fulfils this mandate through an enhanced surveillance initiative which includes targeted surveys. The CFIA works on these targeted surveys with input from other federal partners (e.g., Health Canada) and Provincial and Territorial (P/T) representatives.

2.2 Targeted Surveys

Targeted surveys are used to test various foods for specific hazards and are a complementary approach to the CFIA's regular programs and inspection activities. The surveys are designed answer specific questions about hazards in food. Generally, they test for the occurrence and magnitude of defined hazards in targeted foods, often with the testing focusing on a specific segment of the population (i.e., consumers with an allergy or intolerance). Surveys may be developed using a number of factors such as policies and/or regulations, existing data from food safety investigations, inspections, and other regular agency activities.

This targeted survey focused on the presence of four undeclared allergens, including milk, egg, peanut, soy, as well as gluten, in infant formulas and foods marketed for infants under one year of age. The information gathered will identify if these commodities require follow up with industry in order to provide further guidance, education and monitoring for the presence of allergens when they are not expected or declared.

2.3 Acts and Regulations

The *Food and Drug Act* (F&DA) 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 & Regulations* (FDAR).

If a pre-packaged food product contains a list of ingredients and is unsafe for people with food allergies because it contains an allergen that is not declared, this may be a contravention of the F&DA. Failure to declare allergenic components may be contrary to Subsection 5(1) of the F&DA. These products may therefore be subject to regulatory measures taken by the CFIA, which can include a product recall, if warranted.

Health Canada (HC) proposed enhanced labelling regulatory amendments to the *Food and Drugs Regulations* (F&DR) for priority allergens, gluten sources and sulphites in pre-packaged food sold in Canada. Health Canada published its proposed regulatory amendments in *Canada Gazette*, Part I, on July 26, 2008 to allow for public comment. The amendments, as proposed, would require that food allergen and gluten sources be declared on a label 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 product. The proposed amendments also require the labelling of added sulphites. In addition to requirements around gluten labelling, mustard seed is proposed for addition to the list of priority allergens. Further information on these proposed regulations can be found on the HC web site, http://www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/proj1220-modifications-eng.php.

Note:

Between the time the data was generated and the time of the survey report was released, Health Canada's Enhanced Allergen Labelling Regulations have been published in Canada Gazette, Part II and will come into force August 4, 2012.

3 Allergens Survey

3.1 Rationale

The presence of an undeclared allergen or gluten in a food for sensitive individuals can be life threatening or contribute to chronic health issues. Current estimates indicate that food allergies affect as many as 6% of young children and 3% to 4% of adults[1] and celiac disease has been recognized as a common chronic disease affecting 1 in every 100-200 people[2]. In Canada, eight main allergens (known as priority allergens) have been identified by HC as responsible for causing the majority of allergic reactions[3]. These allergens are: milk, eggs, peanut, sesame

[1] Health Canada. *Food Allergies and Intolerances* [online]. 2010. Accessed June 3, 2010, http://www.hc-sc.gc.ca/fn-an/securit/allerg/index-eng.php.
[2] Health Canada. *Celiac Disease, The Gluten Connection* [online]. 2010. Accessed June 3, 2010, http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/securit/gluten_conn-lien_gluten-eng.pdf.
[3] Health Canada. *Food Allergies* [online]. 2009. Accessed June 3, 2010, http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/food-aliment/allerg-eng.php.

seeds, tree nuts, soy, wheat and seafood. Sulphites have also been recognized as having the potential to produce serious symptoms similar to an allergen in sensitive individuals. There is no cure for a food allergy, and the most important strategy for a person with a food allergy, or a person choosing food for an individual with a food allergy, is avoidance. Allergens and gluten sources should be appropriately labelled to ensure consumers have complete, accurate information when choosing food products.

This survey was designed to sample infant formulas and foods marketed for consumption by infants under the age of one year. The main objective of this survey is to identify if undeclared priority allergens and/or gluten sources are present in sampled infant formulas and food products. The information gathered will be an indicator of potential food safety concerns relating to undeclared allergens in the infant formulas and food products tested.

3.2 Allergens and Gluten

When a food allergen is consumed it can trigger a reaction of the immune system in sensitive individuals. The immune system in a sensitive individual produces antibodies, called immunoglobulin E (IgE) in response to the presence of allergenic proteins in the body. When the immune system is re-exposed to the allergenic protein the IgE antibodies and other defence chemicals are released causing allergic reactions that can vary by type, severity and rates of development. Symtoms of an allergic reaction can include hives, swelling, trouble breathing, weakness, cramps, vomiting, drop in blood pressure, shock, loss of consciousness and even death[4].

Gluten is a protein found in wheat, barley, rye, and triticale. Individuals with a sensitivity to gluten include those with celiac disease and gluten sensitivity. For these individuals the consumption of gluten damages the small intestine. This damage prevents the body from absorbing the nutrients it needs to be healthy. Other serious health consequences such as certain cancers and infertility can also occur[5]. The only treatment for this condition is a gluten free diet.

3.3 Sample Distribution

The survey targeted a variety of infant formulas and infant foods. Samples were taken based on availability at retail, no specific brands were targeted. Samples were collected in 2009-2010 and were all nationally available brands and products. The distribution of samples by commodity is listed in Table 1. A total of 40 infant formula samples were collected; the samples consisted of powdered formula, ready-to-serve formula, and concentrated formula and were milk-based, soy based and non-milk/non-soy based. A total of 160 food samples were collected; these included cereals, fruit and vegetable purées, and mixed meals (e.g. meat and potatoes). A more detailed breakdown of samples can be found in Appendix A.

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[4]Health Canada. *Food Allergies and Intolerances* [online]. 2010. Accessed June 3, 2010, http://www.hc-sc.gc.ca/fn-an/securit/allerg/index-eng.php

[5]Belanger, Jeanette, E, Wooltorton, Eric. Is the timing of infant cereal introduction a risk factor for celiac disease autoimmunity?, *Canadian Medical Association Journal* [online],173, 1324 (2005). Accessed June 3, 2010, http://www.cmaj.ca/cgi/content/full/173/11/1324.

Table 1. Sample distribution			
Commodity	**Form**	**Base**	**Number**
Formulas	Powdered	Milk	18
		Soy	9
		Other	1
	Liquid	Milk	5
		Soy	2
		Other	0
	Ready to Eat	Milk	3
		Soy	1
		Other	1
Cereals	Cereal	Oat	9
		Barley	1
		Wheat	5
		Rice	11
		Mixed	14
Food Products	Vegetable	--	33
	Fruit	--	39
	Meat	--	45
	Milk	--	3

3.4 Methodology

The samples were tested for beta-lactoglobulin (milk protein), casein (milk protein), egg, peanut, soy and gluten. Food allergen proteins were detected and measured by CFIA laboratories using ELISA-based accredited methodology.

The methods and limits of detection were as follows:

- Beta-Lactoglobulin, ELISA Systems, Beta-Lactoglobulin Residue, ESMRDBLG-48, detection limit 0.10 ppm beta-lactoglobulin
- Casein, ELISA Systems, Casein Residue, ESCASPRD-48, limit of detection 0.52 ppm casein
- Egg, Neogen Veratox Quantitative Egg Assay, 8450, limit of detection 2.5 ppm egg
- Gluten, r-Biopharm, Ridascreen Gliadin, R7001, limit of detection 5ppm gluten
- Peanut, Neogen Biokits (formerly Gen-Probe/Tepnel), 902048Q, limit of detection 1 ppm of peanut, and Neogen Veratox Quantitative Peanut Assay, 8430, limit of detection 2.5 ppm peanut
- Soy, Neogen Veratox Quantitative Soy Assay, 8410, limit of detection 10 ppm soy protein isolate

3.5 Limitations

A total of 200 samples were collected and analysed in the 2009-2010 infant formula and food allergen survey. In comparison to the total number of products available, 200 total samples represent a small fraction of infant food. This data is meant to provide a snapshot of the targeted commodities and has the potential to highlight commodities that warrant further investigation.

4 Results and Discussion

4.1 Infant Formulas

Forty infant formula samples, consisting mainly of milk or soy based products, were sampled and analysed. A total of 196 individual allergen tests were completed on the 40 samples. The 26 milk based samples were tested for the presence of egg, peanut, soy and gluten, the 12 soy based samples were tested for the presence of milk, egg, peanut and gluten and the 2 samples that were not milk or soy based were tested for milk, egg, peanut, soy and gluten. All test results were in compliance with the F&DA.

One liquid, milk based, sample had a low quantifiable level of soy protein. Soy oil and soy lecithin were identified in the list of ingredients, and parents of soy allergic infants might be expected to avoid this product for that reason. All other milk based formulas and the formulas suitable for individuals with a milk and soy sensitivity did not test positive for soy protein. All milk based formulas had either soy oil and/or lecithin in the list of ingredients. Both of the formulas suitable for individuals with a milk and soy sensitivity contained soy oil in the list of ingredients.

To gain an understanding of the level of milk protein present in milk based formulas and to function as a positive control, 10 of the milk based formulas were tested for the level of milk protein present. Of the 10 samples tested 8 had quantifiable results for casein and/ or beta-lactoglobulin. The 2 samples that did not have quantifiable levels of milk protein had label claims indicating that the product was easier to digest based on the whey protein present in the product being partially hydrolysed. Of the 8 samples that did have quantifiable levels of milk proteins, 5 had low levels of detectable beta-lactoglobulin and undetectable casein. These 5 samples also had label claims indicating that the product was easier to digest based on the whey protein being partially hydrolysed. The other 3 samples had quantifiable levels of beta-lactoglobulin and casein. Further information can be found in Appendix B.

4.2 Infant Cereals

Forty cereals for infants were sampled, with a total of 166 individual allergen tests completed. Samples included cereals containing barley, wheat, oats and rice as well as mixed cereals and

cereals with fruit and yoghurt. The cereals were tested for allergens and gluten that were not indicated on the label. A total of 4 out of 11 rice cereals sampled were positive for gluten, gluten was not on the label, in the list of ingredients or in a precautionary statement, no gluten-free claim was made on the label. However, one rice cereal had malt in the list of ingredients. Generally people following a gluten-free diet would be aware that malt, malt extracts or malt flavourings are potential gluten sources.

As oats are frequently cross contaminated with other grains (ranging from 2.5% to 24% on a weight per weight basis)[6] a certain level of gluten resulting from this cross contamination was expected during this survey. There is no numerical value for the gluten that may be present as the gluten content in the different cross contaminating grains is variable. The levels of gluten observed in this survey are not unexpected given the degree of cross contamination frequently encountered. The cross contaminating grains are not as a result of an intentional addition, therefore, there is no violation of Canadian labelling requirements. However, individuals suffering from gluten intolerance and/or wheat allergies should be aware that this cross contamination may exist. The Government of Canada has responded to this finding by encouraging the food industry that makes these products to voluntarily use precautionary labelling in order to advise the public that oat cereal may contain wheat. The Government of Canada will continue to work with the food industry to ensure the safety of the Canadian food supply.

Health Canada was consulted on the other 3 samples and based on currently available science the majority of evidence supports that a daily gluten intake of < 10 mg is unlikely to cause significant histological abnormalities. Further information can be found in Appendix B. It is likely that the gluten present in the 3 samples was due to cross contamination and the test results were shared with the manufacturer or importer for their consideration during review of processing. All the samples were in compliance with the F&DA.

One wheat and one mixed cereal sample that had clear precautionary warnings on the label indicating that the product may contain milk and was not suitable for individuals with a milk allergy were tested for milk protein to determine if a quantifiable level of milk protein was present. Milk protein was detected in both samples indicating that this was an appropriate use of a precautionary statement as milk was not a part of the formulation. This further reinforces that sensitive individuals, and/or those choosing food for sensitive individuals, should avoid products that have a precautionary statement indicating possible presence of an allergen.

Oats are often contaminated with gluten proteins from other cereal grains such as wheat, barley and rye. People avoiding gluten should not consume oats unless the oats are specially prepared to avoid cross contamination with other grains and they have consulted with their doctor[7]. The oat cereals were tested for gluten, this provided information on the level of gluten present in these cereals. All nine of the oat cereals had quantifiable levels of gluten. Further information can be found in Appendix B.

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[6] Canada Grain Commission. *Oats-Chapter 8 Official Grain Grading Guide* [online]. July 2007. Accessed June 27, 2011, http://www.grainscanada.gc.ca/oggg-gocg-7e-eng.htm.

[7] Health Canada. *Consultation - Proposed Policy Intent for Revising Canada's Gluten-free Labelling requirements* . 2010. Accessed June 3, 2010, http://www.hc-sc.gc.ca/fn-an/consult/gluten2010/index-eng.php.

4.3 Food Products

A total of 120 food products for infants were sampled, on which 655 individual allergen tests were completed. Samples consisted of a range of foods for infants from 4-12 months of age and were fruit, vegetable or meat based. The samples were distributed across recommended timing of introduction, further information on the breakdown can be found in Appendix A. Samples were tested for milk, egg, peanut, soy, and gluten if they were not indicated on the label in either the list of ingredients or a precautionary statement. A fruit based dessert recommended for infants six months of age had a low but quantifiable level of milk protein, casein, present. Health Canada was consulted regarding the analytical result and took into consideration the serving size and the concentration of casein in the product and determined that this product was unlikely to pose a health risk. The manufacturer was informed about the result for consideration and appropriate action. All other test results did not have a quantifiable level of protein present and all samples were in compliance with the F&DA.

5 Conclusion

Two hundred infant formulas and infant food samples were collected and analysed for undeclared allergens. All samples were properly labelled, and were in compliance with the F&DA. This survey was limited in sample size, however, it met the objective of gathering baseline information on the occurrence of undeclared priority allergens and gluten in infant formulas and foods targeted at infants. Based on the results, no gaps in food safety for allergens in these foods were identified.

6 Appendix

APPENDIX A. **Breakdown of samples tested by commodity and stage for introduction into an infant's diet**

Table 1. Breakdown of samples tested by commodity			
Commodity	**Base**	**Food description**	**Number of samples**
Formula	Milk	Ready to eat	3
		Concentrated liquid	4
		Powder	19
	Soy	Ready to eat	1
		Concentrated liquid	2
		Powder	9
	Other	Ready to eat	1
		Powder	1
Total formula			40
Cereal	Barley	Plain	1
	Wheat	Plain	2
		With fruit	3
	Oat	Plain	5
		With fruit	4
	Rice	Plain	9
		With fruit	2
	Mixed	Plain	6
		With Fruit	8
Total cereal			40
Infant food	Fruit	Apple	10
		Banana	4
		Mixed	18
		Peach	2
		Pear	4
		Prune	1
	Total fruit		39
	Vegetable	Green bean	2
		Yellow bean	1
		Carrot	4
		Corn	1
		Mixed	11
		Green pea	4
		Sweet potato	6
		Squash	4
	Total vegetable		33
	Meat	Beef	14
		Chicken	17
		Pork	8
		Turkey	5
		Lamb	1
	Total meat		45
	Milk		3
Total infant food			120
Total all samples			200

Table 2. Breakdown of food samples tested by stage for introduction into an infant's diet		
Stage	**Base**	**Number of Samples**
Stage 1 **6 months**	Vegetable	24
	Fruit	33
	Meat	14
	Milk	2
Stage 2 **7-8 months**	Vegetable	5
	Fruit	6
	Meat	25
	Milk	1
Stage 3 **9-10 months**	Vegetable	4
	Fruit	0
	Meat	6
	Milk	0

APPENDIX B**. Numerical results for tests that had quantifiable protein in infant formula and infant food**

Table 1 Numerical results for tests that had quantifiable protein in infant milk-based formulas			
	Beta-lactoglobulin (ppm)	**Casein (ppm)**	**Soya (ppm)**
Powder	8599	4.9	nd
	2.3	nd	nd
	0.7	nd	nd
	0.5	nd	nd
	0.7	nd	nd
	9068	5	nd
	1244	4340	nd
Liquid	nd	nd	12.8
	0.7	nd	nd

*nd not detected

Table 2 Numerical results for tests that had quantifiable protein in infant cereal				
Cereal	**Stage***	**Beta-lactoglobulin (ppm)****	**Casein (ppm)****	**Gluten (ppm)****
Oat	1	nd	nd	3123
	1	nd	nd	166
	1	nd	nd	1287
	1	nd	nd	3106
	1	nd	nd	777
	2	nd	nd	636
	2	nd	nd	555
	3	nd	nd	492
	3	nd	nd	1117
Wheat	2	0.7	3.5	nd
Mixed	2	nd	1.3	nd
Rice	1	nd	nd	5.7
	1	nd	nd	10
	1	nd	nd	5
	1	nd	nd	80

* Stage 1 was recommended for infants 6 months, Stage 2 was recommended for infants 7-8 months, Stage 3 was recommended for infants 9-10 months

**nd not detected