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The effect of the Food Allergen Labeling and Consumer Protection Act (FALCPA) on the accidental food allergen ingestion rate in adults with self-reported food allergies

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The Effect of the Food Allergen Labeling and Consumer Protection Act (FALCPA) on
the Accidental Food Allergen Ingestion Rate in Adults with Self-reported Food

Allergies

by

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Thesis

Submitted to the Department of Health and Human Services

Eastern Michigan University

in partial fulfillment of the requirements

for the degree of

MASTER OF SCIENCE

in

Human Nutrition

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ABSTRACT

Background: The Food Allergen Labeling and Consumer Protection Act (FALCPA) recently required bolded allergens or “contains” statements on food product labels. Very few U.S. studies have looked at the accidental food allergen ingestion rate in adults. Since the emotional and medical costs of allergic reactions can be high, it is important to determine if the FALCPA is helping to reduce the accidental food allergen ingestion rate in adults with self-reported food allergies.

Objectives: The primary research objective of this study was to determine whether the new allergen labeling requirements of the FALCPA law has had an effect on the accidental food allergen ingestion rate of adults with self-reported food allergies. Secondary objectives were to determine both the prevalence of self-reported food allergies in adults and the frequency of food product label reading in those who had self-reported food allergies.

Methods: Surveys were completed by adult mall shoppers (n=386) in Northern California including 57 adults with self-reported food allergies.

Results: The overall prevalence of self-reported food allergies for the top 8 allergens covered by FALCPA was found to be 12.4%. Respondents with self-reported food allergies were found to much more frequently read both allergen information and manufacturer warning statements on product labels than people without food allergies. The annual accidental food allergen ingestion rate of adults decreased by

a significant 24.4% in the two years since the FALCPA was passed. Additionally, the percent of accidental food allergen ingestion events due to store-bought food decreased while the percent from restaurant-prepared food increased. Restaurant-prepared food was the number one cited reason for accidental ingestion both prior to and after the passage of the FALCPA.

Conclusions: Adults with self-reported food allergies are reading the allergen information and warning statements on food product labels. Data suggest that passage of the FALCPA is helping to reduce the accidental food allergen ingestion rate in adults with self-reported food allergies, especially from store-bought food products.

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Chapter 1: Introduction and Background

Introduction

Regular reporting of news stories about people with food allergies who have extreme reactions makes it appear that a significant portion of the U.S. population has food allergies and that this figure is on the rise. In actuality, persons suffering from food allergies diagnosed by a physician represent only 2% to 5% of the U.S. population, approximately 7 million Americans (1). The percentage of the U.S. population who self-report food allergies has been found to be higher at 9%-12% (2). An international study found 12% of U.S. adults reported having a food allergy (3). The percentage of children with food allergies, though, does appear to be increasing, not only in the United States but also in England (1,4). Food allergic reactions can range from mild oral symptoms to severe anaphylactic shock in which multiple body systems react simultaneously. An estimated 30,000 episodes of food-related anaphylaxis occur each year in the U.S., resulting in approximately 2000 hospitalizations and 150 deaths (5). The main preventative recommendations for people with food allergies are to carefully read product labels and carry medications in case of a reaction (6). Therefore, it is extremely important that product labels be accurate and credible. The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) has required that the top eight allergens be bolded on food labels or be listed in a “contains (allergen)” statement at the end of the ingredient list. The present study sought to determine whether this law has had an effect on decreasing the accidental food allergen ingestion rate of adults with self-reported food allergies.

Allergic Reaction Mechanism

A food allergic reaction is the body's exaggerated response to a food protein (7). As the protein is viewed as a foreign entity, specific antibodies are produced to destroy it. The majority of food allergic reactions are immunoglobulin E (IgE) antibody-mediated reactions (class 1 food allergies) in which the sensitization of the allergen occurs in the gastrointestinal tract (8). Sensitization can also occur to allergens which have cross-reactivity with IgE plant protein allergens, especially fruits (class 2 food allergies) (9). Class 2 food allergies include pollen food allergy syndrome in which birch, ragweed, and mugwort pollens cross-react with proteins in carrots, celery, apples, pears, and kiwi (9), and latex-associated food allergy syndrome, in which allergen proteins in latex cross-react with proteins in avocado, banana, kiwi, and papaya (10).

In class 1 food allergies, as a food is digested for the first time, allergenic proteins are absorbed in the intestine, prompting certain intestinal cells to produce specific IgE. The IgE antibodies link to receptors on mast cells, located in the mucosa and the skin, as well as to basophils circulating in the blood (8). Mast cells store mediators, mainly histamine. The next time the food is eaten, the contact of the allergens with the IgEs stimulates the mast cells to release histamine as well as make new potent eicosanoid mediators (prostaglandins, leukotrienes, and cytokines) (8). Oral tolerance, an absence of an immunological response to a food allergen after first contact, prevents an allergic reaction in most people (8).

IgE mediated reactions involve the skin, respiratory system, gastrointestinal tract, and cardiovascular system. These reactions have a distinctive pattern in that they are variable and unpredictable in both symptoms and severity (8). The mediator, histamine, binds to a variety of target cells via H1 and H2 receptors (7) causing vasodilation, tissue inflammation, muscle contraction, and mucous secretion (8). The most frequent food allergen response is urticaria (hives) which is usually linked to both gastrointestinal symptoms (stomach pain, nausea, and vomiting) and respiratory symptoms. Oral allergy syndrome (OAS) is very common and includes itching of the mouth, lip swelling, and swelling of the larynx, mouth, and throat (8). Anaphylaxis is a rare but potentially fatal reaction caused by several different body systems reacting simultaneously to the histamine release – skin, respiratory system, gastrointestinal, and cardiovascular system – causing throat swelling, hives, breathing difficulties, and decreased blood pressure (11).

The most common food allergies are related to proteins found in milk, eggs, peanuts, and fish (8). Allergies to egg and milk are usually outgrown in childhood (up to 80% of infants with egg allergy and 85% with cow's milk allergy are tolerant by age 5), but peanut protein sensitivity is usually not outgrown (12), although there are conflicting studies on this topic. One such study found 21.5% of subjects aged 4 to 20 had negative food challenge results and had therefore outgrown their peanut allergy (12). The recurrence of a peanut allergy after a negative food challenge test may have to do with the amount and frequency of peanut ingestion post challenge. Fleischer et al. (13) found an overall recurrence rate of 7.9% in children who had

outgrown their peanut allergy but a 20% rate for those children who had only eaten peanuts infrequently after outgrowing their allergy.

Diagnosis of a Food Allergy

Diagnosis of a food allergy is based on a medical history, an objective examination, allergy tests, and both elimination diet and food challenge tests. A medical history is critical as often allergy tests indicate food allergies that do not manifest clinically. Both of the main diagnostic tests, skin prick tests (SPT) and IgE blood tests, have relatively high false positive rates due to cross-reactivity (when IgE antibodies recognize similar structures in another allergenic source). The double-blind, placebo-controlled food challenge (DBPCFC) is the only validated test for diagnosing food allergies (8). The food challenge is used in patients for determining if there is a need for the permanent avoidance of foods essential to the diet, such as milk, eggs, or nuts.

Threshold Dose

Because of the potential severity of accidental peanut ingestion, many studies have been done to determine the threshold dose of nut proteins that elicit an allergic reaction. In one study, adults with positive SPT and IgE levels for peanut protein underwent DBPCFC tests with increasing doses of peanut protein (14). The threshold dose was defined as the dose when objective (lip swelling, vomiting, laryngeal edema) or repetitive (itching of mouth, stomach pain) subjective reactions occurred. The threshold dose for subjective reactions ranged from 100 ug up to 1

gram of peanut protein. A 3 mg dose (1/50 peanut) was the dose at which 50% of the population with peanut allergy would have a subjective allergic reaction. The threshold dose for objective reactions was established for only 6 patients, ranging from 10 gm for 1 subject and 30 mg for the 5 others. Another double blind, placebo controlled threshold dose study (15) that involved hazelnut-allergic adults found that the threshold dose for subjective reactions ranged from 1 mg up to 100 mg of hazelnut protein (6.4-640 mg hazelnut meal). A 6 mg dose (1/25 hazelnut) was the dose at which 50% of the hazelnut allergic population would suffer a subjective allergic reaction.

Prevention

As there are currently no vaccines or medications to prevent food allergic reactions, the main recommendations include the following: strict avoidance of the allergenic food, careful reading of ingredient labels, not eating products that lack a nutritional label, wearing of an ID bracelet that indicates the type of food allergy, and keeping a self-injectable epinephrine pen (epi-pen) on hand for accidental ingestion of allergens (6).

Research Statement

With the costly and sometimes fatal consequences of a food allergic reaction, an important area in which research is critically needed is the study of the effect that the passage of the Food Allergen Labeling and Consumer Protection Act has had on the accidental food allergen ingestion rate of adults with self-reported food allergies.

Rationale for the Study

Peanuts are one of the most allergenic foods and cause the most unpredictable reactions. They are the most common cause of death by food anaphylaxis in the U.S. (16). Among children who had only a mild reaction to peanut protein on the first exposure, almost 50% had anaphylactic reactions on a later exposure (7). Another study found 31% of subsequent food allergic reactions were more severe than the initial reaction, with about 1/3 of peanut allergic patients having severe reactions after peanut ingestion (17).

There is presently no agreement as to the prevalence of food allergies in the U.S. population, but many studies have found that the percentage of people with food allergies is increasing. A study that analyzed data from a 2001 U.S. Food and Drug Administration (FDA) food safety survey found the prevalence of self-reported food allergies to be 9.1%, with 5.3% of the respondents self-reporting a doctor-diagnosed food allergy (2). Another study found the self-reporting of peanut and/or tree nut allergies specifically was 1.2% (approximately 3 million people), similar to the figure obtained in a survey that was done 5 years prior (1). The percentage of children under age 18 with a peanut and/or tree nut allergy, though, had doubled from .6% to 1.2% in the same time period. Sixty-six percent reported that they had had more than 5 reactions during their lifetimes. The Food Allergy and Anaphylaxis Network estimates that close to 7 million Americans (2% adults, 6% children) have physician-diagnosed food allergies, with approximately 3 million having allergies to peanuts and/or tree nuts (18).

It is difficult to estimate the prevalence of food anaphylactic reactions since a health problem classification code (known as the International Classification of Diseases, edition 9 or ICD-9) for food anaphylaxis or food allergy was not established until 1999. An estimated 30,000 episodes of anaphylaxis occur each year in the U.S., resulting in 2000 hospitalizations and approximately 150 deaths (5). Very few studies exist on the subject, but the literature suggests that emergency room medical records underreport anaphylaxis by as much as 50% (19,20). Healthy People 2010 has a developmental objective to reduce deaths from anaphylaxis caused by food allergies (21).

With the high cost both medically and emotionally of food allergic reactions, it is important to know whether the passage of the Food Allergen Labeling and Consumer Protection Act (effective January 1, 2006) has had an effect on the accidental food allergen ingestion rate in adults with self-reported food allergies.

Chapter 2: Review of Related Literature

Allergens and Product Labeling Law

Since the most effective strategy to prevent food allergic reactions, including anaphylaxis, is the careful reading of food labels to avoid accidental allergen ingestion, product labeling is an important area of concern for public policy. The U.S. Food and Drug Administration (FDA) is the department that administers the Food, Drug and Cosmetic Act (FDCA), under which the product labeling code is outlined. Prior to January 1, 2006, the FDCA required a complete listing of all ingredients of a food of two or more ingredients with two exceptions (22). Spices, flavorings, and colorings could be declared collectively (“natural flavors”), and incidental additives present in insignificant levels and having no technological or functional effect in the finished product could be omitted from the label. The FDCA also initially allowed ingredient labels to contain technical and scientific terms for common allergens (e.g. ammonium caseinate for milk, albumin for egg).

The Food Allergy and Anaphylaxis Network (FAAN) was instrumental in lobbying the FDA to list allergens on product labels in plain language regardless of amount (18). The Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004, effective January 1, 2006, amended section 403 of the FDCA to read that any foods (except for raw agricultural products) that contained a major food allergen must have either the word “contains” followed by the name of the food source from which the major food allergen was derived, or the common name of the allergen followed in parentheses by the name of the food source, in the list of ingredients on

the label. Flavorings, colorings, or incidental additives that contained a major food allergen were also subject to the law (23). The 8 major food or food groups covered by the new law and accounting for more than 90% of food allergies were milk, egg, fish, shellfish, tree nuts, peanuts, wheat, and soybeans. The goal of the law was to ensure that foods containing one of the top 8 allergens (or derivative) used the common or usual name of the allergen source on the product label (18).

Good Manufacturing Processes

In addition to following the FALCPA, manufacturers were required to abide by the good manufacturing practices (GMP) that were codified in Title 21 of the Code of Federal Regulations (24). These practices described methods, equipment, facilities, and controls that were needed to produce safe and wholesome food under sanitary conditions. Food manufacturers voluntarily began to use warning statements to indicate if a product could possibly contain contamination from food allergens (e.g. manufactured on equipment that also processes products containing nuts) although the FDA had advised manufacturers that these statements did not take the place of strict adherence to GMP (22). A spokesperson for the FAAN has stated that they think the warning statements are too broad and confusing, especially due to the proliferation of these statements since passage of the FALCPA (25).

Manufacturer Warnings and Consumer Perception of Risk

In the past two years, there have been a few studies that have looked at product food allergen labeling warnings and consumer perception of the risk associated with the consumption of these products. A recent study found only about

63% of the people who had self-reported allergies read labels to avoid foods to which they were allergic (2).

In one FDA-commissioned survey (part of the July 2006 report to Congress on issues with GMPs and product labeling), consumers with food allergies were shown to prefer the proposed warning “Allergy Information: may contain peanuts” to any of the five basic advisory warnings used by manufacturers (26). In a conflicting FDA-commissioned survey, consumers with food allergies indicated that they found the two statements – “Manufactured on equipment that also produces peanuts” and “Produced in a facility which processes peanuts” – more believable and helpful and thought the food with this label would be less likely to contain peanuts than the two statements – “May contain peanuts” and “Allergy Information: may contain peanuts.”

In one of the few post-FALCPA surveys, 64% of respondents noticed that major food allergens had been added to ingredient lists in 2006, and 83% noticed the new language “contains (specified allergen)” (27). The same study also found that consumer avoidance of products depended upon the perceived risk of the manufacturer’s allergen warning, although the warning statements were not accurate reflections of the actual risk of peanut residue in the products. Compared to a survey done in 2003, survey participants were more likely to purchase food products with precautionary statements in 2006 (27). The study showed 8 different peanut advisory labels to parents of children with food allergies and consumers with food allergies. Ninety-one percent indicated they would never purchase products with labels that read “may contain peanuts” or “may contain traces of peanuts”; 85% stated they would never purchase products with “manufactured with same

equipment as peanuts”; 70% said they would never purchase products with “manufactured in a facility that also processes peanuts”; and 65% stated they would never purchase products with a label warning “packaged in a facility that also packages peanuts.” In the same study (27), packaged foods with the above advisory labels were purchased and analyzed. Residual peanut protein of between 3 and 4000 parts per million was detected in 7% of the lots overall, (4% of products with “may contain” warnings, 5.2% of products with “shared equipment,” and 10.3% of products with “shared facility” warning statements). At the recommended serving size for each product, an estimated dose of between 0.1 and 180 mg peanut would be ingested, a level at which highly sensitive individuals would react.

Accidental Ingestion of Food Allergens

A number of studies have surveyed children with food allergies (and their parents) to determine the accidental food allergen ingestion rate. Yu et al. (17) found 50% of children with peanut allergies had an accidental exposure in the prior year and 75% within the past 5 years, giving an annual accidental ingestion rate of 14.3%. Nowak-Wegrzyn et al. (28) reported that 57% of children with food allergies had experienced an accidental ingestion within the past 2 years, with 38% having at least one acute reaction to food at school. In a study of U.S. adults, Vierk et al. (2) found that 78.2% had their last allergic reaction to food less than 5 years ago and 28% less than one month prior.

The most frequently mentioned locations for accidental ingestion of food allergens have been the home (reported by approximately 65% of those with food

allergies versus 40% of those with peanut allergy specifically), a relative's or friend's home (34%), restaurants (10-15%), and the work site (10%) (2,17,28). An Internet-based survey conducted by Eigenmann et al. (29) also found the home to be the number one site for accidental food allergen ingestion (25.5%), followed by restaurants (17.6%), and relative/friend's home (14%). In the study, 44% of those who had accidental ingestions in restaurants had informed the restaurant staff of their allergy prior to ordering their food.

The Internet study also found that 30% of the accidental ingestions in the home were due to the consumption of processed food. Another survey found that a prepared food had caused the last reaction in about 50% of survey respondents while a packaged food caused it in 28% (2).

With the high rate of accidental food allergen ingestion, especially in regards to labeled food products, as well as the confusion over manufacturers' warning labels, there is a need to determine if the new allergen labeling law has had an effect on reducing the accidental food allergen reaction rate in adults. Previous literature in this area has focused on identification of changes necessary for ingredient labels post passage of the FALCPA as well as the consumers' presumed level of risk with the consumption of products with various manufacturer warning allergen labels. There is clearly a gap in the literature regarding the effect of the new labeling law on reducing the accidental food allergen ingestion rate in adults with self-reported food allergies. This research question is the primary focus of the present study.

Chapter 3: Research Design and Methodology

Research Objectives

The primary research objective of the present study was to determine if the new allergen labeling requirements of FALCPA (effective January 1, 2006) has had an effect on the accidental food allergen ingestion rate of adults with self-reported food allergies. Secondary objectives were to determine both the prevalence of self-reported food allergies in adults and the frequency of food product label reading in those who had self-reported food allergies.

Population Description

The study sample included 386 subjects aged 18 or older who volunteered to take the survey. The survey was distributed on five weekdays in December 2007 inside the Roseville Galleria, a mall located in Northern California. As approximately 9% to 12% of the U.S. population have self-reported food allergies (2,3), the survey intended to capture data from a minimum of 35 individuals with food allergies or parents of children with food allergies.

Research Design

The descriptive observational study was designed to determine if passage of the Food Allergen Labeling and Consumer Protection Act has had an effect on the accidental food allergen ingestion rate in adults with self-reported food allergies. The study was developed to establish if an association existed between the

independent variable of the new allergen law changes to the food ingredient label and the outcome variable of annual accidental food allergen ingestion rate in the 2 years prior to passage of the FALCPA and the 2 years post Act passage. The study was approved by the Human Subjects Committee at Eastern Michigan University (Appendix A).

Research Instrument and Data Collection

A survey instrument was developed to include questions that dealt with both demographic information and food allergies (Appendix B). Areas of demographic information included age, sex, race/ethnicity, and education level. Food allergy questions pertained to ingredient and allergen label reading frequency, number and type of food allergies, number of accidental food allergen ingestions of the top 8 food allergens both prior to passage of the FALCPA and post Act passage, reasons for accidental food allergen ingestion events, and suggestions for improvements to the allergen section of the food product label. Data were collected from adult shoppers in the Roseville Galleria mall located in Northern California, on five weekdays in December 2007.

Statistical Analysis

The SPSS statistical package for Windows (15.0) was used for all data analyses. Descriptive statistics consisting of percentages were calculated for demographic data. To test the strength of the relationships between the demographic variables and frequency of label reading, Phi coefficients were

calculated. Phi coefficients are suitable for use with frequency data such as the demographic factors and the allergy variable used in this research. The annual accidental food allergen ingestion rate was expressed as the number of incidents divided by the number of person-years at risk (n=57 multiplied by 2 years).

Sample Confidentiality and Consent

The survey instrument did not include any subject-identifying information. It did include a statement of implied consent as well as an assurance of anonymity and confidentiality of the information provided. A data sheet containing contact information for the study researchers as well as the statement that the study had been approved by the Human Subjects Committee at Eastern Michigan was provided to subjects (Appendix C).

Chapter 4: Results

Adult mall shoppers (n=386) were asked to complete surveys regarding food allergies. Fifty-seven of the respondents were adults with self-reported food allergies and seven were parents responding for their children who had food allergies. The demographic composition of adult respondents with self-reported food allergies (n=379) is shown in Table 1. The predominant demographic characteristics of subjects with food allergies were that they were white, female, and college-educated. As the category of parents responding for their children with food allergies amounted to only 11% of the total population with food allergies, the data from these surveys were excluded in final statistical analysis in order to maintain a more homogeneous population of people with self-reported food allergies.

Table 1. Demographic statistics for all allergic and non allergic subjects who completed surveys regarding label reading on food items

Demographic variable	Total sample n (%)	Adult self-reported Food allergy n (%)
All	379 (100.0)	57 (15.0)
Gender		
Female	243 (64.1)	42 (73.7)
Male	136 (35.9)	15 (26.3)
Age in Years		
18-29	109 (28.8)	16 (28.1)
30-39	87 (23.0)	10 (17.5)
40-49	63 (16.6)	11 (19.3)
50-59	61 (16.1)	11 (19.3)
60-69	41 (10.8)	9 (15.8)
70-79	10 (2.6)	0 (0.0)
80-89	8 (2.1)	0 (0.0)
Education		
Less than high school	29 (7.7)	7 (12.3)
High school	16 (4.2)	1 (1.8)
Some college	92 (24.3)	18 (31.5)
College degree	139 (36.6)	17 (29.8)
Post college degree	103 (27.2)	14 (24.6)
Race/ethnicity		
White	305 (80.5)	45 (78.8)
Black	11 (2.9)	1 (1.8)
Hispanic/Latino	19 (5.0)	5 (8.8)
Mexican-American	4 (1.1)	0 (0.0)
Asian	13 (3.4)	2 (3.5)
Pacific Islander	6 (1.6)	1 (1.8)
American Indian/Alaskan	2 (0.5)	0 (0.0)
Other	19 (5.0)	3 (5.3)

In the overall population (n=379), the prevalence of self-reported food allergies was found to be 12.4% for the top 8 allergens (15.0% for all allergens), with 2.4% of the food sensitive subjects being allergic to peanuts, 3.7% to milk, 4.0% to tree nuts, 0.8% to fish, and 3.2% to shellfish (Table 2). When allergies were determined for just the adults with food allergies, the allergen prevalence rates were 15.8% for peanuts, 24.6% for milk, 26% for tree nuts, 5.3% for fish, and 21% for shellfish.

Table 2. Prevalence of reported food allergies by category of food allergy			
Food allergy to:	Number of self-reported food allergies*	Prevalence (%) in Total Sample (n=379)	Distribution of food allergies (%) among all adults with self-reported food allergies (n=57)
Eight most common food allergens			
Peanut	9	2.4	15.8
Tree nut	15	4.0	26.3
Milk	14	3.7	24.6
Egg	5	1.3	8.8
Fish	3	0.8	5.3
Shellfish	12	3.2	21.1
Soy	4	1.1	7.0
Wheat	13	3.4	22.8
One or more of top 8 allergens (n=47)		12.4	82.5
Other food allergens (n=27)**			
Fruit/vegetable	20	5.3	35.1
Herb/spice	4	1.1	7.0
Chocolate	2	0.5	3.5
Seeds	2	0.5	3.5
One or more of top 8 allergens + one or more other allergens (n=17)		4.5	29.8
One or more of other allergens only (n=10)		2.6	17.5

*Persons may report allergies to more than 1 food; therefore, number of self-reported food allergies sum to more than population n

**Includes persons with one or more allergies to top 8 food allergens plus one or more allergies to other allergens, as well as persons with one or more allergies to other allergens (none in top 8)

Of the 57 adults in this present study who had self-reported food allergies, 47 were allergic to at least one of the top 8 food allergens, while 10 were allergic to allergens other than the top 8. Of these 47 adults, 17 (36%) had at least one additional allergen that was not listed in the top 8, with 9 (19.1%) naming fruit/vegetable as an additional allergen and 2 naming an herb/spice (11.8%). Of the 10 respondents who had food allergies that were not in the top eight, 5 (50%) named fruit as an allergen, with bananas being the most frequently named fruit. Therefore, of the 27 respondents listing food allergies that were not in the top eight, 20 (19.3%)

named a fruit/vegetable as their food allergen, making it the most frequently named food allergen with an overall prevalence in the total population of 5.3%.

Of respondents with food allergies (n=57), 64.9% usually or always read the nutrition information on product labels compared to 64% of respondents without food allergies (Figure 1).

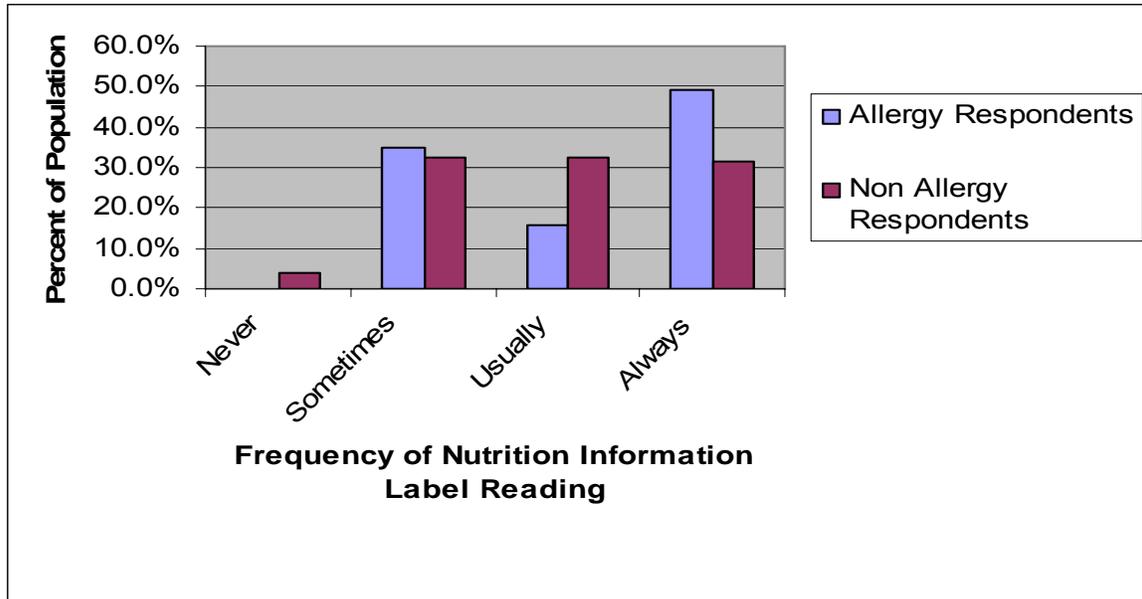


Figure 1. Frequency at which respondents with food allergy (n= 57) and respondents with no food allergy (n= 322) read food label information regarding product ingredients

Respondents with food allergies were much more likely than non-allergy respondents to read allergen information on product labels ($\Phi=0.425$, $p \leq .001$). Of respondents with food allergies, 52.6% usually or always read the allergen information section on the product label compared to 13% of non-allergy respondents (Figure 2). Although only 7% of respondents with food allergies did not know food labels included an allergen section, 17.5% knew the allergen section existed but never read it.

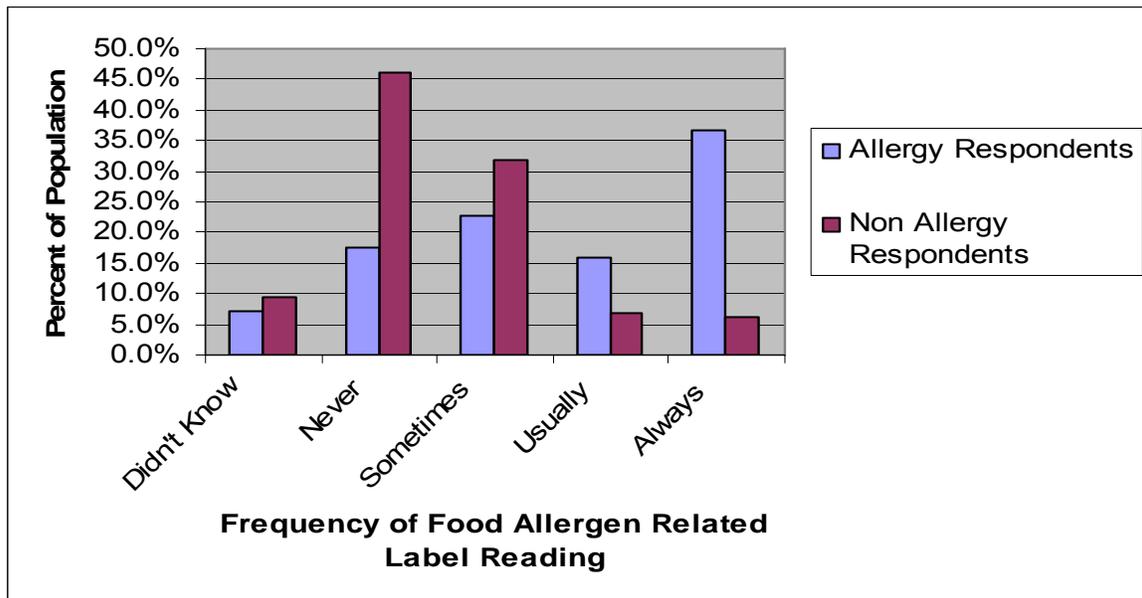


Figure 2. Frequency at which respondents with food allergy ($n= 57$) and respondents with no food allergy ($n=322$) read food label information regarding content of food allergens in food products

Respondents with food allergies reported reading manufacturer warning statements on product labels much more frequently than people without food allergies ($\Phi=0.408$, $p \leq .001$). Of respondents with food allergies, 52.6% usually or

always read the manufacturer warning statements, compared to 15.8% of those respondents who did not have food allergies (Figure 3).

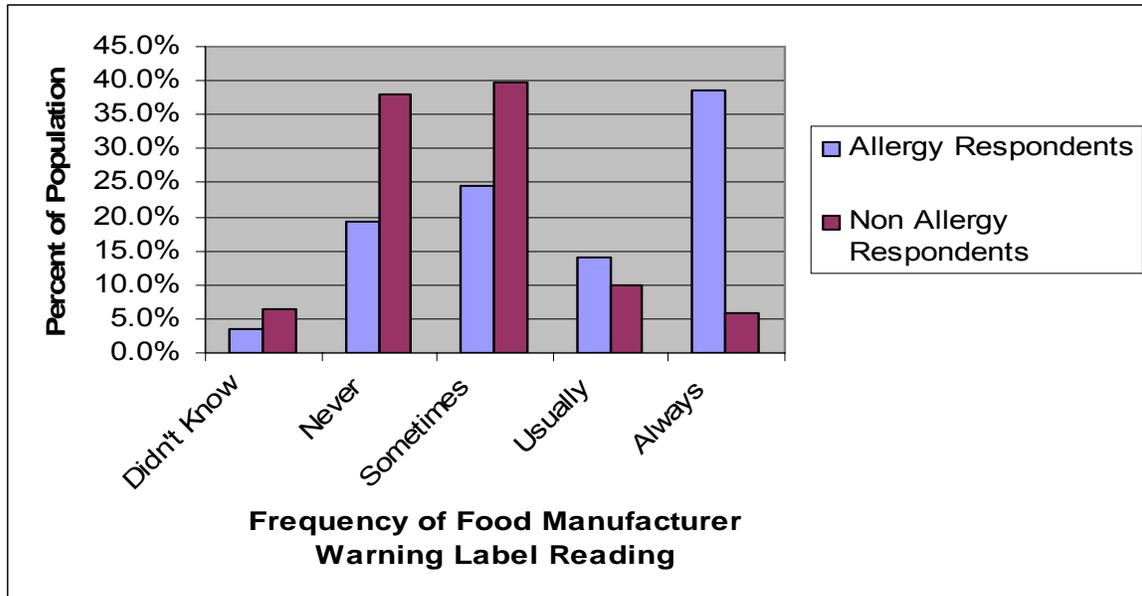


Figure 3. Frequency at which respondents with food allergy (n=57) and respondents with no food allergy (n=322) read food label information regarding food manufacturer warning labels

The annual accidental food allergen ingestion rate (computed with the same formula used by Yu et al. [17]) was found to be 93.9% prior to the passage of the FALCPA and 69.5% after passage of the Act. The 24.4% decrease in rate was significant ($t=5.19$, $p \leq .05$).

In the two years after the new labeling law took effect, the percentage of accidental food allergen ingestion incidents due to store-bought food decreased while the percentage from restaurant-prepared food increased. Store-bought food was the cause of more than 24% of accidental food allergen reactions before the new labeling law compared to only 18% after the law's passage. Prepared food (including home, restaurant, and school-prepared) was responsible for almost 44%

of accidental ingestion reactions prior to the law but 50% after the new law was passed (Figure 4).

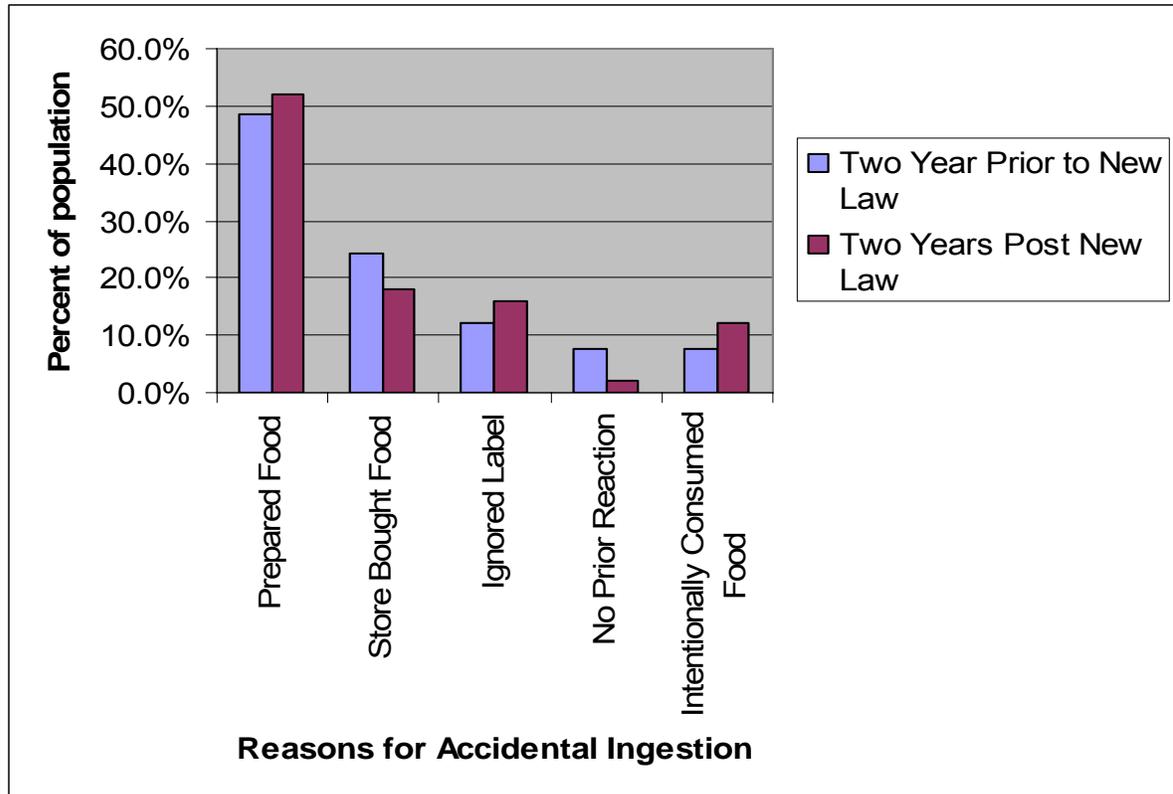


Figure 4. Reasons provided by respondents with food allergy (n=57) for accidental food allergen ingestion in the 2 years prior to passage of the Food Allergen Labeling and Consumer Protection Act and the 2 years post Act passage

The present study also showed that restaurant-prepared food caused 31.8% of accidental food allergen ingestion reactions prior to passage of the FALCPA compared to 34% post passage (Figure 5), making it the most frequently cited source of food that caused accidental food allergen ingestion reactions both prior to and following passage of the new labeling law.

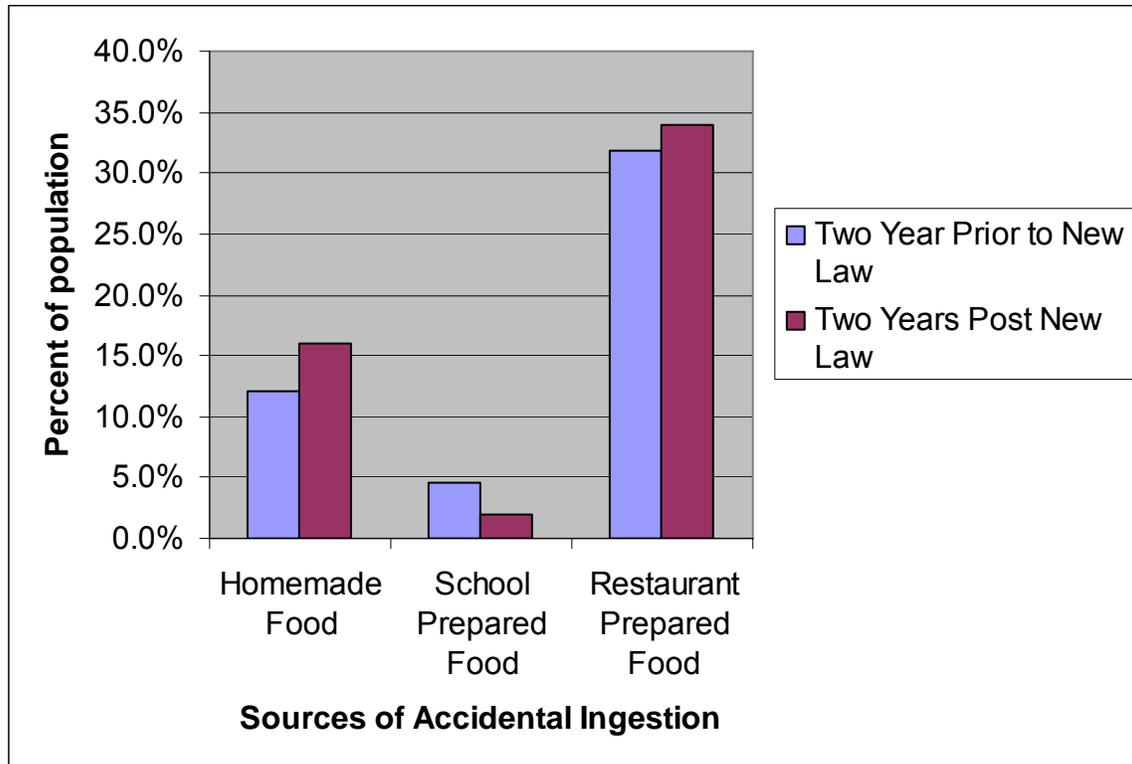


Figure 5. Sources of prepared food provided by respondents with food allergy (n=57) consumed in accidental food allergen ingestion in the 2 years prior to passage of the Food Allergen Labeling and Consumer Protection Act and the 2 years post Act passage

Ninety-three percent of respondents with food allergies (n=57) suggested that changes needed to be made to the allergen section of the product label. The three suggestions that were mentioned most often were for labels to have a separate allergen section (49.1%), larger font (38.6%), and bolder font (28.1%). Other creative ideas were to have the label include a special symbol for products with allergens, to have the allergen section in color, and to have the allergen section printed on either the front of the product label or on the opening tab of the product.

Chapter 5: Discussion and Conclusions

Discussion

The present study surveyed a population of Northern California adults with self-reported food allergies who were predominantly white, female, and college-educated. Similar demographic characteristics of adults with food allergies were reported by Vierk et al. (2) and Sicherer et al. (1).

In the overall adult population, the prevalence of self-reported food allergies was found to be 15.0%, with tree nuts (4.0%), milk (3.7%), wheat (3.4%), and shellfish (3.2%) being the most prevalent of the top 8 food allergens. Of the food allergic adult population specifically, 26.3% were allergic to tree nuts, 24.6% to milk, 22.8% to wheat, and 21.1% to shellfish.

The 15.0% overall prevalence in the present study is slightly higher than percentages reported in studies by both Woods et al. (3) and Vierk et al. (2), which found self-reported food allergy prevalence in U.S. adults to be 12.0% and 9.1%, respectively. Additionally, Vierk et al. found that allergies to milk (2.0%), shellfish (1.5%), fish (0.7%), and tree nuts (0.5%) were the most prevalent of the top 8 food allergens in the total population. As to the food-allergic population specifically, the same food allergies were most prevalent, with 22.0% of food-sensitive participants allergic to milk, 17.0% to shellfish, 8.0% to fish, and 6.0% to tree nuts. An Internet study (29) of adults with physician-diagnosed (versus self-reported) food allergies found the prevalence of peanut allergy to be the most common (47.1%), followed by milk (23.5%), tree nuts (11.8%), and fish/shellfish (9.8%).

The present study included a higher percentage of women and college-educated respondents than either the Woods or Vierk study, which may partially explain why a higher overall prevalence of self-reported food allergies was found. In addition, as the above studies indicated, although self-reported food allergy prevalence is in the range of 9.0 to 15.0% of the total population, the prevalence of each of the top 8 food allergens varied widely between surveys.

The most frequently named food allergen in the present study that was not in the top 8 food allergens was the category fruit/vegetable. With prevalence in the overall adult population of 5.3%, it was the food allergen most often reported. This somewhat surprising finding was also reported by Vierk et al. (2). A study of food allergic events from U.S. emergency rooms (19) found that fruits and vegetables composed 12% of the food allergic reactions (number one being shellfish at 24%) in persons aged 6 and older. Fruits and vegetables are not covered by the FALCPA law as they are not considered one of the top 8 allergens.

Of adults with self-reported food allergies, 100% reported that they read nutrition information on food product labels. Although more than three-fourths of this population also read allergen information (75.4%) and manufacturer warning statements (77.2%), almost 18% never read either of them. In addition, 7% of adults with food allergies did not know the new allergen section was part of the food label. These figures are higher than surveys of U.S. adults conducted by both Vierk et al. (2) and Hefle et al. (27). Vierk et al. (2) found 63% of adults with self-reported food allergies read labels to avoid foods for which they were allergic, although the study did not differentiate between adults who read ingredient label information and

those who read the allergen section as did the present study. Hefle et al. (27) reported that 17% of consumers with food allergies had not noticed the new allergen language on food product labels that appeared after passage of the FALCPA, although 75% of them heeded manufacturer allergen warning statements. While the 75% figure was similar to the present study's finding of 77%, the report of 17% of consumers with food allergies not noticing the new allergen content information on product labels was higher than the 7% the present study found. As more than three-fourths of respondents with food allergies read manufacturer warning statements, there is a need to ensure that these voluntary warnings are consistent and accurate. The FDA does not instruct food manufacturers on the use of these warning statements, but many studies have found confusion on the part of consumers as to their meaning (2, 26, 27, 31).

The annual accidental food allergen ingestion rate in adults significantly declined 24.4% from 93.9% prior to passage of the FALCPA to 69.5% after passage of the Act. While these annual accidental ingestion rates are high, there is a scarcity of studies that report accidental ingestion rates in adults. Vierk et al. (2) found that 28% of adults with self-reported food allergies had a reaction less than one month prior to the survey. Studies of children with a diagnosed peanut allergy have found that accidental ingestion rates ranged from 14.3% to 58.0% (17,30).

The percentage of accidental ingestion events related to store-bought foods after the new labeling law took effect decreased 6.2%, from 24.2% to 18%, while the percentage due to ingestion of prepared food increased by 6.1%, from 43.9% to 50.0%. In addition, the percentage of incidents due to adults with food allergies

ignoring allergen information on product labels increased almost 4%, from 12.1% to 16%. The most frequently reported reason for accidental food allergen ingestion both prior to passage of the FALCPA and after passage of the Act was from restaurant-prepared food, which increased by 2.2%, from 31.8% to 34.0%. Because the present study did not gather data on site-specific reactions (e.g. restaurant, home, school), but rather food-specific reactions (homemade food, restaurant-prepared food, school-prepared food), the results are only comparable to the Vierk et al. (2) study, which found 48% of accidental reactions due to ingestion of prepared food with 35% specifically due to restaurant-prepared food. Vierk's findings are in agreement with the present study's observation of 50% of accidental food allergen ingestions occurring with consumption of prepared food and 34% from food prepared in restaurants. An Internet survey by Eigenmann et al. (29), which reported site-specific reactions, found 25.5% of food allergic reactions happened at home, 17.6% in restaurants, and 13.7% in a relative or friend's home. Almost half of the respondents who had allergic reactions in restaurants had informed the restaurant staff of their allergy before ordering.

Although the new labeling law appears to have had an impact on the percentage of accidental ingestions due to labeled food products, the above studies suggest a need to also control for accidental food allergen ingestions from prepared food, especially restaurant-prepared food. A number of states have bills in progress that require restaurants with a specified number of locations in the state to post nutrition information on menus and menu boards (32), but none of the proposed

laws include the requirement to post allergen information. This is an important area for future study.

Ninety-three percent of respondents with food allergies thought changes needed to be made to the allergen section of the food product label, including larger and bolder font, and a separate allergen section. An international study of consumers with food allergies (31) reported these same suggestions in a survey taken following implementation of new European food product label laws.

One of the limitations of the present study was that it included data from a number of respondents who intentionally ingested food allergens. These respondents either answered “none” to the two questions regarding accidental ingestion prior to passage of the FALCPA and post passage (as they did not have any “accidental” ingestions) or gave a high number (as if they intentionally “accidentally” ingested allergenic foods daily or weekly). Future research should consider this subset of the adult population with self-reported food allergies.

Another limitation of the present study was its retrospective nature. Respondents answered questions regarding the number of accidental allergen ingestion reactions for the two years before the passage of the FALCPA and after passage of the Act. Possible recall error as to the number of allergic reactions may have had an impact on the high accidental allergen ingestion rate computed.

Conclusions

The present study concluded that more than 75% of adults with food allergies read the allergen information and manufacturer warning statements on product

labels compared to less than 56% of the non allergic respondents. This indicates that the new allergen labeling requirements of the FALCPA have reached their target population of adults with food allergies. Further research to improve the design of the allergen section as well as manufacturer warning statements may help decrease the 16% of accidental allergic reactions specifically due to people ignoring the allergen information. With the finding of a significant decrease in the accidental food allergen ingestion rate in adults after passage of the FALCPA and the associated decline in accidental food allergen ingestion events due to store bought foods, the present study provides evidence that the new allergen labeling law has contributed to the decrease in the accidental food allergen ingestion rate of adults with self-reported food allergies. With the high rate of accidental allergen ingestion due to restaurant-prepared food specifically, future studies should evaluate whether inclusion of allergen information in restaurants and on fast food menus would help to further decrease the accidental food allergen ingestion rate in adults with food allergies.

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APPENDICES

Appendix A: Human Subjects Committee Approval



EASTERN MICHIGAN UNIVERSITY

November 15, 2007

Susan Liebert
c/o George Liepa, Ph.D.
School of Health Sciences
Eastern Michigan University
Ypsilanti, MI 48197

Dear Ms. Liebert,

The CHHS Human Subject Committee has reviewed your request entitled: "Change in Accidental Food Allergen Ingestion Rate After New Allergen Labeling Law Effective January 1, 2006" and concluded that the proposal is approved with the following changes: Inclusion of a data sheet that includes the title of the project and the name and contact number of the major professor and HSR committee chair (Liepa) in case participants want to inquire about the study results.

Sincerely,

A handwritten signature in black ink, appearing to read "George Liepa".

George Liepa Ph.D.
Co-Chair, CHHS Human Subjects Review Committee

Appendix B: Food Allergy Survey

COMPLETION OF THIS SURVEY IS ENTIRELY VOLUNTARY. BY FILLING IT OUT YOU ARE GIVING YOUR CONSENT FOR RESULTS TO BE USED AS PART OF A RESEARCH PAPER. YOUR ANONYMITY AND CONFIDENTIALITY WILL BE ASSURED.

Demographic Information:

Age _____
Sex M ___ F ___

Education Level:

High school—no degree _____
High school – degree or GED _____
Some college _____
College degree _____
Post college education _____

Race/ethnicity (please mark one):

White/Non-Hispanic _____
Black _____
Hispanic/Latino _____
Mexican-American _____
Asian _____
Pacific Islander _____
American Indian/Alaska Native _____
Other _____

1. Do you read ingredient labels on food products?

Never _____
Sometimes _____
Usually _____
Always _____

2. Do you read the allergy information on the ingredient label?

Never _____
Sometimes _____
Usually _____
Always _____
I didn't know there was any _____

3. Do you read the allergy warning statements (for example: manufactured on equipment which also processes food with allergens) on the ingredient label?

Never _____
Sometimes _____
Usually _____
Always _____
I didn't know there were any _____

4. If you check for allergen information, please check all reasons which apply?

I have one or more food allergies _____
I have a friend with food allergies _____
I have a sibling or parent with food allergies _____
I have a child with food allergies _____
Just curious _____

NUTRITION FACTS	
Serving Size 32 chips (15g)	
Servings Per Container about 23	
Amount Per Serving	
Calories 70	Fat Cal 40
% Daily Value*	
Total Fat 4.5g	7%
Sat Fat 2.5g	13%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrate 10g	3%
Dietary Fiber less than 1g	3%
Sugars 8g	
Protein 1g	
Vitamin A 0%	Vitamin C 0%
Calcium 0%	Iron 4%
<small>*Percent Daily Values are based on a 2000 calorie diet.</small>	
Ingredients: Semi-sweet chocolate (sugar, unsweetened chocolate, cocoa butter, soy lecithin – an emulsifier, vanilla).	
ALLERGEN INFORMATION: Contains soy. Manufactured on the same equipment that also makes products containing milk. Made in a facility that uses peanuts and tree nuts.	

Other (please specify) _____

PLEASE COMPLETE THE REMAINING QUESTIONS ONLY IF YOU OR YOUR CHILD HAS A FOOD ALLERGY.
SIDE 2

5. Please check any food allergies you or your child currently have:

- none _____
- peanuts _____
- tree nuts _____
- milk _____
- egg _____
- fish _____
- shellfish _____
- soy _____
- wheat _____
- other (please specify) _____

6. Approximate number of times in the **TWO YEARS PRIOR** to **January 1, 2006** that you accidentally ingested any of the above specified **8** foods/allergens **and** had an allergic reaction:

- none _____
 - Once _____
 - Twice _____
 - Three times _____
 - Four times _____
 - Five times _____
 - Six times _____
- If more than six times, please specify the approximate number _____

7. What was the reason(s) for the accidental ingestion of the allergenic food (please check all that applies):

- homemade food _____
- store bought food (not see allergen on label/not read label) _____
- store bought food (ignored allergen warning) _____
- school prepared food _____
- restaurant/fast food outlet prepared food _____
- other (please specify) _____

8. Approximate number of times in the **TWO YEARS AFTER January 1, 2006** that you accidentally ingested any of the above specified **8** foods/allergens **and** had an allergic reaction:

- none _____
 - Once _____
 - Twice _____
 - Three times _____
 - Four times _____
 - Five times _____
 - Six times _____
- If more than six times, please specify the approximate number _____

9. What was the reason(s) for the accidental ingestion of the allergenic food (please check all that applies):

- homemade food _____
- store bought food (not see allergen on label/not read label) _____
- store bought food (ignored allergen warning) _____

school prepared food _____
restaurant/fast food outlet prepared food _____
other (please specify) _____

10. What additional/different information on food ingredient labels would help you notice the allergen information:

larger print _____
bolder print _____
separate allergen section _____
no changes _____
other (please specify) _____

Thank you for your time.

DATA SHEET

STUDY: EFFECT OF THE FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT ON THE ACCIDENTAL FOOD ALLERGEN INGESTION RATE IN ADULTS WITH SELF-REPORTED FOOD ALLERGIES

INQUIRIES ABOUT STUDY RESULTS:

PLEASE CONTACT THESIS CHAIR DR. GEORGE LIEPA, PROFESSOR OF HUMAN NUTRITION, EASTERN MICHIGAN UNIVERSITY
734-487-2499

