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**Allergies in America after the FALCPA:  
*Obstacles Still Facing Allergic Individuals***

**Kara Mungovan  
Class of 2008**

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## **ABSTRACT**

Allergies affect over 12 million Americans; that number is increasing and children are disproportionately affected. Four years ago, Congress enacted the Food Allergen Labeling and Consumer Protection Act of 2004, mandating that all foods containing the eight most common allergens be clearly labeled, and requiring the Department of Health and Human Services to prepare a report on cross-contamination throughout the food industry and on the use of and consumer preferences regarding advisory labeling. The report showed that despite widespread use of allergen control policies, cross-contamination is rampant in food manufacturing facilities. The use of advisory labeling is inconsistent and communicates little valuable information. Consumers do, however, tend to take heed of advisory labels and try to interpret different meanings from differently-worded messages, which indicates they are often misled. We need an industry standard, but we need to be careful not to encourage manufacturers to label all of their products, regardless of risk. I propose a system where manufacturers could choose between several levels of risk. That way, they could be shielded from liability by using at least the lowest level, but they could use their discretion to apply higher risk warnings to truly dangerous products, thus better informing consumers of real risk levels. I also propose that in addressing restaurant regulation, we bear in mind the fact that the social and professional importance of restaurant dining to many people increases as they age. Even though restaurants are currently very dangerous, many teenagers and adults with allergies eat at them, and many experience serious reactions. I propose that we impose mandatory allergy training on restaurant staff, and that we direct restaurants to develop and articulate clear allergy policies, that they communicate openly and honestly to consumers. That way, consumers would know the level of risk they are taking on when they eat at particular restaurants. Further, allergic consumers and their dining partners could more easily choose safer places to eat, which hopefully would exert market pressure restaurants to develop more accommodating policies. I see both of these proposals as necessary in the short term, but hope that eventually the consumer demand for allergy-friendly policies in food manufacturing practices and in restaurants will grow strong enough that we will see the market provide more and more accommodations for people with allergies.

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## INTRODUCTION

*The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.<sup>1</sup>*

While the mission statement's message may be timeless, what it means to protect the public health, or assure the safety of the food supply changes over time, as does the information the public needs when consuming foods. Over time, FDA and Congress have responded to the nation's changing needs, in designing and implementing policies to regulate our food supply. The food label as we now know it is an example of a series of compromises, alterations and improvements reflective of the evolution of our society and advancing technologies. Over the course of the past century or so FDA and Congress have together guided the food industry by setting standards for foods sold to the public and by proscribing what can, what cannot, and what must appear on food labels. Throughout that time, they have been driven by a sense of essentiality, only mandating information they truly thought to be essential for the public to make wise consumption choices, and being careful not to clutter or overload the food label with peripheral or unnecessary information. FDA and Congress have similarly been careful not to respond to fads or trends, acting only upon concrete and reliable scientific data. In response to

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<sup>1</sup> FDA's mission statement, available at <http://www.fda.gov/opacom/morechoices/mission.html> (site last visited May 15, 2008).

hard evidence linking diet and nutrition to health, they mandated nutrition labeling in 1990. This step enabled Americans to benefit from advances in scientific medicine by incorporating healthier food habits into their lifestyles.

By 2004, the prevalence of allergies in the American population had been on the rise for quite some time, and the knowledge surrounding the disease was growing. For people with allergies, foods that contain or are contaminated with their allergens are not safe. In order for food to be safe for these people, they need accurate information about what it contains and whether it may be contaminated. Congress recognized the urgency of this need, and four years ago responded by enacting the Food Allergen Labeling and Consumer Protection Act of 2004. The Act defines “major food allergen” as one the eight foods or food groups that cause 90% of allergies (milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat and soybeans), and mandates that food products containing proteins derived from these foods be clearly labeled. While the Act has made great strides in terms of making the world safer for people with food allergies, there is still more work to be done.

The Act calls for a report on cross-contamination and advisory labeling. In 2006, the Department of Health and Human Services completed the report. The Department found that while many manufacturers do use advisory labeling, there is very little consistency or uniformity among manufacturers (manufacturers use the same or different labels for many different reasons, and to convey many different levels of risk). Consumers seem to try to interpret these labels, but the inconsistent way they are used makes this impossible, and this appears to mislead many consumers. Clearly, we need legislation in this area to address this problem. We have to be careful, however, not to create incentives for manufacturers to shield themselves from liability by using advisory labels across the board, thus making it impossible for food allergic consumers

to distinguish between dangerous and relatively safe foods. I propose a system whereby manufacturers could choose between several levels of risk warnings (perhaps low, medium and high). They could shield themselves by using at least a low warning, but could voluntarily use discretion to label higher levels of warning for foods that carried a higher risk of contamination. Given the current widespread voluntary use of advisory labels in the food industry, I think it is safe to assume that manufacturers wish to provide consumers with valid information, and would use this discretion appropriately.

Thus far, most regulatory efforts have focused upon children, as this age group is the most severely afflicted by allergies, and this group might be considered the most vulnerable – as children may find it difficult to comprehend their disease, and they tend to rely upon the adults around them (who may or may not understand and appreciate the serious nature of their allergies) to feed them. While these regulatory efforts have made great strides in terms of rendering food labels clearer, making schools safer and raising general awareness, there are still some regulatory gaps. Restaurants are left almost completely out of federal regulation of food allergens, and thus can be extremely dangerous places for people with allergies. While many parents of food allergic children may choose to avoid restaurants altogether, or at least severely modify their behavior (by only frequenting corporate chains, avoiding peak times, or demanding extensive conversations with chefs), many of these options are less feasible for older allergy sufferers. As people get older restaurant eating becomes more and more important to their social and professional lives. Many allergic teenagers and adults eat at restaurants regularly, and in so doing regularly take significant risks. Evidence shows that many fatal anaphylactic reactions happen in restaurant settings away from home, and many happen to people in their teenage or adult years. We need to address this problem of restaurants with legislation. When we do so, we

should keep in mind the fact that this legislation is particularly important to teenagers and adults, and design it accordingly.

My policy recommendation is that first and foremost we should acknowledge the inevitable risks associated with allergies and restaurant eating. We should try to minimize these risks, while focusing upon informing consumers of them, and allowing consumers to make their own decisions. We need to educate restaurant staff more thoroughly so that they understand the issues surrounding allergies, allergens and cross-contamination. Further, restaurants should all have clear allergy policies. I would not force restaurants to make accommodations for people with food allergies, but I think it is important that when they are willing to make accommodations their staff is knowledgeable enough to faithfully follow the restaurant's policy, and that when they are not willing to make accommodations they should be honest and open with consumers, and convey what the risks are. I understand that many restaurants would have many different policies and would be willing to make many different types of accommodations. I would not try to standardize the policies, but I would expect that once policies were out in the open, then consumers would find it easier to select restaurants according to their own comfort level with risk, and that this would encourage competition between restaurants on this basis. Hopefully we could first bring in this type of legislation, and then rely upon the market to take over.



## FOOD SENSITIVITIES: ALLERGY VERSUS INTOLERANCE

The term, “food sensitivity” refers to any one of a range of abnormal physiological responses to foods that are safe for the vast majority of the population to ingest. Many people (including some medical professionals) refer to all food sensitivities – all abnormal physiological responses to foods – as allergies. However, sensitivities can involve several different biological mechanisms, and are thus divided into two main groups: food allergies and food intolerances.<sup>2</sup> “There are practical reasons to distinguish between true food allergies and food intolerances from both a clinical and regulatory perspective.”<sup>3</sup> It is important to understand the basic differences between these types of ailments in order to appropriately address them with legislation. Food allergies involve the immune system; they are abnormal immunological responses to certain components of food, termed “allergens,” which are typically proteins that occur naturally in the foods. In contrast, food intolerances are all other food sensitivities for which an immunological mechanism is not responsible.<sup>4</sup>

### **Allergies**

Allergies can be further divided into two categories: immediate hypersensitivity reactions and delayed hypersensitivity reactions<sup>5</sup> (although many people refer just to immediate hypersensitivity reactions when they use the term, “allergy”).

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<sup>2</sup> Steve L. Taylor, *Prospects for the Future: Emerging Problems – Food Allergens*, in FAO, Conference on International Food Trade Beyond 2000: Science-Based Decisions, Harmonization, Equivalence and Mutual Recognition (ALICOM 99/15) (October 1999), paragraph 3 (hereinafter Taylor, *Prospects*), available at <http://www.fao.org/docrep/meeting/x2670e.htm> (site last visited May 15, 2008).

<sup>3</sup> *Id.* at paragraph 3.

<sup>4</sup> *Id.* at paragraph 5; C. Ortolani, M. Ispano, J. Scibilia, E.A. Pastorello, *Introducing chemists to food allergy*, 56 Supplement 67 *Allergy* 5, 5 (2001).

<sup>5</sup> Taylor, *Prospects*, *supra* note 2, at paragraph 4.

## Immediate hypersensitivity reactions

These reactions are mediated by a class of antibodies called immunoglobulin E (IgE). While all humans have low levels of IgE antibodies, some individuals produce IgE antibodies that recognize certain common environmental antigens, or allergens, and these individuals are thus predisposed to developing allergies to foods containing those allergens.<sup>6</sup> Upon a first exposure to a specific antigen, an allergic person experiences a “sensitization” event, but no allergic reaction. At this time, B cells (that exist in many tissues including tissues in the intestinal tract) form IgE antibodies specific to the offending allergen. These IgE antibodies attach to mast cells in various tissues and to basophils in the blood.<sup>7</sup> Upon subsequent exposure, the allergenic protein interacts with IgE antibodies on the surface of mast cells or basophils. This interaction triggers release of allergic response mediators – often histamine or leukotrienes, although other mediators have been described – into tissues and blood,<sup>8</sup> which causes allergic symptoms.

The symptoms begin to develop from within minutes to about an hour after ingestion, can be extremely severe and can develop in response to even minute amounts of the offending food.<sup>9</sup> Over 170 different foods have been noted to cause allergic reactions. “Basically, any food that contains protein has the potential to elicit allergic sensitization in someone in the population.”<sup>10</sup>

There are a wide variety of possible symptoms of immediate hypersensitivity reactions, ranging from mild to life threatening, and usually an individual will experience just a few of

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<sup>6</sup> *Id.* at paragraph 7; Hugh A. Sampson, *Food Allergy. Part 1: Immunopathogenesis and clinical disorders*, 103 *J. of Allergy & Clinical Immunology* 717, 719 (May 1999) (hereinafter Sampson, *Food Allergy*).

<sup>7</sup> Taylor, *Prospects*, *supra* note 2, at paragraph 7; Sampson, *Food Allergy*, *supra* note 6, at 719; *Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food*, prepared by The Threshold Working Group, II. Food Allergy B. Mechanism of Allergic Reaction (March 2006), available at <http://www.cfsan.fda.gov/~dms/alrgn2.html> (site last visited May 15, 2008).

<sup>8</sup> Taylor, *Prospects*, *supra* note 2, at paragraph 7; Sampson, *Food Allergy*, *supra* note 6, at 719; *Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food*, prepared by The Threshold Working Group, II. Food Allergy B. Mechanism of Allergic Reaction (March 2006), available at <http://www.cfsan.fda.gov/~dms/alrgn2.html> (site last visited May 15, 2008).

<sup>9</sup> Taylor, *Prospects*, *supra* note 2, at paragraph 8.

<sup>10</sup> *Id.* at paragraph 4.

them. The gastrointestinal tract is the initial organ of insult, so reactions associated with it – such as nausea, vomiting, diarrhea, abdominal cramping – are common.<sup>11</sup> Skin reactions – such as urticaria or hives, dermatitis, eczema, angioedema, pruritis or itching – are also common.<sup>12</sup> Symptoms associated with the respiratory tract – rhinitis, asthma, laryngeal edema – are less common (except in the case of environmental allergies, where such allergens and pollen or dander are inhaled), but can be extremely severe.<sup>13</sup>

Anaphylaxis<sup>14</sup> is probably the most frightening symptom of an allergic reaction. It has a rapid onset and severe hypotension can occur, which can be fatal if not treated immediately. Anaphylaxis can have multiple causes, but among anaphylactic reactions treated in emergency rooms in the US, food is the leading known cause.<sup>15</sup> “The symptoms of anaphylaxis are generally related to the skin, gastrointestinal tract, respiratory tract, and cardiovascular systems,”<sup>16</sup> and may include (but are not limited to): pruritis, flushing, urticaria, angioedema, vomiting, diarrhea, abdominal cramps, respiratory difficulty, wheezing, hypotension, syncope, and shock.<sup>17</sup> “Unfortunately, there have been no consensus criteria for the diagnosis of anaphylaxis, thus contributing to the difficulties in identifying cases and timely initiation of treatment.”<sup>18</sup>

Food allergy is not only a significant health concern, it is a growing one.<sup>19</sup> Congress estimated in 2004 that 2 percent of adults and 5 percent of children are allergic to various types of foods, and that the 8 major allergens (milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts,

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<sup>11</sup> Taylor, *Prospects*, *supra* note 2, at paragraph 8; Sampson, *Food Allergy*, *supra* note 6.

<sup>12</sup> Taylor, *Prospects*, *supra* note 2, at paragraph 8; Sampson, *Food Allergy*, *supra* note 6.

<sup>13</sup> Taylor, *Prospects*, *supra* note 2, at paragraph 8; Sampson, *Food Allergy*, *supra* note 6.

<sup>14</sup> Anaphylaxis was first described over a century ago. Portier P, Richet C., *De l'action anaphylactique de certains venins* [The anaphylactic reaction to certain venoms], 54 C R Seances Soc Biol 170 (1902).

<sup>15</sup> Hugh A. Sampson, *Anaphylaxis and emergency treatment*, 111 *Pediatrics* 1601, 1601 (2003) (hereinafter Sampson, *Emergency treatment*).

<sup>16</sup> Sampson, *Emergency treatment*, *supra* note 15, at 1603.

<sup>17</sup> Julie Wang & Hugh A. Sampson, *Food Anaphylaxis*, 37 *Clinical and Experimental Allergy* 651, 652.

<sup>18</sup> *Id.*

<sup>19</sup> Hugh A. Sampson, *Update on food allergy*, 113 *J. of Allergy & Clinical Immunology* 805, 805 (May 2004) (hereinafter Sampson, *Update*) (“Food allergy is now recognized as a worldwide problem in westernized nations, and like other atopic disorders, it appears to be on the increase.”)

wheat and soybeans) account for 90% of food allergies.<sup>20</sup> In the period between 1997-2002, the number of children with peanut allergy doubled.<sup>21</sup> Another estimate is that between 1996 and 2006 peanut allergies doubled among children under five.<sup>22</sup> There are an estimated 30,000 food-induced anaphylactic reactions each year in the US, which result in 2,000 hospitalizations and 150-200 deaths.<sup>23</sup> Peanuts, tree nuts, fish and shellfish account for most food-induced anaphylactic reactions to foods in the United States and Europe.<sup>24</sup> It is not yet known why the prevalence of allergies is increasing. One theory, explained by Anne Muñoz-Furlong (founder and CEO of the Food Allergy & Anaphylaxis Network) in an article for *Environmental Health Perspectives*, “holds that improved hygiene leaves the human immune system with less to do [...] so it identifies a particular food as dangerous and responds by attacking it.”<sup>25</sup>

Although the severity of the reaction does tend to increase with dose of the offending allergen, even very small quantities of the allergen can interact with the IgE antibodies to trigger the release of massive amounts of mediators, which can cause a very severe response.<sup>26</sup> Precise threshold doses are not yet known, however among very sensitive individuals, exposure to very small amounts of the offending protein can elicit a reaction.<sup>27</sup> It is thus important for allergic individuals to avoid even trace amounts of offending antigens, and important for legislators to bear this need in mind.

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<sup>20</sup> H.R. REP. NO. 108-608, at 3 (2004).

<sup>21</sup> Scott H. Sicherer, Anne Muñoz-Furlong & Hugh Sampson, *Prevalence of peanut and tree nut allergy in the United States determined by means of a random digital dial telephone survey A 5-year follow-up study*, 112 *J. of Allergy & Clinical Immunology*, 1203 (2003).

<sup>22</sup> Richard Dahl, *Food Safety: Allergen Labeling Takes Effect*, 114 *Environmental Health Perspectives* A24 (2006), available at <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1332678> (site last visited May 14, 2008).

<sup>23</sup> See, e.g., Sampson, *Emergency treatment*, *supra* note 15, at 1602; Hugh A. Sampson, *Peanut Allergy*, 346 *New England J. of Medicine* 1294 (2002).

<sup>24</sup> Sampson, *Emergency treatment*, *supra* note 15, at 1602.

<sup>25</sup> Dahl, *supra* note 22.

<sup>26</sup> Taylor, *Prospects*, *supra* note 2, at paragraph 15.

<sup>27</sup> Steve L. Taylor et al., *Factors affecting the determination of threshold doses for allergenic foods: How much is too much?* 109 *J. of Allergy & Clinical Immunology* 24 (January 2002).

## Delayed hypersensitivity reactions

Delayed hypersensitivity reactions are also immune responses; they are mediated by tissue-bound immune cells (they are thus termed “cell-mediated” reactions). Celiac disease<sup>28</sup> is the only well-defined reaction in this category,<sup>29</sup> and thus will be the only one discussed in this paper. Celiac-sufferers experience an abnormal T lymphocyte response in the small intestine to gliadin, which is the alcohol-soluble portion of the protein gluten, found in wheat, oat, rye and barley,<sup>30</sup> which provokes an inflammatory process resulting in damage to the absorptive epithelium of the small intestine:<sup>31</sup> extensive loss of absorptive villi and hyperplasia of the crypts.<sup>32</sup> While the tissue damage is localized to the small intestine, the absorptive process is disrupted, which can adversely affect many other physiological functions.<sup>33</sup>

It takes 24-72 hours for this damage to occur, so symptoms are usually delayed for this length of time. They can persist for several days, however, even if the offending food is avoided, until the intestinal damage is repaired.<sup>34</sup> Symptoms are typical of a malabsorption syndrome and include chronic diarrhea, steatorrhea, bloating, flatulence, weight loss, anemia, bone pain, chronic fatigue, weakness and muscle cramps.<sup>35</sup> Children who suffer from the disease may fail to gain weight, and experience growth retardation.<sup>36</sup> While the severity varies significantly from patient to patient – ranging from a “debilitating malabsorption syndrome to a ‘silent,’ subclinical disorder”<sup>37</sup> – reactions do not reach the level of severity involved in the more severe cases of

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<sup>28</sup> Also known as “celiac sprue” or “gluten-sensitive enteropathy.”

<sup>29</sup> Taylor, *Prospects*, *supra* note 2, at paragraph 18.

<sup>30</sup> Sampson, *Food Allergy*, *supra* note 6, at 722.

<sup>31</sup> Taylor, *Prospects*, *supra* note 2, at paragraph 18.

<sup>32</sup> Sampson, *Food Allergy*, *supra* note 6, 722.

<sup>33</sup> Taylor, *Prospects*, *supra* note 2, at paragraph 18.

<sup>34</sup> *Id.* at paragraph 19.

<sup>35</sup> *Id.*; Sampson, *Food Allergy*, *supra* note 6, at 722.

<sup>36</sup> Taylor, *Prospects*, *supra* note 2, at paragraph 19.

<sup>37</sup> Sampson, *Food Allergy*, *supra* note 6, at 723.

immediate hypersensitivity reactions. Celiac sufferers' level of tolerance also very low;<sup>38</sup> the threshold is not yet known, but patients are thought to react to trace amounts of gluten. Although fatalities have not been reported, "the morbidity of this illness is considerable unless strict adherence to a gluten-free diet can be achieved."<sup>39</sup> For patients with celiac disease, chronic ingestion of gluten has been associated with increased risk of T-cell lymphoma and other malignancy.<sup>40</sup>

Celiac disease is an inherited trait, and while the prevalence does appear to vary from country to country, different methods of diagnosis may account for this difference (also, latent celiac disease is difficult to detect). The disease rarely occurs in Asian or African populations, and occurs most commonly in European populations and their descendants. The prevalence in the U.S. is estimated at 1 in 2,000 to 3,000 people.<sup>41</sup>

## ***Food intolerances***

Food intolerances do not involve the immune system. Reactions are generally milder than with allergies and people suffering from them can usually tolerate small amounts of the offending food. There are three major classifications: metabolic food disorders, anaphylactoid reactions, and idiosyncratic reactions.<sup>42</sup>

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<sup>38</sup> Taylor, *Prospects*, *supra* note 2, at paragraphs 21-22.

<sup>39</sup> *Id.* at paragraph 22.

<sup>40</sup> Sampson, *Food Allergy*, *supra* note 6, at 723.

<sup>41</sup> Taylor, *Prospects*, *supra* note 2, at paragraph 20.

<sup>42</sup> *Id.* at paragraph 5.

## Metabolic Food Disorders

These are often genetically acquired traits, and result from a defect in the ability to metabolize a food component. The best examples of metabolic food disorders are lactose intolerance and favism.<sup>43</sup>

Lactose is the primary sugar in milk. It is a disaccharide, consisting of two different monosaccharides: galactose and glucose. The human intestine cannot absorb lactose, so the enzyme, lactase or  $\beta$ -galactosidase, in the intestinal mucosa, breaks it down into its constituent monosaccharides.<sup>44</sup> Lactose intolerance is an inherited deficiency of this enzyme. Affected individuals cannot break down lactose, so it passes into the colon. There are bacteria in the colon that metabolize the lactose into carbon dioxide and water, which causes bloating, flatulence, abdominal cramping, and frothy diarrhea.<sup>45</sup> Most people are born with enough lactase, so lactose intolerance is uncommon among young children, but lactase activity often decreases over a person's lifetime. Lactose intolerance is more frequent among the following ethnic groups: African Americans, Native Americans, Hispanics, Asians, certain Jewish groups, and Arabs. As many as 60-90% of older adults in those groups are affected. The prevalence among Caucasians is about 6-12%.<sup>46</sup>

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<sup>43</sup> Favism is an intolerance to fava beans (including inhaling pollen from the *Vicia faba* plant), resulting from an inherited deficiency of erythrocyte glucose-6-phosphate dehydrogenase (G6PDH), which is an enzyme that is critical to prevention of oxidative damage to erythrocyte membranes. Fava beans naturally contain several oxidants – including vicine and convicine – which can damage erythrocyte membranes in individuals who are G6PDH-deficient. Symptoms of this disease include acute hemolytic anemia, with pallor, fatigue, dyspnea, nausea, abdominal and/or back pain, fever and chills. In rare cases, hemoglobinuria, jaundice and renal failure can occur. This disease is most common among Oriental and Jewish communities in Israel, Sardinians, Cypriot Greeks, American blacks and certain African populations, but is virtually non-existent in northern European populations, Native Americans and Eskimos. *Id.* at paragraph 25. Favism does not appear to have a significant impact on the U.S. population, and will not be considered in this paper.

<sup>44</sup> *Id.* at paragraph 24.

<sup>45</sup> *Id.* at paragraphs 23-24.

<sup>46</sup> *Id.* at paragraph 24.

Lactose intolerant individuals must avoid dairy products that contain lactose, but most people have at least some level of lactase activity, so they can tolerate at least some amount of lactose in their diets<sup>47</sup> (also, over-the-counter medications containing lactase are available, which allow some lactose intolerant individuals to consume milk products by supplementing their natural lactase supply). Understandably, cross-contamination and the presence of trace amounts of milk are not important issues for the lactose intolerant population. Further, although they react to milk, unlike people with milk allergy, they have a metabolic reaction to the lactose, and not an immune reaction to the protein.

## Other Food Intolerances

Three other food sensitivities have been characterized: anaphylactoid reactions,<sup>48</sup> idiosyncratic reactions<sup>49</sup> and histamine poisoning.<sup>50</sup> These reactions were not the target of the FALCPA, and will not be further discussed in this paper.

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<sup>47</sup> *Id.* at paragraph 24.

<sup>48</sup> Supposedly there are chemicals in some foods which can destabilize mast cell membranes, which releases chemical mediators such as histamines (similar to IgE-mediated allergies). Since IgE antibodies are not involved, this is a non-immunologic release. There is only circumstantial evidence linking this mechanism to food sensitivities, and none of these chemicals able to destabilize mast cell membranes in this way has yet been identified. *Id.* at paragraph 26.

<sup>49</sup> When individuals experience adverse reactions to food, and the mechanism is unknown, this is referred to as an idiosyncratic reaction. Sulfite-induced asthma is a good example, because although it has been well-documented that sulfites cause asthma in 1-2% of asthmatics, the mechanism by which this occurs is as yet unknown. Although the threshold is unknown, affected individuals appear to be able to tolerate small amounts (FDA has imposed mandatory labeling when residual SO<sub>2</sub> levels exceed 10ppm, which has appeared to be effective in protecting the affected population). *Id.* at paragraphs 27-28.

<sup>50</sup> Histamine poisoning (also known as scombroid fish poisoning) results from ingesting foods containing high levels of histamine. Since it can affect all persons, it is not a true food sensitivity, but the symptoms are similar to IgE-mediated allergies, since histamines are involved. *Id.* at paragraph 29.



# HISTORY OF REGULATION OF FOOD LABELING IN THE UNITED STATES

## ***Background***

The importance of maintaining the integrity of the food supply has long been recognized – in fact, it dates back to ancient times: “Ancient botanists, beginning with Theophrastus (370-285 B.C.), established ‘standards’ by describing the available food supply and warning against its adulteration with other substances. Standards of identity for bread were established in the Roman Empire and in medieval England, to assure the integrity of the food supply.”<sup>51</sup> While many societies have recognized the need to regulate their food supply, there have been a variety of approaches. In this country, the government has regulated both what may be sold as food and what manufacturers may say about their products. Congress and FDA have generally sought to use food labeling laws to force manufacturers and sellers to tell the truth to the public about their products and what they contain: “In various ways, these definitions of misbranding are designed to force food suppliers to tell the truth about their products.”<sup>52</sup>

The purpose of the food label, as the government sees it, is to provide consumers with important information about the content and nutritional value of the food product at the critical moment of sale, in order to help consumers make informed decisions. This purpose may sometimes be at odds with manufacturers’ goals of persuading consumers to make purchases, while minimizing manufacturing costs, so the government often must step in to regulate what

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<sup>51</sup> Peter Barton Hutt, *Regulating the Misbranding of Food*, 43 Food Technology 288 (Sept. 1989) (hereinafter Hutt, *Misbranding*), reprinted in Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law Cases and Materials* 37 (Robert C. Clark et al. eds., Foundation Press 2d ed. 1991) (in citations to Hutt, *Misbranding*, page numbers will refer to pages in Hutt & Merrill book).

<sup>52</sup> Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law Cases and Materials* 36 (Robert C. Clark et al. eds., Foundation Press 2d ed. 1991).

manufacturers may, may not or must say. “Precisely because the food label inspires and provides the critical stimulus for a food purchase, for nearly 100 years federal law has recognized the U.S. government’s interest in ensuring that the food label aids consumers in making wise food selections.”<sup>53</sup> A brief history of food labeling regulation in this country will provide the backdrop against which allergen labeling legislation is designed.

## ***Federal Food and Drugs Act of 1906***

The Federal Food and Drugs Act of 1906<sup>54</sup> (the “1906 Act,” also known as the “Wiley Act”) was the first federal law to regulate food. Since that time, many changes in society, food technology, and medical sciences have brought about many changes in the food label. The food label as we now know it represents over a century of legislative efforts and compromises aimed at protecting consumers and providing them with important information, while resisting overloading them with too many facts on the one hand, or discouraging technological innovations on the other.

Section 8 of the 1906 Act defined misbranded foods, and proscribed the sale of any foods whose label bore a statement that was “false or misleading in any particular.”<sup>55</sup> That section specifically exempted any food that was a “compound,” “imitation” or “blend,” provided that it did not contain “any added poisonous or deleterious ingredients,” and that the compound, imitation or blend be clearly labeled as such. The term “blend” was construed to mean “a mixture of like substances, not excluding harmless coloring or flavoring ingredients used for the purpose of coloring and flavoring only.”<sup>56</sup> Section 8 also made clear that it was not intended to

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<sup>53</sup> Fred H. Degnan, *Biotechnology and the Food Label: A Legal Perspective*, 55 Food & Drug L.J. 301, 301 (2000).

<sup>54</sup> Pub. L. No. 59-384, 34 Stat. 768 (1906) (codified at 21 U.S.C. §§ 1-15 (1934) (repealed in 1938 by 21 U.S.C. § 392(a)).

<sup>55</sup> 21 U.S.C.A. § 8.

<sup>56</sup> *Id.*

compel manufacturers to disclose trade formulas, so long as their foods contained no “unwholesome added ingredient,”<sup>57</sup> and “except in so far as the provisions of this Act may require to secure freedom from adulteration or misbranding.”<sup>58</sup> In terms of labeling requirements, “Section 8 was not at all about ‘requiring’ information to appear on the food label. Rather, it focused on whether information that manufacturers placed voluntarily on the food label was truthful and not misleading.”<sup>59</sup>

Section 7 of the Wiley Act was concerned with preventing manufacturers from selling food that had been adulterated or was inferior in some way, including food that contained “any added poisonous or other added deleterious ingredient which may render such article injurious to health,”<sup>60</sup> and food that had been substituted or mixed with a substance that rendered it inferior.<sup>61</sup>

### ***Federal Food, Drug, and Cosmetic Act***

In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act<sup>62</sup> (the “FD&CA”), which repealed and replaced the 1906 Act. Since then, Congress has adopted few statutory changes – with the notable and significant exceptions of the NLEA and the FALCPA, discussed below – so changes in food labeling regulation up until the NLEA have primarily been the result of FDA’s evolving policies and its implementation of those policies.<sup>63</sup> Congress’ goal in enacting the FD&CA in 1938 was to provide consumers with adequate information to enable them to make wise decisions.<sup>64</sup> This was a primary goal throughout the hearings: “So this bill [...] does

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<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> Degnan, *supra* note 53, at 302.

<sup>60</sup> 21 U.S.C. § 7.

<sup>61</sup> *Id.*

<sup>62</sup> Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301 et seq. (1994)).

<sup>63</sup> Hutt, *Misbranding*, *supra* note 51, at 37.

<sup>64</sup> Degnan, *supra* note 53 at, 302.

offer requirements for affirmative labeling which will make possible the purchase more intelligently and therefore more discriminatingly of food and drug products.”<sup>65</sup>

In the decades from the enactment of the FD&CA up until 1969, FDA relied primarily upon five provisions of the FD&CA to regulate food misbranding: mandatory food labeling; standards of identity for food; imitation food; special dietary food labeling; and prohibition of false or misleading claims.<sup>66</sup> Throughout this time, FDA’s approach was restrictive, and as technology improved, FDA’s regulatory efforts became increasingly at odds with applying these new advances to the food supply.<sup>67</sup> In December 1969, Nixon convened the White House Conference on Food, Nutrition, and Health, in response to charges of malnutrition and hunger in the US. Although the purpose of the Conference was not to discuss regulatory issues, “its conclusions had a dramatic and unexpected impact on FDA policy in regulating food misbranding.”<sup>68</sup> FDA had conducted a formal public hearing in 1968 and 1969 in which it had proposed a very restrictive approach to food standards, imitation labeling, special dietary foods and nutrition claims. This approach was “thoroughly criticized and rejected” by the Conference Report, which did not focus upon nutrition quackery, but rather “emphasized the need for sound nutrition, the capability of modern food technology to provide products to fill that need, and the use of increased public information about nutrition.”<sup>69</sup>

The Conference Report recommended drastically different policies from those in effect, that “profoundly changed FDA’s approach to food regulation and permitted the full use of

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<sup>65</sup> Hearing Before the S. Comm. on Interstate & Foreign Commerce, 74th Cong. (1935) (statement of Walter G. Campbell, Chief of FDA), reprinted in Charles Wesley Dunn, *Federal Food, Drug, and Cosmetic Act: A Statement of Its Legislative Record* 1237 (G.E. Stechert & Co.1987) (1938).

<sup>66</sup> Hutt, *Misbranding*, *supra* note 51, at 37.

<sup>67</sup> Hutt, *Misbranding*, *supra* note 51.

<sup>68</sup> *Id.* at 40.

<sup>69</sup> *Id.*

modern food technology.”<sup>70</sup> FDA had new leadership, which was committed to implementing that new policy.<sup>71</sup> This Conference marked the beginning of a new era for food labeling in the US. “The White House Conference represented the end of the restrictive approach to food regulation proposed by FDA during the 1960s.”<sup>72</sup> After the Conference, FDA’s approach to food regulation was profoundly changed in a way that “permitted the full use of modern food technology.”<sup>73</sup> Since that time, food technology has advanced rapidly, and has dramatically altered our nation’s food supply – manufactured foods are not simple concoctions of several household ingredients, but rather they are processed according to complex and precise multi-step scientific formulae. With these technological innovations, along with changes in culture and eating habits, have come a host of new regulatory issues and problems. Relationships between good health and diet have continued to be studied, and knowledge in this field is ever-expanding – as has the general public’s thirst for it, and manufacturers’ desire to make claims on food labels. Further, complicated manufacturing processes, including increased use of extracts, proteins, emulsifiers, binding agents, stabilizers and other components of food in fortification as well as other procedures have resulted in manufactured goods containing any number of unexpected (and often incomprehensible to the lay person) ingredients. Gone are the days when tomato soup was made from just tomatoes – these days a consumer is faced with an ingredient list containing all sorts of additives, ranging from soy protein and color to unpronounceable chemicals and a whole host of tomato products, like tomato sauce, tomato puree, tomato paste, etc. These changes have raised significant issues for consumers who are sensitive to certain food

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<sup>70</sup> *Id.* at 37.

<sup>71</sup> *Id.*

<sup>72</sup> *Id.* at 40.

<sup>73</sup> *Id.* at 37.

products. Labels can be obscure and difficult to read and understand, so avoiding certain foods can present unexpected challenges.

## ***Prohibitions and Affirmative Requirements***

Section 403 of the FD&CA mandated that all food labels should bear the following information (at a minimum): the name of the food, a statement of the ingredients, the net quantity of contents, the name and address of the manufacturer or distributor. These same four categories of mandatory information remain, to this day<sup>74</sup> (although additional categories of information – namely nutrition and allergy information – are now mandatory). Since the 1906 Act had been negative (in its prohibition of false and misleading claims), at the time the FD&CA was enacted, this requirement that certain information must appear on the food label was a novel concept in food labeling.<sup>75</sup> Congress realized that this step was essential to informing consumers about food in a meaningful way, but understood that only the most essential information should be required: “[t]hat Congress sought to require only this information reveals a deliberate attempt to limit the amount of information that could be compelled to appear on the food label.”<sup>76</sup>

FDA was authorized under Section 401 of the FD&CA to promulgate definitions and standards of identity for any food product in order to “promote honesty and fair dealing in the interest of consumers.”<sup>77</sup> FDA implemented this authority, and “[b]y 1970, it was estimated that half of the American food supply was subject to an FDA food standard.”<sup>78</sup> FDA’s policy was thus to adopt “recipe” standards of identity. These standards would list permitted ingredients,

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<sup>74</sup> 21 U.S.C. 343 (g)(2) and 21 U.S.C. 343 (i)(1) (name of the food) 21 U.S.C. 343 (g)(2) and 21 U.S.C. 343 (i)(2) (ingredients) 21 U.S.C. 343 (e)(2)(net quantity of contents) 21 U.S.C. 343 (e)(1) (manufacturer, packer or distributor information).

<sup>75</sup> Degnan, *supra* note 53, at 302.

<sup>76</sup> *Id.* at 302.

<sup>77</sup> Hutt, *Misbranding*, *supra* note 51, at 37.

<sup>78</sup> *Id.* at 37.

and if a manufacturer wanted to use a new ingredient, it could not do so until the standard was amended to include it. This system worked because “modern food technology was just beginning to flourish.”<sup>79</sup> While manufacturers were using some preservatives, emulsifiers, thickeners, and other functional food ingredients, many foods were still quite simple.<sup>80</sup> Also, FDA did not have independent statutory authority to require pre-market safety testing and approval of new functional food ingredients. But as food technology developed, this approach become outdated and unworkable.<sup>81</sup> Congress passed the Food Additives Amendment of 1958 and the Color Additive Amendments of 1960, and then finally in the early 1970s, the agency abandoned its old “recipe” approach, in favor of systematically amending the old standards to allow any “safe and suitable” functional ingredient; once food additives or colors had been approved as safe for use, they could be incorporated into foods with no need to amend the existing food standard.<sup>82</sup> FDA’s old policy had been that any new food that resembled a traditional food, or any new food that referenced a traditional food in its name was automatically illegal. But FDA has abandoned this position.<sup>83</sup> While this new approach allowed the food technology industry to flourish, there were no longer restrictions upon recipes – meaning that almost any foods or food products could turn up in any processed foods, which meant food-sensitive individuals could be exposed to offending foods in unexpected places. Of course, ingredient lists helped, but as technology improved, manufacturers began extracting components out of foods, and the common or usual name of these products are often not recognizable to consumers. For example, many consumers would be surprised to find that tuna packed in casein contains milk protein, or that albumin is actually an egg product.

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<sup>79</sup> *Id.* at 38.

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

<sup>82</sup> *Id.* at 41.

<sup>83</sup> *Id.*

Beginning in the 1940s, FDA also regulated fortification of foods, which gained focus in the 1930s, and gained increasing popularity particularly after World War II.<sup>84</sup> Out of a concern about the overfortification of the American food supply, in the early 1960s there was an FDA proposal to limit fortification to a list of eight classes food, with 12 essential nutrients, within specified levels. Following the Conference, however, FDA abandoned this approach.<sup>85</sup>

The 1906 Act had prohibited false or misleading statements in advertising, and Section 403(a) continued this prohibition in the 1938 Act, adopting essentially the same language as had appeared in the 1906 statute. “Most fraudulent or outrageous food claims had long since disappeared as a result of regulatory action taken under the 1906 Act,”<sup>86</sup> however new regulatory problems were emerging as food fortification and vitamin-mineral supplements gained in popularity and scientific evidence increasingly related diet with health: manufacturers wanted to make label claims about specific health benefits of their products.<sup>87</sup>

FDA did permit general health claims for food products, but prohibited specific claims that foods or their component foods could prevent particular diseases or illnesses.<sup>88</sup> The American Heart Association published a major report in August 1957, which recommended a reduction in dietary cholesterol and saturated fats. Subsequently, manufacturers of common food products began to make reference to this new information on their labels and in their advertising claims. FDA considered references to cholesterol or saturated fat “nutritional quackery,” and sought to prevent them.<sup>89</sup> However, as time progressed, the scientific evidence behind these claims began to mount, and so pressure on FDA to change its position mounted. By the late

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<sup>84</sup> *Id.* at 38.

<sup>85</sup> *Id.*

<sup>86</sup> *Id.* at 39.

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> *Id.* at 40.



1960s, FDA was taking very little regulatory action to enforce its position (although it still stuck to it in public).<sup>90</sup> In the early 1970s, FDA took the position that information on the label about product composition was lawful, but specific claims linking product composition to disease prevention was unlawful. So manufacturers could include information about cholesterol and fatty acid content on nutrition labels, but were not allowed to make claims about heart disease prevention.<sup>91</sup>

FDA announced a new policy in March 1985, that specific claims about disease prevention would be allowed, provided “they are recognized as valid by qualified experts, they emphasize that good nutrition is a function of the total diet, the claims are reasonably uniform within the marketplace, and they do not result in dietary ‘power races.’”<sup>92</sup>

The FD&CA, as originally enacted, did not mandate nutritional information on food labels. In the decades after its enactment, consumers became increasingly interested in this information, and manufacturers increasingly tried to provide it. Regulators became concerned that nutritional information on food labels was incomprehensible and confusing to many consumers. “At the 13th Annual National Food Policy Conference (1990), Dr. Sullivan, Secretary of the Department of Health and Human Services stated, ‘The grocery store has become the tower of Babel, and consumers need to be linguists, scientists, and mind readers to understand many of the labels they see.’”<sup>93</sup> In 1990, Congress recognized that current labeling requirements were outmoded, and overhauled the label. It passed the Nutrition Labeling and

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<sup>90</sup> *Id.*

<sup>91</sup> *Id.* at 42.

<sup>92</sup> *Id.* at 42.

<sup>93</sup> Jean Lyons & Martha Rumore, *Food Labeling – Then and Now*, 2. J. Pharm. L. 171, 180 (1994), quoting Louis W. Sullivan, Remarks by the Secretary of Health and Human Services at the National Food Policy Conference, 2 REG.AFFAIRS 169-174 (1990).

Education Act of 1990<sup>94</sup> (NLEA), requiring for the first time a fifth piece of information to appear on food labels: complete nutrition labeling.<sup>95</sup> “The goals of this Act were to clear up the confusion on food labeling to help the public make healthy choices and to encourage product innovation.”<sup>96</sup> Just as the 1938 Congress had sought to inform consumers so that they could make wise and healthy decisions, the 1990 Congress shared that same goal – it just determined that one more piece of information was crucial to that decision. “The framers of the 1990 legislation, like their counterparts in 1938, shared a comparable regard for the importance of the food label. [...] Thus, the NLEA shared the goal of the 1938-enacted section 403: to enable consumers to choose foods wisely by using the label as a vehicle for communicating essential information.”<sup>97</sup>

In 2000, one commentator noted that “[d]espite the passing of more than forty years, the NLEA shows that Congress believed that only nutrition labeling was as essential as the four other fundamental pieces of information required by the 1938 Congress to merit an unconditional labeling requirement.”<sup>98</sup> Clarity on the food label has similarly been an important goal for FDA and the agency has thus been careful not to include too much information. When FDA adopted final rules amending regulations requiring nutrition labeling, it expressed the following concern:

*However, the agency notes that while the 1990 amendments direct the agency to include in the nutrition label information that will assist consumers in maintaining healthy dietary practices, not all information related to maintaining healthy dietary practices can be included on the food label. If all such information were included, all essential*

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<sup>94</sup> Pub. L. No. 101-535, 104 Stat. 2353 (codified at 21 U.S.C. §§ 301, note, 321, 337, 343, 343 notes, 343-1, 343-1 note, 345, 371).

<sup>95</sup> Degnan, *supra* note 53, at 302.

<sup>96</sup> Lyons & Rumore, *supra* note 93, at 181.

<sup>97</sup> Degnan, *supra* note 53, at 302.

<sup>98</sup> *Id.* at 303.

*nutrients would be declared on the nutrition label. Not only would space constraints not allow for this, but the large amount of information would interfere with consumers' abilities to use the information of the greatest public health significance. Such a result would be contrary to the intent of Congress.*<sup>99</sup>

The following are the main provisions of NLEA:

- Mandatory nutrition labels for almost all food sold for human consumption;<sup>100</sup> restaurant food, take-out food, food prepared in a retail establishment and sold for immediate consumption, infant formula, and medical food excepted.<sup>101</sup>
- Authorizes certain claims relating to health and diseases, but these claims must be consistent with terms defined by FDA regulations; and certain terms, such as “free,” “low,” “light,” “lite,” “reduced,” “less,” and “high” are standardized and can only be used in accordance with FDA regulations.<sup>102</sup>
- Preempts state laws regarding food standards, health claims and nutrition labeling.<sup>103</sup>
- Nutrition labels must contain the following information:
  - o Serving sizes in typical household amounts.<sup>104</sup>
  - o Number of servings per container.<sup>105</sup>
  - o Number of calories derived from any source and the number of calories derived from fat in each serving.<sup>106</sup>

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<sup>99</sup> Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label, 58 FR 2079, 2107 (references omitted).

<sup>100</sup> 21 U.S.C. 343(q)(1).

<sup>101</sup> 21 U.S.C. 343(q)(5)(A)(i) and (ii).

<sup>102</sup> 21 U.S.C. 343(r).

<sup>103</sup> 21 U.S.C. 343-1.

<sup>104</sup> 21 U.S.C. 343(q)(1)(A)(i).

<sup>105</sup> 21 U.S.C. 343(q)(1)(B).

<sup>106</sup> 21 U.S.C. 343(q)(1)(C).

- The amount of total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in a serving size or other unit of measure was to appear on the label.<sup>107</sup> Information on thiamine, riboflavin and niacin was no longer required to appear on the label. This change was supposed to reflect changing health concerns of the population.<sup>108</sup>
- Colors that are required to be certified under Section 706(c) are required to be listed by name.<sup>109</sup>

In 1997, the Food and Drug Administration Modernization Act mandated wide-ranging reforms to agency practices, which included: (1) eliminating the requirement of FDA’s pre-market approval for most packaging and other substances that come into contact with food and may migrate onto it, replacing it with a system whereby the manufacturer can notify FDA of its intent to use a new substance and unless FDA objects within 120 days, it can go ahead and use it;<sup>110</sup> and (2) expanding the procedures whereby FDA may authorize nutrient content claims and health claims.<sup>111</sup> In 2003, the Department of Health amended its regulations and imposed the requirement that beginning on January 1, 2006 nutrition boxes on food labels should include trans fat content.<sup>112</sup>

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<sup>107</sup> 21 U.S.C. 343(q)(1)(D).

<sup>108</sup> Lyons & Rumore, *supra* note 93, at 181.

<sup>109</sup> 21 U.S.C. 343(i).

<sup>110</sup> Food and Drug Administration Modernization Act, § 309, amending 21 U.S.C. 348.

<sup>111</sup> Food and Drug Administration Modernization Act, §§ 301-304.

<sup>112</sup> 68 Fed. Reg. 41434 (July 11, 2003), 21 C.F.R. 101.9(c)(2)(ii). The final rule indicated that it was partially in response to a citizen petition from the Center for Science in the Public Interest (CSPI), and the Food Labeling Guide on FDA’s website (intended as a guide for industry). It referred to published human studies that show that the intake of trans fatty acids increases levels of low density lipo-protein cholesterol (LDL-C, or “bad cholesterol”) in the blood. It also referred to reports published by the Institute of Medicine of the National Academy of Sciences and the Federal government which recommend that Americans reduce their intake of cholesterol-raising fats, including trans fat in a nutritionally adequate diet. The final rule is available at <http://www.cfsan.fda.gov/~dms/21g-7b.html#transfat> (site last visited May 14, 2008).

Section 201(n) of the FD&CA “amplifies the general prohibition against false and misleading labeling that has been a cornerstone of FDA regulation since 1906.”<sup>113</sup> This section gives FDA authority to require information in addition to the five required elements under Section 403(e), (g), (i) and (q), provided such information is necessary to prevent the label from being misleading – i.e., if it is “material.”<sup>114</sup> Section 201(n) has two prongs, and FDA can thus require two types of information:

FDA can require facts which are material in light of the consequences which may result from consuming the food in the prescribed or customary way. FDA has used this prong in the past to require disclosure of ingredients that could exacerbate diseases or conditions. For example, manufacturers must designate whether the gluten they use is derived from corn or from wheat, to accommodate consumers who suffer from celiac disease.<sup>115</sup> In the 1980s, FDA tried to require disclosure of a certain color additive – FD&C Yellow No. 5 – that had been reported to cause allergic reactions.<sup>116</sup> It subsequently required disclosure of another additive – FD&C Yellow No. 6 – when it approved its use.<sup>117</sup> After industry objections it suspended and later withdrew this requirement.<sup>118</sup> Colors that are required to be certified under Section 706(c) are required to be listed by name.<sup>119</sup> Beginning in 1985, FDA responded to new information about food allergies to sulfites and began to require declaration of sulfites on package labels when they could be detected using a specific analytic method sensitive to 10ppm.<sup>120</sup> This requirement is still in effect today. Similarly, foods containing the sweetener aspartame must bear a warning for

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<sup>113</sup> Degnan, *supra* note 53, at 303-04.

<sup>114</sup> FD&CA § 201(n); 21 USC 321(n).

<sup>115</sup> Degnan, *supra* note 53, at 304 (citing 21 U.S.C. 184.1321 (1999)).

<sup>116</sup> Hutt & Merrill, *supra* note 52, at 82 (citing 42 Fed. Reg. 6835 (February 4, 1977), 44 Fed. Reg. 37212 (June 26, 1979), 45 Fed. Reg. 60419 (September 12, 1980), codified in 21 C.F.R. 74.705(d)(2)).

<sup>117</sup> *Id.* at 82 (citing 51 Fed. Reg. 41765 (November 19, 1986)).

<sup>118</sup> *Id.* at 82 (citing 53 Fed. Reg. 49138 (December 6, 1988)).

<sup>119</sup> 21 U.S.C. 343(i).

<sup>120</sup> Hutt & Merrill, *supra* note 52, at 83 (citing 50 Fed. Reg. 13306 (April 3, 1985), 51 Fed. Reg. 25012 (July 9, 1986), codified in 21 C.F.R. 101.100(a)(4)).

people with phenylketonuria (an inborn error of metabolism requiring avoidance of the amino acid phenylalanine).<sup>121</sup> In 1990, FDA proposed to make nutrition labeling mandatory under Section 201(n), reasoning that nutritional information was material to people consuming food.<sup>122</sup> This strategy was never tested, because three months after this proposal Congress passed the NLEA, which mandated nutrition labeling by amending Section 403(a).

FDA can also require facts which are material in light of the manufacturer's other representations. "In essence, this component of section 201(n) reflects a 'tell the whole truth' standard that applies if a manufacturer opts to tell something about its product and, in the process, fails to provide all 'material' information."<sup>123</sup> FDA used 403(a)(1) in conjunction with 201(n) in 1973 to require that manufacturers who added nutrients to a food or made claims about a food's nutritional value disclose other important nutritional information about the food. It argued that the claims made about the nutritional value rendered other nutritional information material.

Under Section 403(a), labels are prohibited from being "false or misleading in any particular." Manufacturers are prohibited from deceiving consumers regarding quality, quantity or identity, and they are required to provide certain information (e.g., full ingredient lists). "There affirmative requirements thus make assumptions about the types of information that consumers need to make wise choices."<sup>124</sup> For years, Congress and FDA have been very careful in mandating that only the information they believe absolutely necessary to consumers appear on food labels. "[F]or over sixty years, FDA has had in its enforcement and policymaking arsenal section 201(n)'s authority to require information to appear on the food label. The agency has

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<sup>121</sup> 21 C.F.R. 172.804(d)(2).

<sup>122</sup> Degan, *supra* note 53, at 304 (citing 38 Fed. Reg. 2125 (1973)).

<sup>123</sup> *Id.*

<sup>124</sup> Hutt & Merrill, *supra* note 52, at 36.

exercised that authority sparingly, largely reserving its use for the disclosure of truly important, noncollateral and nonlabel-cluttering ‘material’ information.”<sup>125</sup> Given this caution, when additional information is required on food labels, it is only because either FDA or Congress (or both) strongly believes in its importance. As such, it is clear that only in recent years have legislators recognized the essential nature of allergen information to food-sensitive consumers. In fact, the attitude toward ingredient listing has changed: “[i]n recent years, attention has focused on the consumer’s ability to identify and avoid specific ingredients, but in 1938, the new requirement of ingredient declaration was viewed primarily as a matter of economics.”<sup>126</sup> This shift towards enabling consumers to avoid foods has brought up the difficult issue of cross-contamination. While it is irrelevant if ingredient declaration is a matter of economics, it could mean the difference between life and death to someone with a severe allergy.

## ***Imitation Food***

Although the 1906 Act had prohibited imitation food altogether, the FD&CA allowed for it, provided it was clearly labeled as such.<sup>127</sup> The FD&CA did not define the term “imitation,” but a definition “had evolved only indirectly from infrequent cases involving the subsection. While those cases presented no clear definition of an imitation food, they did illustrate the

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<sup>125</sup> Degnan, *supra* note 53, at 306.

<sup>126</sup> Hutt & Merrill, *supra* note 52, at 75. Although, there were rumblings even back in the 1930s that there was something more than just economics behind labeling requirements: “Our thought has been that the purchaser of food products, the one who is going to take those food products into his system, is entitled, as a matter of simple right, to know what he is eating. “There are two reasons to justify that position. The first is an economic reason. It will prevent, in such circumstances, the substitution of products which may be of lesser food value or may be less expensive. The second, and the compelling reason, to my mind, is the element of health.” Hearing Before the S. Comm. on Commerce, 73d Cong. (1934) (statement of Walter G. Campbell, Chief of FDA), reprinted in Charles Wesley Dunn, *Federal Food, Drug, and Cosmetic Act: A Statement of Its Legislative Record* 11176 (G.E. Stechert & Co.1987) (1938). However, Campbell then went on to explain exactly what the term “allergy” meant, as it was an as yet uncommon and unfamiliar term. Allergies were certainly by no means the focal point of the legislative efforts of the era.

<sup>127</sup> FD&CA § 403(c); 21 U.S.C. 343(c).

applicability of the labeling directive to both standardized and nonstandardized foods.”<sup>128</sup> The “high point of FDA’s use of the imitation provision to inhibit the marketing of new food products”<sup>129</sup> was when a manufacturer made a substitute ice cream from soy beans and marketed it as “Chil-Zert,” and FDA brought a successful action against it,<sup>130</sup> requiring that it be labeled as an imitation ice cream.<sup>131</sup> From then on, more substitute food products were made, as a result of improving technology, but FDA did not seek to prevent them via legal action.<sup>132</sup> However, FDA did adhere to the position that one it had established a standard of identity, the name of that standardized food could not be used as part of the name of a nonstandardized substitute food<sup>133</sup> FDA’s unclear policy led to some confusion in the food industry,<sup>134</sup> which tended to curb innovation. So in 1973, FDA promulgated a regulation that distinguished between “imitation” and “substitute,” defining “imitation” as a substitute that was nutritionally inferior (a product was nutritionally inferior if there was a reduction in content of an essential nutrient that was present at a level of two percent or more of the U.S. Recommended Daily Intake), and removing the requirement that the new food product be labeled as an imitation.<sup>135</sup> This important step allowed manufacturers to take advantage of modern food technology to bring new and innovative products to market, without the stigma of labeling them as imitations. Subsequently, the range and variety of substitute products on the market significantly increased.

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<sup>128</sup> Federation of Homemakers v. Alexander Schmidt, Commissioner of Food and Drugs, et al., 539 F.2d 740, 742 (D.C.Cir. 1976) (footnote omitted).

<sup>129</sup> Hutt, Misbranding, *supra* note 51, at 39.

<sup>130</sup> United States v. 651 Cases, More or Less, of Chocolate Chil-Zert, 114 F.Supp. 430, 433 (N.D.N.Y.1953).

<sup>131</sup> Hutt, Misbranding, *supra* note 51, at 38-39.

<sup>132</sup> *Id.* at 39.

<sup>133</sup> *Id.*

<sup>134</sup> *Id.* at 42.

<sup>135</sup> 21 C.F.R. 1.8(e)(1) (1975).



## ***Special Dietary Food Labeling***

Section 403(j) authorized FDA to promulgate regulations requiring label information about vitamin and mineral content and other properties of foods marketed for special dietary purposes; FDA promulgated regulations governing vitamin-mineral supplements, fortified food products and certain other special dietary foods including infant food, hypo-allergenic food, and weight control food in November 1941 (following a public hearing).<sup>136</sup> The 1941 regulations established minimum daily requirements (MDR) for the use of vitamins and minerals,<sup>137</sup> and required that dietary supplement labels disclose the percent of the MDR contained in the daily recommended amount of the product.<sup>138</sup> However, all these regulations just imposed label requirements, and did not limit other claims made, nor permissible formulations for different products. As a result, many more types of special dietary products were manufactured and marketed, and many claims were made about them and their efficacy. FDA could not get the situation under control (despite numerous attempts through court actions and educational approaches).<sup>139</sup> “Frustration with the case-by-case approach prompted the FDA to turn to comprehensive rulemaking in 1962.”<sup>140</sup> In 1962, FDA began to work on stricter vitamin and mineral supplement labeling requirements, and published a proposal to revise the regulations.<sup>141</sup> It proposed to replace “minimum daily requirements” with “daily requirements” and declared which nutrients were essential, in which amounts, and which should not be included in supplements.<sup>142</sup> FDA published its final revisions to the 1941 regulations in 1966, which elicited

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<sup>136</sup> Hutt, Misbranding, *supra* note 51, at 39.

<sup>137</sup> Thomas P. Wilson, *The Regulation of Dietary Supplements – FDA’s New Jurisdictional Dilemma*, 14 *Foodservice Research International* 77, 78 (2003).

<sup>138</sup> Melinda Ledden Sidak, *Dietary Supplements and Commercial Speech*, 48 *Food & Drug L.J.* 441, 442 (1993).

<sup>139</sup> Hutt, Misbranding, *supra* note 51, at 39.

<sup>140</sup> Sidak, *supra* note 138 at 442.

<sup>141</sup> Hutt & Merrill, *supra* note 52, at 212 (citing 27 Fed. Reg. 5815 (June 20, 1962)).

<sup>142</sup> *Id.*

“fierce opposition by the supplement industry” that “led to a tortuous administrative hearing, a court challenge which in 1974 invalidated and remanded to the agency for further consideration several portions of the rules, and eventually congressional intervention.”<sup>143</sup> Congress added Section 411 to the FD&CA (the Vitamins and Minerals Amendments, or “Proxmire Amendments”<sup>144</sup>) in 1976, which “significantly curtailed FDA’s authority to restrict the composition of dietary supplements.”<sup>145</sup> FDA tried to amend its regulations to accommodate both Section 411 and the 1974 ruling, but eventually in 1979 it chose to revoke the challenged regulations.<sup>146</sup> Congress enacted NLEA in 1990 (see above), which regulates health claims, but excludes dietary supplements from its scope. After a series of political battles, Congress enacted the Dietary Supplement Health and Education Act of 1994 (DSHEA),<sup>147</sup> which exempts dietary supplements from the requirements of pre-market approval that are required for food products, and set the regulatory standard for determining the safety of dietary supplements. Under DSHEA, Congress regulates supplements under a different set of regulations from those which apply to conventional food products and drugs. Under DSHEA, “the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to register their products with FDA nor get FDA approval before producing or selling dietary supplements. Manufacturers must make sure that product label information is truthful and not misleading.”<sup>148</sup>

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<sup>143</sup> Sidak, *supra* note 138, at 442 (footnote omitted).

<sup>144</sup> Pub. L. No. 94-278, 1976 HR 7988; named “Proxmire Amendments” in “Milestones in U.S. Food and Drug Law History” on FDA’s website, available at <http://www.fda.gov/opacom/backgrounders/miles.html> (site last visited May 14, 2008).

<sup>145</sup> Hutt, *Misbranding*, *supra* note 51, at 42.

<sup>146</sup> Sidak, *supra* note 138, at 442.

<sup>147</sup> Pub. L. No. 103-417, 108 Stat. L. 4325.

<sup>148</sup> Statement taken from FDA’s “Dietary Supplements” page, available at <http://www.cfsan.fda.gov/~dms/supplmnt.html>, last visited May 14, 2008 (asterisk omitted).

# FOOD ALLERGEN LABELLING AND CONSUMER PROTECTION ACT OF 2004 (FALCPA)

## ***Need for the FALCPA***

The potentially severe consequences of a person with food allergies ingesting an allergen, combined with the sensitivity of many food allergic people, make prevention of reactions critical. Unfortunately the only way to prevent an allergic reaction is to completely avoid all allergens. In today's society, this is no easy task, and for these food-allergic individuals, the food label is an invaluable resource – one upon which she must rely for her own safety and well-being. Inaccurate or misleading labels can have very serious consequences, and thus it is crucial to make sure manufacturers maintain accurate labels. Dr. Taylor summarized the importance of the food label as follows:

*Although the symptoms of food allergies can be treated with certain drugs including antihistamines and epinephrine, the only prophylactic approach to the treatment of allergies is the specific-avoidance diet. For example, those who are allergic to peanuts must avoid ingesting peanuts. However, the construction and implementation of safe and effective avoidance diets is often a challenge for individuals with food allergies. These individuals must avoid all forms of the offending food that contain protein because the allergens are found in the protein fraction. For example, cows' milk-allergic individuals would need to avoid all dairy products and most dairy ingredients such as casein and*

*why. The ingredient statement on the label of packaged foods provides critical information to food-allergic consumers.*<sup>149</sup>

Although “[f]ood allergies have probably affected mankind since the dawn of time,”<sup>150</sup> they have only recently drawn the attention of legislators and the food industry. “Allergic reactions have probably occurred for decades if not centuries. However, awareness of food allergies as a food safety issue for the food industry began to occur in the 1980’s.”<sup>151</sup> This recent increase in attention could be due to the recent increase in prevalence (see pp. 7-8). As food allergies have increased in prevalence, both the food industry and the government have responded. “Accordingly, the food industry and governmental regulatory agencies began to focus more attention on food allergies in the 1990’s.”<sup>152</sup> Given allergies’ quick increase and the unique challenges allergies present, this has been no easy task, and it was only to be expected that the appropriate response would hardly be obvious or uncomplicated, and that the road to a functional system of manufacture and regulation of manufacturers would be anything but straight (or short).

In the past couple of decades, changes have been implemented and progress has been made. Just a stroll through any supermarket or convenience store can reveal just how much awareness in the industry has increased. Labels warning people about the presence or potential presence of dangerous allergens are everywhere. Just a casual conversation with the average person can reveal just how much awareness among the general population has increased. Just a mention of the term “allergy” is almost always met with looks of recognition, and often elicits

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<sup>149</sup> Taylor, *Prospects*, *supra* note 2, at paragraph 14.

<sup>150</sup> *Id.* at paragraph 1.

<sup>151</sup> Steve L. Taylor, Food Allergens: From Chaos, Confusion, and Concern to Commitment and Control, Inaugural Lectureship before the Department of Food Science and Technology of the Ohio State University (as Recipient of First Annual OSU Food Science Harris Award) (October 2004) (hereinafter Taylor, *Chaos & Confusion*), available at <http://fst.osu.edu/harris/lecture.htm> (site last visited May 14, 2008).

<sup>152</sup> *Id.*

stories about friends or acquaintances who suffer the same. These changes result from a combination of market responses, and Congress' and FDA's regulatory actions.

In October 2004, Dr. Taylor commented on the food industry's response prior to the passage of the FALCPA: "Initially, the food industry response to concerns about food allergies was chaotic and confused because of a lack of knowledge and training. However, the U.S. and Canadian food industries responded very well, although progress varies from one company to another. As a result the packaged food supply is much safer for food-allergic consumers than it was 10 years ago. Thus, within a period of 10 years or so the situation moved from chaotic and confused to committed and reasonably well controlled."<sup>153</sup> So Professor Taylor saw the market's response as effective. He also seemed satisfied with the regulators' response, seeing increased recalls as an indication of some degree of progress: "From a regulatory perspective, enforcement was improving and product recalls arising from undeclared allergens are the leading cause of recall actions in the U.S. These regulatory actions contributed to the positive attitude of the industry."<sup>154</sup> However, Congress did not stop at increasing recalls – rather, it responded to the importance of notifying consumers about the presence of allergens in food products by enacting the Food Allergen Labeling and Consumer Protection Act of 2004.<sup>155</sup> The statute is the first of its kind, and thus fills a gap in legislation – previously, there were no statutes mandating the plain English identification of food allergens on labels. "There are no labeling standards currently in place for food allergies. [The FALCPA] fills this gap by ensuring that the food source from which a major food allergen is derived is clearly labeled in plain English."<sup>156</sup> Congress intended to improve the lives of people with food allergies today, as well as to increase the scientific

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<sup>153</sup> *Id.*

<sup>154</sup> *Id.*

<sup>155</sup> Pub. L. No. 108-282, 118 Stat. 891 (Title II).

<sup>156</sup> H.R. REP. NO. 108-608, at 3 (2004).

understanding of the disease for the future. Its purpose was not only to protect consumers,<sup>157</sup> but to go beyond protection to empower them. “Since there is currently no cure for food allergies, consumers need to be empowered to know whether or not food allergies are present in the foods they consume.”<sup>158</sup> Another goal of the FALCPA was to “direct the Secretary to engage in a number of activities to increase scientific and public understanding of issues related to food allergies.”<sup>159</sup>

### **Summary of the FALCPA’s Provisions**

Congress finds that approximately 2% of adults and 5% of children suffer from food allergies, and identifies eight major foods or food groups that account for 90% of these food allergies: milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat and soybeans.<sup>160</sup> The FALCPA defines the term “major food allergen” as one of these eight foods or food groups, or a food ingredient that contains protein derived from any one of these foods or food groups, with two exceptions: highly refined oils or ingredients derived from highly refined oils, and food ingredients exempted through either the petition or notification procedures outlined below.<sup>161</sup>

### **Labeling of Food Allergens**

The FALCPA amends the FD&CA by adding new Section 403(w), with the following provisions:<sup>162</sup>

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<sup>157</sup> *Id.* at 2 (2004), “[The FALCPA] lays out a number of new requirements for the labeling of food in order to protect consumers with food allergies.”

<sup>158</sup> *Id.* at 3.

<sup>159</sup> *Id.* at 7.

<sup>160</sup> FALCPA § 202.

<sup>161</sup> FALCPA § 203(c) amends FD&CA § 201(qq) (21 U.S.C. 321) (as amended by section 102(b)) by adding this definition.

<sup>162</sup> FALCPA § 203 amends FD&CA § 403 by adding new subsection (w). The explanations of these changes will reference the new FD&CA § 403(w). The rest of the explanations will reference the FALCPA.

Food shall be deemed to be misbranded if it or one of its ingredients is a major food allergen unless the food allergen is properly labeled.<sup>163</sup> Proper labeling can be accomplished in one of two ways. The manufacturer can either print the words “contains [major food allergen]” immediately after or adjacent to the ingredient list,<sup>164</sup> or it can print the name of the food source from which the major food allergen is derived in parentheses directly after the common name of the major food allergen in the ingredient list.<sup>165</sup> There are two exceptions to this provision. First, the name of the food source is not required if the common name of the ingredient uses the name of the food source in it<sup>166</sup> (for example, if “milk casing” is included in the list of ingredients, the manufacturer does not have to print the word “milk” in parentheses after the ingredient<sup>167</sup>). Second, if the name of the food source appears elsewhere in the ingredient list, then the manufacturer need not include the name of the food source (for example, if the ingredient list includes “milk casing,” then the manufacturer does not have to include the term “milk” in parentheses after “whey”<sup>168</sup>). However, this exception does not apply if the name of the food source that appears elsewhere in the list of ingredients appears as part of the name of a food that is not a major food allergen.<sup>169</sup> For example, peanut oil is a highly refined oil, and according to the House Report, does not cause food allergies, so if any ingredient containing peanut protein did not have the word “peanut” in its name, then the manufacturer could not be exempted from the requirement of printing “peanut” in parentheses after the ingredient if “peanut oil” appeared elsewhere in the list.<sup>170</sup>

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<sup>163</sup> FD&CA § 403(w)(1).

<sup>164</sup> FD&CA § 403(w)(1)(A).

<sup>165</sup> FD&CA § 403(w)(1)(B).

<sup>166</sup> FD&CA § 403(w)(1)(B)(i).

<sup>167</sup> H.R. REP. NO. 108-608, at 17 (2004).

<sup>168</sup> *Id.*

<sup>169</sup> FD&CA § 403(w)(1)(B)(ii).

<sup>170</sup> H.R. REP. NO. 108-608, at 17 (2004).

In the case of the three food groups (tree nuts, fish, Crustacean shellfish), the specific type of nut (almonds, pecans, walnuts, etc.), or species of fish (salmon, tuna, cod, etc.) or Crustacean shellfish (lobster, shrimp, etc.) must be listed.<sup>171</sup>

Even though there are exemptions under current law from other food labeling requirements for flavorings, coloring or incidental additives, a flavoring, coloring or incidental additive that is or contains a major food allergen is subject to the requirements of 403(w)(1).<sup>172</sup>

## **Exemptions from Labeling Requirements**

The FALCPA creates two procedures by which an entity may seek to secure an exemption for a food ingredient from the new food allergen labeling requirements of 403(w)(1). Under the first procedure, an entity may petition the Secretary to exempt a food ingredient from the new requirements. The petitioner has the burden of providing scientific evidence that the food ingredient does not cause an allergic response that poses a risk to human health. The Secretary has 180 days within which to approve or deny the petition, and after such time, the petition is deemed denied unless the petitioner and the Secretary mutually agree upon an extension.<sup>173</sup>

Under the second procedure, an entity may file a notification with the Secretary that states scientific evidence that demonstrates that the food ingredient does not contain allergenic protein, or that the ingredient does not cause an allergic response that poses a risk to human health. The Secretary must decide to not approve the notification within 90 days of receipt, otherwise the entity filing the notification may use the food ingredient as a food ingredient that is

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<sup>171</sup> FD&CA § 403(w)(2).

<sup>172</sup> FD&CA § 403(w)(4).

<sup>173</sup> FD&CA § 403(w)(6); H.R. REP. NO. 108-608, at 18 (2004).



not a major food allergen.<sup>174</sup> This procedure might be more commonly used once thresholds for the allergens have been established: “[w]hile the Committee recognizes that thresholds for the eight major allergens have not yet been established by the scientific community, if they are established, ingredients containing allergenic proteins below the established threshold would be eligible for the notification procedure.”<sup>175</sup>

The requirements of Section 203 will take effect on January 1, 2006,<sup>176</sup> and raw agricultural commodities are exempted.<sup>177</sup>

## **Cross-Contact and Advisory Labeling**

The Act directs the Secretary to prepare a report within 18 months of enactment regarding cross-contamination and the use of advisory labeling in the food industry, including addressing which types of advisory labeling are most effective in alerting consumers with food allergies or their caretakers about the level of risk of cross-contact between products and major food allergens.<sup>178</sup>

The Secretary is directed to conduct inspections pursuant to Section 704 of the FD&CA of facilities in which foods are manufactured, processed, packed or held, to ensure that operators of these facilities are complying with practices designed to reduce or eliminate cross-contact between foods and residues of major food allergens that are not intentional ingredients,<sup>179</sup> and that major food allergens are properly labeled on foods.<sup>180</sup>

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<sup>174</sup> FD&CA § 403(w)(7), H.R. REP. NO. 108-608, at 18 (2004).

<sup>175</sup> H.R. REP. NO. 108-608, at 18 (2004).

<sup>176</sup> FALCPA § 203(d).

<sup>177</sup> FD&CA § 403(w)(1).

<sup>178</sup> FALCPA § 204.

<sup>179</sup> FALCPA § 205(1).

<sup>180</sup> FALCPA § 205(2).

## **Gluten-free**

The Secretary is directed to issue a proposed rule to define and permit the use of the term “gluten-free” on food labels within two years and in consultation with appropriate experts and stakeholders. The Secretary is directed to issue a final rule within four years.<sup>181</sup> Congress intended for the Secretary to move quickly in implementing this section: “[g]iven the devastating nature of celiac disease, the Committee urges the Secretary to move expeditiously in implementing the requirements of this section.”<sup>182</sup>

## **Research and Industry Guidance**

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Commissioner of Food and Drugs, is directed to improve the national data on the “prevalence of food allergies,” the “incidence of clinically significant or serious adverse events related to food allergies” and the “use of different modes of treatment for and prevention of allergic responses to foods.”<sup>183</sup> The Secretary, acting through the Director of the National Institutes of Health, is directed to convene an ad hoc panel of nationally recognized experts in allergy and immunology to “review current basic and clinical research efforts related to food allergies.”<sup>184</sup> The Committee “encourages the panel to review existing scientific data on food allergy reaction thresholds for each of the major food allergens. It is the Committee’s hope that this information will be helpful to the FDA as it continues to review scientific data on food allergy reaction thresholds.”<sup>185</sup> The panel should make recommendations to the Secretary for

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<sup>181</sup> FALCPA § 206.

<sup>182</sup> H.R. REP. NO. 108-608, at 19 (2004).

<sup>183</sup> FALCPA § 208.

<sup>184</sup> FALCPA § 208.

<sup>185</sup> H.R. REP. NO. 108-608, at 19 (2004).

enhancing and coordinating research activities concerning food allergies, and the Secretary is directed to make them public.<sup>186</sup>

The Act directs the Secretary, in the Conference for Food Protection, to revise the Food Code to provide guidelines for preparing allergen-free foods in food establishments, including restaurants, grocery store delicatessens, grocery store bakeries, and school cafeterias. Public and private entities have developed guidelines and recommendations for the preparation of allergen-free foods in public and private food establishments, and the Secretary is directed to consider these in pursuing this revision.<sup>187</sup>

The Secretary is directed to include technical assistance relating to the different modes of treatment for and prevention of allergic responses to foods in the technical assistance it provides relating to trauma care and emergency medical services to State and local agencies under section 1202(b)(3) of the Public Health Service Act.<sup>188</sup>

### ***Reactions to the FALCPA***

The FALCPA's "plain language" requirements have widely been regarded as helpful and consumer-friendly. They represent an incredibly important step both in terms of recognizing and acknowledging the serious nature of food allergies, and in providing concrete assistance to make allergy sufferers' lives easier. Dr. Taylor nicely summarized the contribution of the FALCPA's plain language requirement in an interview for the Environmental Perspective: "In the past, you've seen terms like 'casein' and 'whey'... Consumers often had to learn the hard way that those terms are synonymous with 'milk.'"<sup>189</sup>

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<sup>186</sup> FALCPA § 208.

<sup>187</sup> FALCPA § 209.

<sup>188</sup> FALCPA § 210.

<sup>189</sup> Dahl, *supra* note 22.

Further, the FALCPA addresses the important and complex issues surrounding cross-contact and advisory labeling. Obviously, we have a long way to go in this area, but the Report prepared by the Secretary represents an affirmative first step.

Back in October of 2004, while Dr. Taylor expressed support for many of the FALCPA's provisions, he was also critical of the FALCPA because it does nothing to distinguish amounts of allergenic ingredients, such that even trace amounts – so long as they are added intentionally – have to be labeled. In a speech given at the Department of Food Science and Technology of the Ohio State University, he made the following remarks: “However, the situation has recently become more chaotic just when real progress was being made. The legislative arm of government weighed in with the passage of the Food Allergen Labeling and Consumer Protection Act of 2004. While most of the provisions of FALCPA are commendable, FALCPA will require the labeling of all ingredients derived from commonly allergenic foods regardless of the amounts present in the finished product. This will lead to the declaration of many more such ingredients on the product label thereby decreasing food choices and the quality of life for food-allergic consumers. Many of these ingredients are present at such miniscule levels that allergic consumers would not likely react to them, and most of these products have been safely consumed by food-allergic individuals for years. Thus, the food industry once again finds itself in the midst of chaos. The distinction is that many of the forthcoming changes will do little to further protect food-allergic consumers and the focus will switch from consumer protection to label compliance.”<sup>190</sup> This criticism is valid, as it is inadvisable to encourage consumers to avoid entire food groups even when they do not have a real need to do so. However, even though food-allergic consumers may have been safely consuming certain processing aids, such as soy

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<sup>190</sup> Taylor, *Chaos & Confusion*, *supra* note 151.

lecithin,<sup>191</sup> for years, this does not appear to be a valid reason to exclude it from the FALCPA's labeling requirements – after all, people have been consuming major allergens for years, and only within the past two decades have a significant number experienced allergic reactions. A better policy might be to allow manufacturers some way of signaling to consumers that certain allergens are present only in miniscule amounts, while others are present in larger amounts. Perhaps once a reliable method for determining thresholds of allergens has been established, manufacturers can take advantage of Section 343(w)(7)'s notification procedure, and get their processing aids exempted.

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<sup>191</sup> In an expert opinion in 2006, Dr. Taylor expressed the view that although the FALCPA does mandate labeling of soy lecithin as a major allergen, this product poses no allergenic risk. Opinion available at <http://www.farrp.org/articles/Ingredient%20Info/feolecithin0106.pdf> (site last visited May 15, 2008).

## EXEMPTIONS FROM THE FALCPA

Exemptions from FALCPA's allergen labeling requirements can be sought by petition under 343(w)(6) and by notification under 343(w)(7). FDA must post these petitions and notifications to a public site.<sup>192</sup> These two processes do not appear to have been much used by the food industry, and when they have been used, FDA appears to have been very careful in scrutinizing the materials filed. As of June 21, 2007 (the last time the site was updated), three petitions had been received under 21 U.S.C. 343(w)(6). One received an objection letter, one was withdrawn by the petitioner, and one had only come in a week before the update, and no response has yet been recorded.

As of December 14, 2006 (the last time the site was updated), seven petitions had been received under 21 U.S.C. 343(w)(7) (received by FDA between September 30, 2005 and December 7, 2006). All of them received objection letters.

Congress has stated that “[w]hile the Committee recognizes that thresholds for the eight major allergens have not yet been established by the scientific community, if they are established, ingredients containing allergenic proteins below the established threshold would be eligible for the notification procedure.”<sup>193</sup> Steps have been taken to determine thresholds for major food allergens and for gluten in food. The Center for Food Safety and Applied Nutrition (CFSAN) established an ad hoc, internal, interdisciplinary group, the Threshold Working Group. This group's task was to “evaluate the current state of scientific knowledge regarding food allergies and celiac disease, to consider various approaches to establishing thresholds for food

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<sup>192</sup> Petitions received under 343(w)(6) are available at <http://www.cfsan.fda.gov/~dms/falpeti.html> (site last visited May 11, 2008), and notifications received under 343(w)(7) are available at <http://www.cfsan.fda.gov/~dms/falnoti.html> (site last visited May 11, 2008).

<sup>193</sup> H.R. REP. NO. 108-608, at 18 (2004).

allergens and for gluten, and to identify the biological concepts and data needed to evaluate the scientific soundness of each approach.”<sup>194</sup> In June 2005 the group prepared and submitted a draft report, and the final report was completed in March 2006. The report itself summarizes its findings in the following way: “This report summarizes the current state of scientific knowledge regarding food allergy and celiac disease, including information on dose-response relationships for major food allergens and for gluten, respectively. The report presents the biological concepts and data needed to evaluate various approaches to establish thresholds that would be scientifically sound and efficacious in relation to protection of public health. Each approach has strengths and weaknesses, and the application of each is limited by the availability of appropriate data. It is likely that there will be significant scientific advances in the near future that will address a number of the limitations identified in this report.”<sup>195</sup> Perhaps once thresholds have been determined FDA will be more inclined to approving notifications and the food industry will use them to gain exemptions from the FALCPA’s labeling requirements.

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<sup>194</sup> *Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food*, prepared by The Threshold Working Group, Overview section (March 2006), available at <http://www.cfsan.fda.gov/~dms/alrgn2.html> (site last visited May 15, 2008).

<sup>195</sup> *Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food*, prepared by The Threshold Working Group, Executive Summary (March 2006), available at <http://www.cfsan.fda.gov/~dms/alrgn2.html> (site last visited May 15, 2008).

## CROSS-CONTAMINATION AND ADVISORY LABELING

Section 204 of the FALCPA directed the Secretary to submit a report (the “Report”<sup>196</sup>) on cross-contact<sup>197</sup> and the use of advisory labeling<sup>198</sup> in the food industry to the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce. CFSAN prepared such a report, and in July 2006 submitted it to Congress.

Since allergic reactions are immune responses and can be triggered by tiny amounts of allergens (see p. 8), cross-contact is clearly a serious issue that can present very significant problems for food-allergic consumers. Consumers must guess at the chances different food products may have been contaminated with trace amounts of allergens, guided only by common sense and the manufacturer’s guidance in the form of advisory labeling. Advisory labeling is another problematic area, since it is done by manufacturers on a purely voluntary basis. There is no standard for its use, so the information it conveys is extremely limited – different statements are used by different manufacturers in different contexts, and there is no defined correlation between different statements and risks. The FALCPA’s labeling requirements did not address this particular problem, but instead Congress opted for more research and data collection<sup>199</sup> before legislating changes in industry manufacturing practices of advisory labeling requirements.

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<sup>196</sup> The Report is available at <http://www.cfsan.fda.gov/~acrobat/alrgrep.pdf> (site last visited May 15, 2008).

<sup>197</sup> In the Report, FDA stated that cross-contact occurs: “when a residue or other trace amount of a food allergen is present on a food contact surface, production machinery, or is air-borne, and unintentionally becomes incorporated into a product not intended to contain the allergen. Cross-contact may also result from customary methods of growing and harvesting crops, as well as from the use of shared storage, transportation, or production equipment.” The terms “cross-contact” and “cross-contamination” are used interchangeably in this paper. Report, at 1, footnote 1.

<sup>198</sup> In the Report, FDA states that the purpose of advisory labeling is “generally to alert food allergic consumers to the possibility of allergen cross-contact.” Report, at 1, footnote 2.

<sup>199</sup> FALCPA § 204.



## ***Summary of the Report's Findings***

The purpose of the report is to address multiple issues regarding cross-contact with major food allergens during manufacture and processing that results in unintended contamination with such allergens; the way in which “current good manufacturing practice” (CGMP) might reduce or eliminate cross-contact; the industry’s use of advisory labeling; and consumer preferences and understandings about advisory labeling.<sup>200</sup>

FDA conducted allergen-focused inspections of 1,470 facilities in FY 2002 and conducted comprehensive analysis of the results. It conducted inspections of a further 372 facilities in FY 2003 and FY 2004 and analyzed this data also, although not as comprehensively as the FY 2002 data.<sup>201</sup> They focused upon the following practices at each facility:<sup>202</sup>

- Receipt of allergenic ingredients.
- Review of product labels.
- Equipment characteristics.
- Equipment cleaning practices and equipment cleaning efficacy checks.
- Handling of rework.
- Inspection of finished product labels.

FDA cautions against generalizing the findings from their inspections to all food production facilities, since they targeted facilities with a manufacturing environment they believed created a possibility of cross-contact. These results, however, are suggestive of trends throughout the food industry.<sup>203</sup>

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<sup>200</sup> Report, at 4.

<sup>201</sup> *Id.*

<sup>202</sup> *Id.* at 3.

<sup>203</sup> *Id.* at 22.

FDA also relied upon a report prepared by the Institute of Food Technologists (IFT) specifically for the FDA report.<sup>204</sup>

## **Risks and sources of cross-contamination**

FDA concluded that foods can become unintentionally contaminated with major food allergens at almost any step of the manufacturing process prior to final packaging.<sup>205</sup> The manufacturers and processors in the IFT survey identified the following main potential allergen sources: raw materials, processing aids, rework product, carry-over from shared equipment, clean-in-place fluid and miscellaneous sources.<sup>206</sup> Although it is difficult to determine the true prevalence of unintended contamination, nearly all manufacturers and processors are aware of the potential for cross-contact in their operations, and nearly all have allergen control programs in place designed to prevent unintentional contamination of food products with major allergens. This, in and of itself, indicates the perceived likelihood of such contamination, and suggests the strong likelihood of contamination in facilities where control programs are not in place<sup>207</sup> (although it is encouraging that manufacturers are aware of a problem and attempting to deal with it).

## **Impact of CGMP on reducing cross-contamination**

Although there is no known processing technology that can exclude automatically or continuously major food allergens from foods at risk of contamination, the use of CGMP is critical to reduction and elimination of cross-contact of foods with major food allergens. The Report states that such CGMPs would likely be implemented through a firm's allergen control

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<sup>204</sup> *Id.* at 4.

<sup>205</sup> *Id.* at 5.

<sup>206</sup> *Id.* at 6.

<sup>207</sup> *Id.*

plan. The value of an allergen control plan is widely recognized throughout the food industry in this country. Effective allergen control plans are usually tailored to each facility to address the risk factors that are unique to particular ingredients, products or manufacturing processes. They use a combination of control procedures to eliminate or reduce the risk of cross-contact.<sup>208</sup>

The results show that a certain percentage of food production facilities do apply control measures to attempt to address the issue of cross-contact with food allergens, but the extent to which a facility does so varies according to the control measure or the activity assessed. There is also a certain percentage of facilities that do not apply control measures to handling of allergens. The extent to which these facilities contribute to the presence of unintended allergens in food, or to the adverse health effects associated with allergen contamination is as yet unknown. FDA notes that these gaps suggest that increasing awareness among firms of the potential for cross-contact in food manufacturing is an area for improvement.<sup>209</sup>

Highlights from the FY 2002 inspections:

- 96.8% of facilities used one or more of the eight major food allergens as an ingredient; 62.7% used ingredients containing one or more of the eight as a sub-ingredient; 47.1% used ingredients derived from one or more of the eight.<sup>210</sup>
- For all facilities using one or more of the eight, milk was the allergen most frequently used, followed by wheat and egg.<sup>211</sup>

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<sup>208</sup> *Id.* at 9.

<sup>209</sup> *Id.*

<sup>210</sup> *Id.*

<sup>211</sup> *Id.*

- 55% of facilities identified ingredients as allergens and/or segregated them when receiving raw materials for products. Smaller facilities were less likely than larger facilities to do so.<sup>212</sup>
- 75% of facilities confirmed the accuracy of label ingredient statements either upon receipt of the labels or prior to their use,<sup>213</sup> and 68% inspected finished product packages prior to distribution to ensure that an allergen-containing product was properly labeled. Larger facilities were more likely than either midsize or smaller facilities to do so.<sup>214</sup>
- 80% of facilities applied one or more control measures to production equipment to prevent allergen cross-contact, with larger facilities being more likely to do so than mid-size facilities, which in turn were more likely to do so than smaller facilities.<sup>215</sup> Of these:
  - 33% used dedicated equipment.
  - 76% used shared equipment with clean-up between manufacture of the allergen-containing product and manufacture of the product without an allergenic ingredient.
  - 34% used shared equipment with production of the allergenic product scheduled last.
  - 7% used other methods.

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<sup>212</sup>*Id.*

<sup>213</sup>*Id.*

<sup>214</sup>*Id.* at 27.

<sup>215</sup>*Id.* at 24.

- 83% of facilities checked the effectiveness of their cleaning of food contact surfaces; larger facilities were more likely to do so.<sup>216</sup>
- Less than 6% of facilities were deemed to have equipment that was not easily accessible or cleanable, and FDA inspectors observed a build-up of residue that could have contained an allergen on equipment even after cleaning in 13% of facilities.<sup>217</sup>
- FDA inspectors concluded that allergen cross-contact was likely to occur in 25% of all inspected facilities. Equipment residues were considered to be the most likely source of cross-contact, followed by airborne food particles and then build-up of product above the processing zone.<sup>218</sup>
- 34% of facilities reworked<sup>219</sup> finished or semi-finished product, and in 92% of these facilities the reworked product was added back only to products containing the same allergens.<sup>220</sup>

## **Advisory labeling currently in use and what it means**

Manufacturers tend to use five basic advisory statements, with numerous variations to both format and content.<sup>221</sup>

(1) “Produced in a plant that processes...[allergen(s)].”

(2) “May contain traces of...[allergen(s)].”

(3) “May contain...[allergen(s)].”

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<sup>216</sup> *Id.* at 25.

<sup>217</sup> *Id.*

<sup>218</sup> *Id.*

<sup>219</sup> “Rework” refers to the practice in which food product material that has already been through some or all of the manufacturing process is reintroduced into an earlier stage of the production process of a subsequently produced food product. *Id.* at 26.

<sup>220</sup> *Id.*

<sup>221</sup> *Id.* at 10-11.

(4) “Produced on shared equipment that processes...[allergen(s)].”

(5) “[Allergen(s)] traces.”

Less than one fifth (17% in the FY 2002 study) of the facilities that were surveyed use advisory labeling on their finished products.<sup>222</sup> The percentage of facilities that used advisory statements increased with facility size, and facilities manufacturing certain products, such as chocolate, were more likely to use advisory labeling. The allergens most often associated with facilities that used advisory labeling were peanuts and tree nuts, followed by soy, milk, egg, wheat, Crustacean shellfish and fish.<sup>223</sup>

The report lists a huge variety of reasons why manufacturers use advisory labels, including: advising consumers of potential allergens for safety reasons; notifying consumers of conditions under which their food product was manufactured and the potential for contamination; being told to do so by the firm’s headquarters or corporate office or regulatory or legal department; as a self-protective measure; because advisory labels were used in incoming raw products; to keep up with industry trends or because the firm thought that was what consumers wanted.<sup>224</sup> The report also found that a high proportion of facilities have cross-control measures in place regardless of whether they use advisory labeling.<sup>225</sup> Facilities using advisory labeling were more likely to use certain control measures (“Dedicated equipment,” “Shared equipment with clean up in between allergen run,” “Production on shared equipment with production scheduled to run allergen formulation last”),<sup>226</sup> but FDA inspectors judged that cross-contact was likely to occur at more of those facilities (46% of facilities using advisory labeling, as compared

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<sup>222</sup> *Id.* at 15.

<sup>223</sup> *Id.* at 15-16.

<sup>224</sup> *Id.* at 12.

<sup>225</sup> *Id.* at 14.

<sup>226</sup> *Id.*

to 21% of facilities not using it).<sup>227</sup> Product was handled in a way to protect against cross-contact at a similar percentage of facilities using and not using advisory labeling. Among those facilities where cross contact was likely to occur, FDA observed similar rates of three specific control problems among facilities using and not using advisory labeling.<sup>228</sup> Taken together, it is difficult to say that the use of advisory labeling conveys much useful information to consumers. While cross-contact is likely to occur at a higher percentage of facilities using advisory labeling than not using it, facilities using advisory labeling also seem to use more control measures. Also, the results indicate that cross-contact was likely to occur at 21% of facilities not using advisory labeling, and was not likely to occur in 54% of facilities using it<sup>229</sup> – so the use of advisory labeling is hardly reliable in determining likelihood of cross-contact.

### **Consumer preferences regarding advisory labeling**

FDA contracted with Knowledge Networks, Inc. to do a survey of food allergic consumers and their caregivers. The purpose of the survey was to evaluate consumer preferences for advisory labeling. The survey was conducted in August 2005 and the respondents were 530 food-allergic individuals, 209 caregivers of food-allergic individuals and 504 non-food-allergic individuals.<sup>230</sup> Four advisory statements were tested:<sup>231</sup>

- (1) “Allergy Information: May Contain Peanuts.”
- (2) “May contain peanuts.”
- (3) “Manufactured on the same equipment as foods that contain peanut.”

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<sup>227</sup> *Id.* at 15.

<sup>228</sup> *Id.*

<sup>229</sup> *Id.*

<sup>230</sup> *Id.* at 17.

<sup>231</sup> *Id.*

(4) “Produced in a facility with an allergy control plan. The possibility of contact with allergenic ingredients has been minimized. May still contain trace amounts of peanut.”

The consumers who were surveyed preferred statement (1) over the other three. Other product label research has already shown that consumers prefer information to be preceded by signal words and they generally view this information as more credible than information not preceded by signal words, so this result is consistent with prior research on product labels.<sup>232</sup> Consumers preferred (3), then (2), and (4) was the least preferred.<sup>233</sup>

FDA also contracted with Synovate, Inc. to conduct an experiment comparing the effects of the four different advisory statements above on consumers’ decisions regarding food purchases and consumption intent. The survey was conducted in September 2005 and the participants were 1,000 food-allergic adults or caregivers of food-allergic individuals and 1,000 non-food-allergic individuals. The participants were randomly assigned to groups, and they were asked to respond to questions about the believability, helpfulness and consumption for one of the four tested advisory statements.<sup>234</sup> The results indicated that consumers found statements (1) and (2) to be less helpful and less believable. They also thought that products bearing labels with these statements were more likely to contain peanuts. They found statements (3) and (4) to be more believable and more helpful. They thought that products bearing labels with these statements were less likely to contain peanuts.<sup>235</sup> Clearly, consumers think differently worded statements have different meanings.

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<sup>232</sup> *Id.*

<sup>233</sup> *Id.* at 17-18.

<sup>234</sup> *Id.* at 18.

<sup>235</sup> *Id.* at 19-20.



## **Allergen recalls**

During FY 1999 to FY 2004, there were 462 recall actions due to the presence of undeclared allergens in a food (from FDA agency information). Bakery products represented the largest groups of recalls among a food product category, followed by ice cream products and then fishery products. The most frequent undeclared allergens were eggs, milk, peanuts and tree nuts.<sup>236</sup>

## ***Discussion of the Report and Policy Recommendations***

### **The First 90%**

The consumers in the Synovate survey thought the four different advisory labels had different meanings, and conveyed different levels of risk that the contaminating allergen was present. They also believed that the presence of an advisory statement on a label rendered the food more likely to be contaminated. The FDA investigations revealed a multitude of different reasons why firms use advisory labels, many of which were related to potential for contamination, but many others of which had nothing at all to do with the level of risk. Facilities using advisory labels were more likely to use certain control measures than facilities not using advisory labels, but cross-contact was judged likely to occur at more of the facilities using advisory labels than at facilities not using them (it was not likely cross-contact occurred at a high proportion of firms using advisory labels, and it was likely cross-contact did occur at a high proportion of facilities not using advisory labels). Further, there is no industry standard for the meanings of different statements, and it is unclear whether the fact that facilities using both control measures and advisory labeling do so because of an increased risk in their particular

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<sup>236</sup> *Id.* at 29.

ingredients, products, or manufacturing processes, or simply out of an increased awareness of allergies – so foods produced at such facilities may be either much more dangerous or much safer than average; it is likely that some are more dangerous and others are safer, and there is no reliable way to tell them apart. Taken together, these results indicate that statements on advisory labels may not be a good indicator allergen-contamination risk, and yet consumers seem to expect that they are, meaning that advisory labeling can often be misleading to many consumers. This is an extremely serious problem not only because widespread use of advisory labels may be preventing many food-allergic consumers from enjoying foods which are actually safe for them, but because there are probably many foods on the market that carry a greater risk of contamination and yet display no advisory label to warn consumers. The absence of standardization is what renders even the most accurate labels relatively useless. Even if certain individual manufacturers may have robust systems in place to warn consumers about dangerous risks, without a standard used throughout the industry consumers remain at a loss to interpret these labels.

There is always a chance of contamination of food with many substances during its production process. Machines and facilities are cleaned with dangerous chemicals, when food is left out it goes bad, if meat is improperly prepared it can contain pathogenic bacteria, vegetables can often be covered in chemicals and workers track in dirt and contaminants from the outside – to name just a very few potential sources of contamination. There is always a risk that some of these things will end up in food and be harmful to consumers. Procedures are in place to minimize these risks and to eliminate certain contaminating pathogens (such as heating to kill bacteria). In manufacturing facilities that use any of the major food allergens in any of their products, there is also a risk of cross-contact of allergens. The main difference between these

risks is that while the risks of many pathogens have been around since we began manufacturing food products, allergies have escalated in prevalence only in the past two decades. So the food industry has long-standing procedures in place to decrease contamination with pathogens, and it has only recently started to tackle the problems associated with cross-contamination of trace amounts of other foods (for food sensitivity reasons – of course, quality control measures that have long been in place help to reduce certain instances of cross-contact, but they do not specifically address many types of cross-contact of major food allergens that could be extremely harmful to food-allergic consumers). Furthermore, while most people can appreciate the risks associated with most contaminating pathogens, it may just not be that obvious to many employees that contamination with trace amounts of otherwise harmless food could be harmful to allergic individuals. There is no way to reverse contamination with food allergens once it has happened – once the contaminating protein is present – even in trace amounts – it cannot be removed.

While this might seem scary and even overwhelming, we must accept that there will almost always be at least some amount of residual risk – just like there is a residual risk that bleach, spoiled meat, plastic or rat hair gets into food. We must minimize the risk, but accept that it is still there. The key, in my opinion, is to be able to assess what that risk is, and convey it clearly and reliably to consumers, so that they can make informed decisions. Whereas in the case of contaminants for food that are dangerous to everyone, it is generally considered appropriate for the government to establish guidelines and thresholds, in the case of allergies, different people react differently to allergens. Obviously advisory labels should not affect people without allergies, but for people with allergies it is important for them to know what allergens may be present, combined with the likelihood of their presence, so that they can use this information,

along with knowledge of the severity and sensitivity of their own allergies, and their own willingness to take on risk, to make decisions with which they are comfortable.

Currently, it is extremely difficult to find products in certain categories (bakery products, dried fruit, breakfast cereal, chocolate and candy, to name but a few) that do not carry advisory labels. If consumers heed these warnings, they often will have to avoid these categories. This is regrettable, as it severely limits and restricts these consumers' diets. If they chose not to restrict their diets in this way (or if they have so many allergies that it simply becomes impractical to exclude all products with a warning), and wish to consume products that carry only a small risk, then they have no way of distinguishing which products carry high risk and which just carry the standard risk associated with almost all food products.<sup>237</sup> When warning labels are ubiquitous, they are really quite meaningless. Therefore it is important that advisory labels not over-estimate risk.

When we are designing legislation in this area, it is extremely important to try to avoid encouraging manufacturers to put warning labels on all of their products – almost regardless of actual risk – in order to shield themselves from liability. The main issue is not really just “are facilities letting people know when there are or could be allergens present?” Since there almost always could be allergens present, what we need is to get consistent, reliable information to consumers about what the real chances of allergens being present actually are (we need to

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<sup>237</sup> Almost all manufactured food products carry at least some risk of being contaminated at some point from when the raw ingredients were harvested, to when they were transported, and processed, packaged and shipped (possibly multiple times). Some foods, however, are at increased risk because of particular manufacturing processes used in certain plants. For example, all corn could be contaminated with soy beans because some corn is grown on fields adjacent to soy bean fields. So any product containing corn has at least a slight chance of being contaminated with soy. Corn products processed in plants where soy beans are also processed carry an increased chance of soy contamination, while corn products processed on the same lines as soy products carry a still greater chance of contamination. It would be appropriate for manufacturers to label any of the three product types with warnings about possible soy contamination, even though the risks posed to consumers by each one are very different. In the current system, there is no way for consumers to distinguish which type of risks manufacturers are describing when they use advisory labeling.

convey a sort of spectrum of risk, as opposed to a binary, risk or no risk message). It seems from the Report that many facilities have a good handle on identifying allergens and possible sources of contact, and many seem to know how to minimize risks of cross-contact. So I think we really need to take an approach to encourage some “more of the same,” in terms of manufacturing processes so that more firms begin to identify and minimize risks, and firms that are already doing so are encouraged to continue with their efforts (the CGMP statute is probably the right place to go for this – we could just work on making these rules more specific and more stringent). As far as advisory labeling goes, if we bring in any legislation to mandate advisory labels, then the most effective way to give this legislation “teeth” is obviously to attach liability to failing to provide warnings on labels. As soon as we attach this type of liability, we will encourage firms just to print warning labels on all of their products across the board. This is very unhelpful to allergic consumers, because they either have to cut out most processed foods from their diets, or take risks, having no way of determining which ones are the most dangerous.

There are two ways we could deal with this problem. First, we could have very strict regulations about what types of manufacturing situations would give rise to the need for advisory labels. Once firms could demonstrate that certain conditions were met and certain others not met, then they could escape liability for failing to label. In this context, it appears that this approach would be somewhat lacking and ineffective because it appears that the manufacturing process varies greatly across facilities and across food products. Manufacturers are probably in the best position to evaluate the risks associated with each stage of processing, and are thus probably the best actors to determine what the risk levels are. They probably also need some discretion, to evaluate their particular facilities and lines on a case-by-case basis. Bright line rules or “checklists” would not allow for this kind of individualized evaluation by the manufacturers.

The second, and more practicable and advisable, possibility is to introduce several different potential warnings, clearly associated with several different levels of risk (for example, one warning indicating a low risk, another indicating a medium risk and a third indicating a high risk). We could provide guidelines to manufacturers as to what each warning meant, and leave it up to them to assess the risk of their own processes in their own facilities. This would not only help communication between manufacturers and consumers, but it would also help manufacturers interpret warning labels on incoming raw or semi-processed ingredients (many manufacturers reported that they just transferred warning labels from packages they received). As long as manufacturers included one of the warnings, then it would be difficult to hold them liable when an allergic reaction occurred, because they had warned of a risk (if a risk materializes, it is difficult to prove that it did so because of a high risk or a low risk). So although manufacturers still might feel incentives to use warning labels across the board, at least they would be able to distinguish levels of risk on different products, so consumers could decide which products were most dangerous to them, and consumers with mild or relatively less sensitive allergies could distinguish between foods that they could consume safely and those that they should avoid.

In reducing the liability to manufacturers as long as they included at least the lowest level of risk on food labels, we would be reducing the incentives to be over-inclusive in their warnings; but we would instead be creating incentives for them to include just the lowest level of risk, as this would increase the market for their product, while shielding them from liability. Clearly, this is a serious problem. A good solution would be to introduce certain elements from the “checklist” approach. There could be certain defined criteria which would automatically require manufacturers to label higher levels of risk (for example, maybe if there were no

dedicated lines and machinery was difficult to access, then they would be required to use the highest level or risk warning). Manufacturers that met the criteria and failed to use the appropriate warnings would be exposed to liability; but manufacturers who did not meet the criteria would still be free to use higher levels of risk warnings. This is similar to the first suggestion I rejected above. However, it is different in that it has flexibility built into the system, since manufacturers would usually have discretion to use warnings as they felt appropriate, except in certain very clear-cut situations (a type of “checklist plus discretion” approach). Of course, we would be relying upon their discretion and good faith to voluntarily reduce their own market share by increasing warnings, but I think the current widespread voluntary use of advisory labels indicates a genuine desire to warn consumers and a willingness to lose market share in so doing. So I think it is feasible to expect that manufacturers would make a concerted effort to use the appropriate warnings.

It would also be advisable to review the system in several years. Probably by then industry practices would have developed to categorize the different risk levels, and maybe we could begin to codify them. The more guidance we could make available to the industry, the more accurate we could expect the advisory labels to be.

## **The Other 10%**

While the implications of the Report may seem scary for people who are allergic to one or more of the foods/food groups identified by the FALCPA, at least the attention is focused upon the needs of this group. The results are actually even scarier for people allergic to other foods/food groups. The report reveals the huge risk of contamination of processed foods with the eight major allergens, even though firms are attempting to manage this risk. This suggests that the risks for other foods is also huge, as there is no reason to believe there is any reason why

peanuts or dairy products would be more likely to get into other foods than, say, rice or sesame seeds. Many firms are now aware of allergies, but this awareness is focused on the eight specific allergens. This is to be expected, since the FALCPA defined “major food allergen.” It is also to be expected that firms will do very little to manage and warn about the risk of contamination of other potential allergens. Of course, it is also possible that with the increased awareness of the eight major allergens will come greater awareness of allergies in general, and firms may take steps to minimize cross-contact across the board (or even if they do not specifically try to do so, better manufacturing processes that minimize cross-contact with the major allergens will have a spillover effect and reduce cross-contact in general). However, given that the report makes no mention even of other allergens, it seems unlikely that other allergens will receive much attention at all in the future. It will probably be up to consumers to infer that among products with high risks of contamination with the major allergens, there is likely a high chance of contamination in general. This is obviously not ideal, as that assumption may not be that accurate.



# AGE OF THE ALLERGIC POPULATION AND REGULATORY GAPS

## *Regulation of Restaurants*

The FALCPA's labeling requirements do not apply to foods sold in restaurants (although they do apply to many packaged foods purchased by the restaurants to be used as ingredients). The FALCPA did make some attempt at regulation of restaurants (as well as grocery store delicatessens and bakeries, and elementary and secondary school cafeterias) by directing the Secretary to revise the Food Code to "provide guidelines for preparing allergen-free foods in food establishments."<sup>238</sup> Congress' purpose here was "preventing unintentional cross-contact with major food allergens."<sup>239</sup> In the 2005 Food Code,<sup>240</sup> the term "major food allergen" is defined,<sup>241</sup> and there is a requirement that the "person in charge" be capable of "[d]escribing foods identified as major food allergens and the symptoms that a major food allergen could cause in a sensitive individual who has an allergic reaction."<sup>242</sup> Further, foods packaged in restaurants must contain the allergen label information required in the FALCPA.<sup>243</sup>

Restaurants have historically been regulated by local health departments. There are various state laws governing restaurants, and the National Restaurant Association (NRA) promotes awareness and issues guidelines and recommendations, and offers training tools and tips to restaurant owners and staff. In 2001, the NRA published a Food Allergy Training Guide, developed by the Food Allergy & Anaphylaxis Network, in cooperation with the NRA's Health

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<sup>238</sup> FALCPA § 209.

<sup>239</sup> H.R. REP. NO. 108-608, at 20 (2004).

<sup>240</sup> Available at <http://www.cfsan.fda.gov/~dms/foodcode.html> (site last visited May 11, 2008).

<sup>241</sup> 2005 Food Code, 1-201.10(B).

<sup>242</sup> 2005 Food Code, 2-102.11(C)(9).

<sup>243</sup> 2005 Food Code, 3-602.11(B)(5).

& Safety Regulatory Affairs Department. The kit is available online on the NRA's website,<sup>244</sup> along with other information and training materials regarding food allergens in the restaurant setting.

Some restaurants and restaurant chains have taken the initiative and been proactive in assisting customers with food sensitivities. Many restaurants take food allergies extremely seriously, and are very accommodating in explaining the menu and offering changes and substitutions. Certain menus of chain restaurants offer to accommodate special requests,<sup>245</sup> and some chains even provide ingredient lists and allergen information,<sup>246</sup> or even gluten free menus.<sup>247</sup>

While all of these efforts are extremely helpful, and are doubtless steps in the right direction, there is still a lot of work to be done. Many restaurants are not nearly as accommodating as the examples above, with broken or unreliable lines of communication between the server and the chef, few or no menu items that can easily be made allergen-free, and kitchens with high levels of cross-contamination. Even among restaurants that are set up to be accommodating and have official allergy-friendly policies, members of their wait staff and kitchen staff can often vary greatly in their understanding of allergens and allergies and in their willingness to accommodate. For a person with food allergies, eating in a restaurant can feel like walking through a mine field because there are so many things that could go wrong. Firstly, the

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<sup>244</sup> The kit is available for purchase at [http://www.restaurant.org/store/showdetl.cfm?&Product\\_ID=517&DID=12](http://www.restaurant.org/store/showdetl.cfm?&Product_ID=517&DID=12) (site last visited May 16, 2008).

<sup>245</sup> E.g., Not Your Average Joe's. This restaurant's menu says "Special Request We aim to please. Let us know. We'll do everything possible to customize your selections." Menu available at [http://www.notyouraveragejoes.com/print\\_menus/print\\_ready/ne\\_menu/nyaj\\_menu\\_ne.pdf](http://www.notyouraveragejoes.com/print_menus/print_ready/ne_menu/nyaj_menu_ne.pdf) (site last visited May 11, 2008).

<sup>246</sup> E.g., Chili's has an extremely helpful website, with downloads (which expire and are updated monthly) suggesting menu options suitable for people with allergies to each of the 8 major allergens. Menu and allergen information can be downloaded from <http://www.chilis.com/menu/default.asp> (site last visited May 11, 2008). Chipotle lists ingredients for each menu item on its website, [http://www.chipotle.com/#flash/food\\_ingredients](http://www.chipotle.com/#flash/food_ingredients) (site last visited May 11, 2008).

<sup>247</sup> Not Your Average Joe's has a gluten free menu, available at [http://www.notyouraveragejoes.com/menu\\_gf/](http://www.notyouraveragejoes.com/menu_gf/) (site last visited May 11, 2008).

customer must explain her allergies to her server, who must understand and remember them. The customer relies upon the server to answer questions about menu items, and make suggestions – so the customer relies upon the server to be knowledgeable about the menu, or admit when she is not, and ask someone who is (any language barrier – particularly if the allergic person is traveling in a foreign country or even just eating at an authentic ethnic restaurant – can make this communication even more difficult). The customer then relies upon the server to convey the message (about menu changes, or even just a request to watch for cross-contamination) to the kitchen staff – for this, the server must remember the requests and there must be an appropriate system whereby she can communicate the requests to the kitchen. The chefs must then receive the message, and prepare the food allergen-free. This means reading labels, checking ingredient lists, and reducing the risk of contamination by using separate cookware and gloves, and clean surfaces (and also either re-prepping food or hoping that it was not contaminated when it was prepped). The correct dish must then be brought out to the customer. A breakdown in any one of these steps could prove disastrous and even fatal for a customer with a severe food allergy. Such a customer relies upon the restaurant to be well-managed, with a clean kitchen where cross-contamination is minimized, and to have a reliable system of communication in place, which includes the wait staff and the kitchen staff having enough time to make special accommodations. Further, she relies on the staff to be knowledgeable enough to understand her situation, appreciate its seriousness and be able to keep her safe by avoiding allergens. Lastly (and even perhaps most importantly), she relies upon the staff being willing to help her when she explains her situation.

Dining experiences in restaurants across America today for people with food sensitivities are inconsistent, to say the least. They range from pleasant and comfortable, to downright

miserable and even fatal because restaurants handle (or choose not to handle) food sensitivities in such different ways. There is currently no legislation in place that would regularize this industry's practices regarding food allergens.

### ***Age of the Allergic Population and Discussion***

In an article in the July-August 2001 issue of FDA Consumer magazine, Robert A. Wood, M.D., director of the pediatric allergy clinic at Johns Hopkins Medical Institutions in Baltimore was quoted saying: “[t]he prevalence of food allergy is growing and probably will continue to grow along with all allergic diseases.” He then said that research performed over the past three decades showed that in developed and developing countries, the number of people with allergies was skyrocketing, but that this was not happening in underdeveloped areas.<sup>248</sup>

In our assessment of the FALCPA, and changes made to the food industry, it is important that we keep in mind the population we are trying to help. Allergies are not only increasing in prevalence among the general population, they are particularly prevalent among children. Further, allergic children are in a particularly vulnerable position – they are often given foods by adults whom they trust, particularly in school, nursery school or daycare settings. Often these adults do not necessarily understand allergies and how to deal with them, so in many cases, children must be mature and responsible for themselves. As such, it is important that legislators bear this in mind. I think it is evident that they have – they have made important strides in targeting the most severely afflicted group. A lot of the attention has been focused on children with allergies up until now, and in many ways, that is a very, very good thing.

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<sup>248</sup> Ray Formanek, Jr., *Food Allergies: When Food Becomes the Enemy*, FDA Consumer Magazine (July-August 2001), available at [http://www.fda.gov/fdac/features/2001/401\\_food.html](http://www.fda.gov/fdac/features/2001/401_food.html) (site last visited May 15, 2008).

In drafting the FALCPA, Congress demonstrated an awareness that children make up a significant part of the allergic population and indicated an intent to protect them. Accordingly, it included in its very first finding the discrepancy in allergy prevalence among adults and children (2% of adults as compared to 5% of infants and young children suffer from allergies).<sup>249</sup> It subsequently cited a study showing that many parents of food-allergic children were unable to correctly identify ingredients derived from food allergens in certain food labels.<sup>250</sup> In describing the report on cross-contact and advisory labeling the Secretary was to prepare, Congress directed the Secretary to describe the preferences of “consumers with food allergies *or the caretakers of consumers*” regarding advisory labeling.<sup>251</sup> In the House Report accompanying the FALCPA, the Committee on Energy and Commerce showed it was conscious that many people who have food allergies are children, and made apparent its goal of specifically addressing their needs when it directed the Secretary to “focus on which types of advisory labeling are effective in alerting consumers with food allergies *or their caregivers* about the risk of cross-contact.”<sup>252</sup>

Further, support groups, FDA and the food industry all seem to have responded to allergies with an eye to their effect on children and adolescents. In the two studies FDA contracted for in preparation of the July 2006 Report to Congress, not only were food-allergic consumers surveyed, but caregivers of food-allergic consumers were also included (in the survey conducted by Knowledge Networks, Inc., of the 209 caregivers of food-allergic individuals and 530 food allergic individuals were surveyed), indicating that children made up a significant proportion of the target population of the surveys.

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<sup>249</sup> FALCPA § 202(1)(A).

<sup>250</sup> FALCPA § 202(4).

<sup>251</sup> FALCPA § 204(4) (emphasis added).

<sup>252</sup> H.R. REP. NO. 108-608, at 18 (2004) (emphasis added).

The Food Allergy & Anaphylaxis Network (FAAN) is self-described as serving as “the communication link between patients and others,”<sup>253</sup> has a membership of almost 30,000 people worldwide, including “families, dieticians, nurses, physicians, school staff and representatives from government agencies and the food and pharmaceutical agencies,” and announces its vision to “be a world leader in food allergy and anaphylaxis awareness and the issues surrounding the disease.” This organization does a huge amount of important work in many areas relating to allergies (from advocacy, to education, to awareness and fundraising, to name but a few) and its website is an invaluable resource to all those individuals faced with food allergies. The website appears to cater overwhelmingly to parents of allergic children and to children. The homepage has links to “School Program,” “Teen Website” and “Kids Website.”<sup>254</sup> Further, the membership page is addressed to parents of allergic children: “Food allergy can be isolating. You’re always asking about ingredients, teaching your child to say ‘no’ when offered cookies and treats from others...” and includes the testimonial of at least one parent of an allergic child (it is unclear whether the other testimonial is from a parent).<sup>255</sup> Throughout the entire website, the recurring photograph is of a group of small children playing outside.

FDA’s website is an excellent resource for all people with allergies, providing useful and accurate information in an accessible and understandable format. It indicates an awareness that it is mainly children who suffer from allergies, and childcare providers are seeking information. Many parts of the website are clearly aimed at parents of allergic children. In an article in the March-April 2006 FDA Consumer magazine, posted in the “Consumer Information” part of the “Information about Food Allergens” section of FDA’s website, Muñoz-Furlong (founder and CEO of FAAN) is quoted explaining how the FALCPA particularly helps children in that by

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<sup>253</sup> <http://www.foodallergy.org/about.html> (site last visited May 15, 2008).

<sup>254</sup> <http://www.foodallergy.org/> (site last visited May 15, 2008).

<sup>255</sup> <http://www.foodallergy.org/membership.html> (site last visited May 9, 2008).

requiring manufacturers to use the common or usual name of the food source from which a major allergen is derived, it makes labels more understandable to them – even young children can recognize the term “milk” and know that it is harmful to them, whereas the same cannot be expected of “ammonium caseinate.” When foods are labeled in this way, parents can teach their children about which foods to avoid in the grocery store.<sup>256</sup> In the “Questions and Answers” part of the same section, FDA points out that the FALCPA was designed to be especially helpful to children and their caregivers.<sup>257</sup> In a December 20, 2005 news release announcing that the FALCPA labeling regulations were about to take effect on January 1, 2006, FDA lauded the statute for its particular helpfulness to children: “This labeling will be especially helpful to children who must learn to recognize the presence of substances they must avoid. For example, if a product contains the milk-derived protein, casein, the product’s label will have to use the term ‘milk’ in addition to the term ‘casein’ so that those with milk allergies can clearly understand the presence of the allergen they need to avoid.”<sup>258</sup>

In terms of pending legislation, on April 8, 2008, the Food Allergy and Anaphylaxis Management Act of 2008 (FAAMA)<sup>259</sup> was approved by the House. Next it will be considered by the Senate Health, Education, Labor, and Pensions Committee, and if approved it will be presented to the full Senate. The purpose of the Act would be “[t]o direct the Secretary of Health and Human Services, in consultation with the Secretary of Education, to develop a voluntary policy for managing the risk of food allergy and anaphylaxis in schools.” The Act makes a

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<sup>256</sup> Linda Bren, *Food Labels Identify Allergens More Clearly*, FDA Consumer Magazine (March-April 2006), available at [http://www.fda.gov/fdac/features/2006/206\\_foodlabels.html](http://www.fda.gov/fdac/features/2006/206_foodlabels.html) (site last visited May 15, 2008).

<sup>257</sup> *Information for Consumers: Food Allergen Labeling and Consumer Protection Act of 2004 Questions and Answers* (December 2005, updated July 2006), available at <http://www.cfsan.fda.gov/~dms/alrgqa.html> (site last visited May 15, 2008).

<sup>258</sup> *FDA to Require Food Manufacturers to List Food Allergens – Consumers with Allergies Will Benefit from Improved Labels*, FDA News (December 20, 2005), available at <http://www.fda.gov/bbs/topics/NEWS/2005/NEW01281.html> (site last visited May 15, 2008).

<sup>259</sup> Text of statute available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110\\_cong\\_bills&docid=f:h2063rfs.txt.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:h2063rfs.txt.pdf) (site last visited May 15, 2008).

number of findings, including prevalence of peanut allergies in children,<sup>260</sup> increase in food allergies in elementary-school children,<sup>261</sup> and anaphylaxis in individuals aged 18 or younger.<sup>262</sup>

All of the attention on children has meant that we have made important strides in protecting them from severe and unpleasant reactions. This goal is obviously vitally important; however, it is also important to recognize that while many children have allergies, these children are all growing up, and thus we can expect a shift in the age distribution of the allergic population.<sup>263</sup> While the prevalence of allergies may be higher in children now, we should still expect to see it increase in older age groups in the future as these children age, and so we should take this into consideration when we are designing policies. Both adults and children with food allergies have many needs in common, and all of the efforts that have been put towards helping people with allergies – although some seem to have largely been focused upon helping children – have doubtless been invaluable across the board (also, many of the efforts have been directed at allergic individuals in general, and not necessarily allergic children in particular). However, the needs of allergic persons develop and evolve over time, so all of the attention upon children and schools have left certain regulatory gaps in areas that are not as important for children as for

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<sup>260</sup> “Peanut allergy doubled among children from 1997 to 2002.” FAAMA § 2(2).

<sup>261</sup> “In a 2004 survey of 400 elementary school nurses, 37 percent reported having at least 10 students with severe food allergies and 62 percent reported having at least 5.” FAAMA § 2(3).

<sup>262</sup> “In a 2001 study of 32 fatal food-allergy induced anaphylactic reactions (the largest study of its kind to date), more than half (53 percent) of the individuals were aged 18 or younger.” FAAMA § 2(5).

<sup>263</sup> “While most food allergies are outgrown, allergies to peanuts, tree nuts, fish, and shellfish are considered lifelong.” *College and University Guidelines for Managing Students with Food Allergies*, available at <http://www.foodallergy.org/school/collegeguidelines.pdf> (site last visited May 15, 2008); S. Allan Bock & F.M. Atkins, *The Natural History of Peanut Allergy*, 83 *J. of Allergy & Clinical Immunology* 900 (May 1989) (a 12-year-long longitudinal evaluation of 114 peanut-allergic children, concluding that it is uncommon for patients who are allergic to peanuts to lose their reactivity over time). This idea has recently come into question. A recent study found that peanut allergy was outgrown in 21.5% of patients. Helen S. Skolnick, Mary Kay Conover-Walker, Celide Barnes Koerner, Hugh A. Sampson, Wesley Burks & Robert A. Wood, *The natural history of peanut allergy*, 107 *J. of Allergy & Clinical Immunology* 367, (February 2001). Another very recent study has just suggested that it is possible for certain people to outgrow peanut allergy in their adult years. The article advises that food challenges in adults are appropriate in the clinical setting. J.H. Savage, S.L. Limb, N.H. Brereton & R.A. Wood, *The Natural History of Peanut Allergy – Extending Our Knowledge Beyond Childhood*, 121 (Issue 2, Supplement 1) *J. of Allergy & Clinical Immunology* S147 (2008). So while it does appear possible for some people to lose their sensitivity, for many people, this does not happen; it is logical, therefore, to expect to see the peanut-allergic adult population grow in the future.



older age groups, and we need legislation that is specifically addressed to issues faced by adults with food allergies. For example, while children may eat most of their meals either at home, at school, at friends' houses or at family meals out, as they get older they may start to spend more time away from their families and with friends. Restaurant meals and fast food or take-out may become staples, as may be a college dining hall.<sup>264</sup> Business meetings and/or interviews may take place at restaurants, and trying out new and trendy places may become a weekend (or weeknight) ritual. As parents are around less and less to guide their children as they grow up, and as peer pressures to fit in mount, adolescents and young adults find themselves in new situations and face new challenges. Further, when people with food allergies become parents of either allergic or non-allergic children, they suddenly face many different challenges as well (deciding whether to allow young children, who do not understand allergies, to handle allergens that are potentially lethal to other family members, or whether to deprive them of entire food groups, simply because of a parent's or a sibling's allergies, can be a very difficult decision).

There is a lack of legislation of restaurants, and as such, restaurants can be very dangerous for people with allergies. There are some private ways of getting around this lack of legislation, and each allergic individual or her family may minimize her exposure to risk in the restaurant setting, simply by avoiding restaurants or by modifying her behavior in restaurants. Many websites offer excellent dining tips for allergic people dining out. Many of these suggestions are helpful across the board, and yet others seem somewhat more feasible for families than for young adults. For example, multiple websites offer some version of an allergy card, a pre-printed card or sticky note listing problematic foods to be handed to the server in a

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<sup>264</sup> FAAN has recognized the need for awareness and action in the context of college life, as evidenced by a handout available on its website: *College and University Guidelines for Managing Students with Food Allergies*, available at <http://www.foodallergy.org/school/collegeguidelines.pdf> (site last visited May 15, 2008).

restaurant.<sup>265</sup> An article on WebMD's website offers the following tips: "Food Allergies: Know What to Avoid," (focusing on being able to identify your allergens when they are hidden ingredients, or referred to by an unusual name), "Food Allergy Surprises Hidden Sources" (listing unexpected places where major food allergens might be lurking), "Choosing a Restaurant" (recommending larger, more established restaurants, or corporate chains, where meals and practices are more standardized, and corporate websites may list ingredients), "Food Allergy: Preplanning Strategies" (recommending phoning the restaurant in advance to discuss accommodations, using allergy cards and having a conversation with the server at the restaurant). In its "Food Allergies" section, About.com<sup>266</sup> offers the following 8 tips for eating out: "Do Your Homework" (recommending looking at restaurant websites and trying to speak to the manager outside of peak times), "Avoid Peak Times" (recommending restaurants during lunch and dinner rushes), "Make the Waitstaff Your Ally" (recommending being polite, thorough, helpful, and firm), "Find Multiple Options" (recommending asking questions about and suggesting multiple dishes at once, to save the server from making multiple trips to the kitchen), "Be Aware of Cross-Contamination" (suggesting mentioning the problem to the server and avoiding grilled food if it is cooked on the same grill as an allergenic food, or deep fried food if there are other allergenic deep fried foods on the menu), "Treasure a Good Relationship" (suggesting bringing additional business to and thanking establishments that are particularly accommodating), "Trust Your Instincts" (suggesting asking about or sending back foods that appear to be prepared

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<sup>265</sup> In 2005, the National Restaurant Association collaborated with Phil Lempert, who is NBC's "Today" Show food editor and is also known as the "Supermarket Guru," to promote the Food Allergy Buddy Dining Card Program. Consumers can create personalized allergy buddy cards listing specific food allergens and print them from the website, <http://www.foodallergybuddy.com>. Many other sites, such as <http://www.achooallergy.com/foodallergycards.asp> (site last visited May 10, 2008), <http://www.selectwisely.com/selectwisely/products/cards/fc000005.htm> (site last visited May 10, 2008) and <http://www.allergycards.com> (site last visited May 10, 2008), offer comparable services and products.

<sup>266</sup> <http://foodallergies.about.com/od/livingwithfoodallergies/tp/restaurant.htm> (site last visited May 10, 2008).

incorrectly), “Be Prepared” (suggesting bringing medication and packed snacks for young children).

Clearly, many of these suggestions are helpful to everyone. Suggestions about being polite and helpful with wait staff, reviewing menus in advance and choosing orders to minimize the possibility of cross-contact are helpful to diners of all ages. However, suggestions like avoiding peak times or sticking with corporate chains seem more feasible for families than for young adults. In the case of a family with one allergic member, it is more likely that the family will design all of their plans to accommodate that one member than that a group of friends would do the same for an allergic friend. So whereas simply avoiding the dinner rush could be a helpful way of protecting a child, when that child gets a little older and goes out to dinner with her friends, it might not be quite so feasible to expect to schedule the dinner at 5pm on a Monday, as opposed to 8pm on a Saturday, and the group might not be quite as happy at a restaurant like Chili’s,<sup>267</sup> as opposed to a trendy new restaurant. Similarly, college age students may eat many of their meals in their college dining hall (which may also serve as a social gathering), or at local restaurants. An allergic young professional might not always be able to choose the time or place for a lunchtime business meeting or interview, but may be required to attend. So while parents of allergic children may dedicate themselves to managing and minimizing the risk to their children of allergic reactions in restaurants, and may be willing to make drastic modifications to their behavior, teens and adults may find themselves in very different situations. As people enter their teenage years and beyond, they may find that more and more of their social life, and their professional life demands that they frequent restaurants. They may find they have less and less

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<sup>267</sup> Chili’s has an extremely helpful website, with downloads (which expire and are updated monthly) suggesting menu options suitable for people with allergies to each of the 8 major allergens). See *supra* note 246.

control over the choice of restaurants and the timing of meals. Thus these people are often more and more exposed to the risks associated with restaurant meals.<sup>268</sup>

Of course one could argue that it is up to the particular allergic diner to demand special treatment from friends, or to avoid social gatherings that pose a risk to the diner's health. However, this just simply does not appear to be happening. One 2001 study has reported that out of a national registry of 32 fatal cases of anaphylaxis, 28 of them (88%) occurred in people 13 years of age or older.<sup>269</sup> Further, 7 of them reported the location as "University cafeteria," "College dorm," "College camp" or "College apartment," and 9 of them reported the location as "Restaurant," "Country club," "Banquet" or "Hotel bar." Clearly many of these fatal reactions are occurring in people after childhood, and when they are eating food away from home that does not come from packages. 66% of these fatal reactions occurred in people between the ages of 13-21 – Sampson et al. defines this age group as "at high risk for fatal food-allergic reactions," and studied risk-taking and coping strategies among this group.<sup>270</sup> They assert several possible explanations for why they are high risk: that since there is reduced parental oversight, teenagers need to make choices about their food consumption for themselves, and thus the

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<sup>268</sup> Anecdotal evidence of individual diners' experience supports these different attitudes about restaurant dining and different habits practiced by different age groups. For example, in a chowhound.com discussion board (available at <http://www.chowhound.com/topics/476983> and last visited May 11, 2008), a split from a Los Angeles thread discusses restaurant experiences at popular restaurants in the Los Angeles area. Certain contributors self-identify as students or young professionals (as well as employees in the restaurant industry), or describe eating out in date scenarios. Many relate experiences in which they had severe allergic reactions in restaurants, or particularly good experiences, and recommend or warn about restaurants. The discussion makes apparent that many of the contributors are regularly taking serious risks by eating at restaurants, and these risks materialize from time to time. Many express opinions about understanding the risks, but recognize eating at restaurants as an important part of life, and therefore willingly assume the risks. As a comparison, a discussion board on WebMD's website (available at <http://boards.webmd.com/webx?THDX@@.895e9fdb!thdchild=.895e9fdb> and last visited May 11, 2008), many contributors identify themselves as parents of allergic children, and express very different attitudes – they seem much more cautious and concerned.

<sup>269</sup> S. Allan Bock, Anne Muñoz-Furlong & Hugh A. Sampson, *Fatalities due to anaphylactic reactions to foods*, 107 *J. of Allergy & Clinical Immunology* 191 (January 2001) (hereinafter Bock et al., *Fatalities*). The national registry was established by the American Academy of Allergy, Asthma, and Immunology, with the assistance of the Food Allergy and Anaphylaxis Network.

<sup>270</sup> Margaret A. Sampson, Anne Muñoz-Furlong & Scott H. Sicherer, *Risk-taking and coping strategies of adolescents and young adults with food allergy*, 117 *J. of Allergy & Clinical Immunology* 1440, 1444 (June 2006) (hereinafter Sampson et al., *Risk-taking*).

“burden of recognizing and treating an allergic reaction is placed on them or those around them, often persons other than their parents”<sup>271</sup> (in the national registry study, most of the individuals did not have epinephrine around at the time of their reaction<sup>272</sup>). Without as much parental supervision, adolescents explore their own independence and take risks. Sampson et al. cite previous studies examining risk-taking behaviors in teenagers and attributing them to “a reduced appreciation of potential dangers and a belief that consequences can be controlled.”<sup>273</sup> They further cite a study that found that while teens listed isolation as the hardest part of living with a food allergy, their parents cited fear of death as the most difficult issue.<sup>274</sup> Sampson et al. also reported that only 61% of the teens they surveyed reported carrying self-injectable epinephrine; 64% indicated they read labels all the time; only 58% said they avoided foods with “may contain” labels; and 61% said all of their friends knew about their food allergy. These results stand in stark contrast to attitudes expressed by parents.<sup>275</sup> So it appears that there may be three main reasons explaining why teens might be at higher risk of experiencing a fatal anaphylactic reaction: they are the ones making the decisions about what they eat, and thus deciding which risks to take (as opposed to their parents); the social situations they are often in are different from those they faced as a child, and pressure to take risks often mount; and should a reaction occur,

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<sup>271</sup> *Id.* at 1440.

<sup>272</sup> Bock et al., *Fatalities*, *supra* note 269.

<sup>273</sup> Sampson et al., *Risk-taking*, *supra* note 270, at 1440 (citing M.R. Rolison & A. Scherman, *Factors influencing adolescents' decisions to engage in risk-taking behavior*, 37 *Adolescence* 585 (2002)).

<sup>274</sup> *Id.* (citing S. Noone, A. Muñoz-Furlong & S.H. Sicherer, *Parent and adolescent perceptions on food allergy* [abstract], 111 (supplement) *J. of Allergy & Clinical Immunology* S133 (2003)).

<sup>275</sup> S. Noone, A. Muñoz-Furlong & S.H. Sicherer, *Parent and adolescent perceptions on food allergy* [abstract], 111 (supplement) *J. of Allergy & Clinical Immunology* S133 (2003). Other anecdotal evidence in the form of testimonials from parents of allergic children on FAAN's website and WebMD lend support to the assertion that parents tend to take allergies extremely seriously, and make a concerted effort to minimize risks of exposure of their child to allergens. For example, the following testimonial appears in the “FAAN Membership” section of FAAN's website (available at <http://www.foodallergy.org/membership.html> and last visited May 15, 2008): “When the doctor told us, ‘the next time your son eats a walnut, he could die,’ I thought I was having a nightmare. I looked at my little angel, who had just turned 5 the day before, and thought, he is never going to see his sixth birthday, his graduation from kindergarten, or his high school graduation. He'll never go to college, get married, or have his own kids. I wanted to put him in a bubble and never let him out of my sight.”

their parents are probably not there to take action. As for adults past their teenage years, the same theories about risk-taking behaviors may not be applicable. However, their lifestyles may encourage or even demand that they spend more time at restaurants and take more risks.

The evidence shows that many fatal anaphylactic reactions are taking place outside of the home. The FALCPA imposes strict labeling requirements upon manufacturers of packaged food sold at retail establishments, but does not impose labeling requirements upon restaurants. This suggests that there may be a regulatory gap. Many of these fatal reactions at eating establishments outside the home seem to happen to people older than children, which suggests that this regulatory gap may be adversely affecting adolescents and adults. The focus of many of the regulatory efforts upon children and their needs is consistent with this theory. Further, the fact that allergic children are growing up and often not growing out of their allergies suggests that we should expect to see this group of allergic adolescents and adults continue to grow in the future.

We thus need to extend regulatory efforts to restaurants, and in so doing it is important to recognize that the population most affected by restaurants practices is older than the allergic population we have tended to consider when legislating. Without placing too high a burden on the restaurant industry, or too high expectations upon individual chefs, managers or restaurant owners, I think we need to focus upon making the restaurant experience safer for allergic diners. Keeping in mind that allergic diners do frequent all types of restaurants at all times, we need to institute practices that will keep them safe even at independent restaurants and even during peak times. I think it is also important to recognize that the restaurant setting is inherently dangerous for allergic diners. Many parents of allergic children keep their kitchens free from all allergens in an effort to protect their children. In restaurants that serve the general population, this is simply

not the way they are run, and I am not recommending that they change. In even the most well-managed, conscientious restaurant kitchens, so long as there are allergenic ingredients present and being prepared and incorporated into dishes, there will be a risk of cross-contamination. I think this is a risk allergic diners must accept. I would, however, like to minimize this risk and perhaps most importantly make sure the risks are open and obvious, so that the allergic diner fully understands the risks and knowingly chooses to accept or reject them.

When an allergic person walks into a restaurant, I think the primary responsibility should be on that person to keep herself safe. She is the one who understands her condition the best, and she is the one who makes the decisions for herself. Keeping this in mind, I would like to see restaurants be as accommodating as possible. The first step is knowledge, education and understanding. The NRA already has published its Food Allergy Training Guide, the 2005 Food Code already mandates that at least one person on staff have knowledge of allergies and allergens, and many restaurants have already implemented training for their staff. I think these are steps in the right direction, but there are still many, many people in the restaurant industry who simply do not appreciate and understand (and sometimes even believe in) allergies. I would like to see more stringent legislation impose more training requirements on all people working in restaurants – both in the areas of what allergens are, how they affect hypersensitive people, how cross-contamination occurs, and what to do in the case that an allergic reaction happens. I would also like for restaurants to have in place clear policies regarding allergic diners. If certain restaurants are unwilling to make accommodations, then I do not want to impose any requirements upon them to do so (other than strict enforcement of the 2005 Food Code policies that seek to minimize cross-contact), I simply want them to be clear and upfront about their policies, and their wait staff to have the requisite level of knowledge and understanding to be

able to communicate these risks to their customers.<sup>276</sup> I think it should be up to individual restaurant-owners to design their own policy, and the area I would like to legislate is in educating the staff and mandating that they be upfront and honest and clear about their policies. That way, allergic diners would have the information they need to make informed decisions about the risks they take. Further, should they decide to dine in restaurants that were unwilling to make accommodations, they would know to stick to ordering items where the chances of cross-contamination were lowest, or where they did not need any or as many substitutions.

If we educated the restaurant staff, we would probably see fewer systems break down. Currently, even if a restaurant has a very accommodating policy in place, all it takes is one member of the staff to make a mistake (either because they did not understand or remember a special request, or because they were unwilling to put in the extra effort), and the risk to the allergic diner skyrockets. So by educating restaurant staff, we would automatically make any allergy-friendly policies already in place in restaurants more effective.

I think that while this type of legislation would not put requirements on restaurants to make special accommodations for allergic patrons, we would see an increase in the number of restaurants making such accommodations. Once we educated restaurant staff about the risks, they might find it easier to minimize them, and once they appreciated the seriousness of allergies, they might be more willing to make accommodations. Further, once the policies were out in the open, I think that the market pressures to make accommodations might increase.

Currently, even when allergic people try to choose safer restaurants, it can be difficult for them

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<sup>276</sup> Anecdotal evidence suggests that there is a wide variety of knowledge, training, and attitude among restaurant personnel. The experiences related by diners on the Chowhound discussion board (see *supra* note 268) demonstrate extremely different service, ranging from incompetent (one nut-allergic diner was told by a server that a pistachio was not a nut) to unwillingness to help, to impeccable understanding, sympathy and willingness to accommodate. A similar range of views are expressed by restaurant personnel – from unwillingness to help, to disappointment in patrons who do not tell them about their allergies in advance so that they can make all possible accommodations.



to determine in advance which restaurants are safest. It is even more difficult for dining partners of allergic people to make this determination. While of these dining partners might try to choose safe restaurants, many of these people have absolutely no idea on what to base this choice. If restaurants were required to have open and clear policies on accommodations for patrons with food sensitivities, then not only would the allergic population have better information about where the risks were the highest, but all of their dining partners would as well. Friends of allergic diners who want to be accommodating but now do not know how would have a simple way of choosing safer restaurants, and would probably be more willing to do so. We may even see businesses choosing more accommodating restaurants for business meetings just in case people in attendance had food sensitivities. Hopefully this would put market pressure on restaurants to choose to be more accommodating.

I think it would be best to start with these relatively small legislative changes – training of restaurant personnel and mandatory allergy policies – and then assess their effect. Hopefully the market effects described above would take over, and we would see drastic changes in the restaurant industry. If this happened, then since restaurants would be responding to consumer demands, as opposed to obeying legislation, then hopefully these changes would happen in the most efficient way possible.

## CONCLUSION

Years ago, nutrition labeling was virtually non-existent. In 2008, however, it is everywhere. Of course, it is mandatory on packaged foods under NLEA, but it pops up in far more places than is legally required. Many restaurants provide nutrition information for their dishes (either on menus or online), supermarkets often provide books of information about fresh fruits and vegetables, recipes often indicate caloric and fat contents and internet sites list nutritional information on more foods than any one person could possibly think of. Furthermore, it is hard to imagine that should Congress ever repeal NLEA, manufacturers would stop including nutrition boxes in their labeling. Maybe at one time manufacturers had to be told (or at least had to be told how to be clear), but now the public craves and demands this information, so manufacturers readily supply it. Maybe some day the same will be true for allergen information on labels. Maybe the FALCPA is simply the first step – the step that showed the public that this type of information is out there, and can be invaluable when it is made available. Maybe mandatory advisory labeling (or even voluntary advisory labeling as we now know it) will eventually serve the same purpose, and maybe once we impose some federal legislation on restaurants they will become more accommodating and show the public what is possible. Maybe we will reach a point when there is no looking back.

If this is true, then as the consumer demand grows stronger, legislation will still be extremely important; it will fulfill a type of gap-filling function, protecting the minority of allergy sufferers in the meantime, as they mobilize (and grow in numbers) and demand protection via the market. Allergies are on the rise, and the number of people directly impacted is much higher than allergy prevalence rates suggest. Even in families with only one allergic person, all members are affected to an extent; some households are maintained entirely allergen-

free, while others are less vigilant, but when there is an allergic person, everyone is inevitably impacted. It is possible that as the number of people impacted grows, it will reach a critical point, where these people will have a strong enough voice to make demands of the food industry to accommodate their particular needs. In the meantime, however, we need legislation. We need to realize that allergic people face risks every day, and that while some residual level of risk will always be present, there are steps we can take to minimize these risks, and vastly improve their quality of life. As a society, we have clearly begun to realize this, and taken the first very important steps. We still have a long way to go. In moving forward, I think we need to work with manufacturers in order to create incentives for them to be as helpful as possible in warning allergic consumers about risks, but also in keeping as many options open for them as possible, by resisting the urge to use advisory labeling across the board; I think we need to allow manufacturers to rate the risk level, without being exposed to unlimited liability. Further, as allergic people age, I think we need to consider their evolving needs, and embark upon the task of regulating restaurants. Given the cultural importance of restaurant life, I would never recommend restricting restaurants to the point where they can no longer create authentic and original dishes, but I think we need to recognize the importance of dining out in many allergic people's lives. I think we should bring more education to the restaurant industry, and insist upon clear and open policies regarding accommodations restaurants are willing to make for allergic diners.

These recommended legislative changes are intended to make allergic people's lives safer and more fulfilling in the short term, but hopefully they will eventually no longer be needed in the long term, as consumer demand for accommodations grows – unless we find a cure, and the whole issue becomes moot!