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# Food Allergies and Food Labeling: An International Problem

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## Food Allergies and Food Labeling: An International Problem

### I. Introduction

It is very difficult to estimate the number of people that truly suffer from food allergies worldwide or even in the United States alone. A safe estimate is that 2-5% of the population has a true food allergy when tested with a double blind placebo method.<sup>1,2</sup> People often live their lives as though they have an intolerance or allergy to a food yet they never receive a proper diagnosis, making verification of the allergy impossible.<sup>3</sup>

Although researchers have not been able to pinpoint the exact number of people affected by reactions to foods, even the most conservative estimates should get our attention as they represent thousands of people who struggle every day with their diet in order to control or prevent any possible adverse reactions. The numbers, however, are not enough to persuade many of the importance of this issue, which is why before turning to an examination of the treatment of food allergies and the importance of proper food labeling in that endeavor, it is crucial to spend some time highlighting exactly how debilitating and burdensome living with a food allergy can be.

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<sup>1</sup>Anderson, John A. "Food Allergy or Sensitivity Terminology, Physiologic Bases, and Scope of the Clinical Problem," Food Allergies and Adverse Reactions. Ed. Judy E. Perkin. Gaithersburg, Maryland: Aspen Publishers, Inc., 1990, p. 1.

<sup>2</sup>The double blind placebo challenge is considered the ideal way to test for a food intolerance. During the test, a suspected food or placebo is given to the patient in opaque capsules, and the patient is observed for a reaction. Collins-Williams, C. and L.D. Levy. "Allergy to Foods Other Than Milk." Food Intolerance. Ed. Ranjit Kumar Chandra. New York: Elsevier, 1984, p. 147.

<sup>3</sup>Anderson, p. 1.

As early as 460 BC, Hippocrates observed that some people had adverse reactions to foods which were not problematic for others. He remarked

To me it appears... that nobody would have sought for medicine at all, provided the same kinds of diet had suited with men in sickness and in good health... For cheese does not prove equally injurious to all men, for there are some who can take it to satiety without being hurt by it in the least, but on the contrary, it is wonderful the strength it imparts to those with whom it agrees; but there are some who do not bear it well, their constitutions are different and they differ in this respect, that what in their body is incompatible with cheese is aroused and put into commotion by such a thing; and those in whose bodies such a humor happens to prevail in greater quantity and intensity are likely to suffer the more for it. But if cheese had been pernicious to the whole nature of man, it would have hurt all.<sup>4</sup>

For some, the reaction to a food can be so strong and immediate that the cause is easily understood to be the offending food. Today, it is these reactions that continue to be the easiest to diagnose and treat, but there are other more invidious allergies and intolerances which do not provoke instantaneous, violent reactions, but which do pose long term dangers to those who live with them. An example of the most violent of reactions is acute anaphylactic shock or death resulting from the ingestion of food.<sup>5</sup>

It is very important, however, to keep in mind that most adverse reactions do not manifest themselves in such a dramatic way. In fact the most common reactions to a food involve the respiratory and gastrointestinal systems. Similar to allergies to plants or animals, many people manifest a food allergy with symptoms resembling asthma, or congestion.<sup>6</sup> Gastrointestinal symptoms are manifold, but can include diarrhea, vomiting, bloating, and abdominal cramping or pain.<sup>7</sup>

While these symptoms may seem mild and not worthy of a complete change in diet, that is deceiving because the effects can build up over time. In children, chronic asthma or congestion can lead to frontal headaches and impaired speech and slow learning in school.<sup>8</sup> Similarly, gastrointestinal symptoms, without treatment,

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<sup>5</sup>Frick, Oscar L. "Food Allergy." Nutrition in Gastrointestinal Disease. Ed. Robert C. Kurtz, M.D. New York: Churchill Livingstone, 1981, p. 69.

<sup>6</sup>Id., p. 70.

<sup>7</sup>Id.

<sup>8</sup>Id.

can result in malabsorption and malnutrition.<sup>9</sup> For these reasons the most effective treatment for those with adverse food reactions is the elimination of the food from the diet, especially since, as of yet, drug treatments for most food allergies are ineffective.<sup>10</sup>

## II. Common Food Allergies

It will be useful now to look at some specific food allergies and intolerances and examine the effects they have on their victims. The most common reactions are to egg, peanut, milk, tree nuts, soy, fish and wheat. These seven foods account for nearly 95% of the reactions in children in the United States.<sup>11</sup> There are countless others that could be examined, but looking at these seven should provide a comprehensive look at the reactions food allergies cause and the importance of managing a food allergy with a proper diet.

Before proceeding, it will be helpful to clear up some of the lingo used in this field which can be very confusing, but which can be simplified for the purposes of this paper. The most general term is *Adverse Reaction* which is used to signal an abnormal response triggered by exposure to a food. A more specific term is *Food Allergy* which is used by allergy specialists to describe an adverse reaction to a food which is caused by immunological mechanisms. In contrast, the term *Food Intolerance* is an adverse reaction which is not immunological.<sup>12</sup> Because this paper is not dedicated to the differences between food allergies and food

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<sup>9</sup>Falchuk, Z. Myron, M.D. "Gluten-Sensitive Enteropathy: A Review." Food Intolerance. Ed. Ranjit Kumar Chandra. New York: Elsevier, 1984, pp. 188-190.

<sup>10</sup>Rao, Yalamanchili, A. K., and Sami L. Bahna. "Dietary Management of Food Allergies." Food Allergy. Eds. Lawrence T. Chiaromonte, Arlene T. Schneider, and Fima Lifshitz. New York: Marcel Dekker, Inc., 1988, p. 351.

<sup>11</sup>Zarkadas, Marion MSc, Fraser W. Scott, PhD, John Salminen, BASc, Antony Ham Pong, MBS, FRCPC. "Common Allergenic Foods and Their Labelling in Canada – A Review." Canadian Journal of Allergy & Clinical Immunology 4 (1999):118-141, p.122.

<sup>12</sup>Anderson, pp. 2-3.

intolerances, but rather seeks to examine the importance of both and the steps the federal government could and should take to aid people in managing their adverse reactions (whatever the physical manifestation), the terminology is not terribly important and will therefore shift back and forth between all three depending which food reaction is being examined.

#### A. Egg

Allergies to hens' egg whites are among the most common adverse reactions, especially in children. It is difficult to estimate, but it is believed that as many 6 to 7% of children under the age of two have an egg allergy. It is further believed that this number drops to about 1% by the age of six.<sup>13</sup> Most scientists agree that this allergy predominantly affects children, with most outgrowing their sensitivities to eggs by the age of three.<sup>14</sup> The egg yolk contains only minor allergens, while the egg white contains two major ones, ovalbumin and ovomucoid.<sup>15</sup>

Egg allergies cause a wide range of symptoms which range from dermatitis, to asthma, to anaphylaxis.<sup>16</sup> Of even more concern is the fact that egg allergies have been known to be of such sensitivity that people are affected by the mere inhalation of the allergy causing proteins.<sup>17</sup> This poses serious problems because serious reactions can occur if a sensitive individual is in a kitchen where eggs are being used in the preparation of

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<sup>13</sup>Langeland, Tor and Kjell Aas. "Allergy to Hen's Egg White: Clinical and Immunological Aspects." Food Allergy and Intolerance. Eds. Jonathan Brostoff and Stephen J. Challacombe. London: Bailliere Tindall, 1987, p. 368.

<sup>14</sup>Zarkadas, p.126.

<sup>15</sup>Chiaromonte, Lawrence T. and Yalamanchili A. K. Rao. "Common Food Allergens." Food Allergy. Eds. Lawrence T. Chiaromonte, Arlene T. Schneider, and Fima Lifshitz. New York: Marcel Dekker, Inc., 1988, p. 95.

<sup>16</sup>Langeland, p. 368.

<sup>17</sup>Id.

other foods. Other serious and even fatal reactions have been documented by patients receiving vaccines which contain trace amounts of egg proteins.<sup>18</sup>

Treatment of the egg allergy requires elimination of egg from the diet.<sup>19</sup> Cooking may reduce the incidence of adverse reactions but it does not eliminate it completely, therefore, elimination of both egg white and egg yolk is the recommended treatment.<sup>20</sup> While it may seem easy to eliminate eggs from the diet, it is much more difficult than just refraining from eating eggs themselves. Eggs are present in countless foods processed foods and are often used in unexpected ways, such as being brushed on top of pastries to give a browned look to the food.<sup>21</sup> For this reason, an egg allergy can be quite invidious and difficult to manage. One grandmother of a recently diagnosed egg allergic granddaughter lamented the fact that many foods were off limits to her granddaughter now, including most cakes and cookies and the like.<sup>22</sup>

## B. Peanuts, Tree Nuts, and Seeds

The peanut has long been recognized as a serious allergen. It is most commonly cited as an example of a food which can cause a patient to go into anaphylactic shock.<sup>23</sup> Unlike the egg allergy which is often outgrown, as mentioned above, the peanut allergy is much more likely to persist with age.<sup>24</sup>

The allergen in peanuts has been found to be highly heat tolerant, resulting in patients having severe reactions

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<sup>18</sup>Id.

<sup>19</sup>Perkin, Judy E. "Major Food Allergens and Principles of Dietary Management," Food Allergies and Adverse Reactions. Ed. Judy E. Perkin. Gaithersburg, Maryland: Aspen Publishers, Inc., 1990, p. 60.

<sup>20</sup>Langeland, p. 369.

<sup>21</sup>Perkin, Judy E., Ed. Food Allergies and Adverse Reactions. Appendix C, p. 253.

<sup>22</sup>Joy, Philip, "Getting Around Allergies," The Edmonton Sun, September 16, 1998, p. 38.

<sup>23</sup>Frankland, A. W. "Anaphylaxis in Relation to Food Allergy," Food Allergy and Intolerance. Eds. Jonathan Brostoff and Stephen J. Challacombe. London: Bailliere Tindall, 1987, p. 458.

<sup>24</sup>Chiaramonte, p. 95.

after ingesting roasted nuts.<sup>25</sup> There is a lower incidence of adverse reaction to peanut oil and peanut hull flour, but the possibility is still there so avoidance is recommended.<sup>26</sup>

The symptoms associated with peanut allergies include urticaria, angioedema, wheezing, coughing, vomiting, rhinorrhea, itching, dyspnea, nausea, asthma, tearing of the eyes, and, as mentioned above, anaphylaxis.

The appearance of hives upon exposure to peanuts and peanut butter has also been reported.<sup>27</sup>

As with eggs, the peanut allergy is more difficult to manage than it appears at first glance. While it is easy to eliminate the actual nuts from the diet, peanuts are used in many ways in processed foods. Like eggs, peanuts are a relatively cheap source of protein, and are therefore used in many foods as a protein supplement.<sup>28</sup>

There is also the use of peanut oil which remains a concern to those with a sensitivity. Because the reactions can be so severe, patients diagnosed with a peanut allergy are advised to carry self-injecting epinephrine for emergency use.<sup>29</sup> A peanut allergy can be so severe that even touching an object used by someone else with traces of peanut on their hands can cause a reaction in a sensitive individual.<sup>30</sup>

Besides the peanut, there are many other nuts and seeds which can cause allergic reactions in individuals. Pistachio nuts, cashews, macadamia nuts, pine, nuts and sesame seeds have all been reported to cause reactions in people ranging from the mild to the severe.<sup>31</sup>

It is estimated that 10% of all severe adverse reactions to foods in the United States come from tree nuts in particular.<sup>32</sup> Less research has been done on tree nuts than on its relative the peanut, but the most commonly cited allergens are found in walnuts, cashews, pecans, and pistachios.<sup>33</sup> While an allergic reaction

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<sup>25</sup>Id.

<sup>26</sup>Perkin, "Major Allergens," p. 56.

<sup>27</sup>Id.

<sup>28</sup>Chiaramonte, p. 96.

<sup>29</sup>Perkin, "Major Allergens," p. 56.

<sup>30</sup>King, Laura. "The Deadly Peanut Forbidden Peanut," The Toronto Star, December 5, 1999, *available in* LEXIS, Canadian News Library, Canadian Publications File.

<sup>31</sup>Perkin, "Major Allergens," p. 57.

<sup>32</sup>Zarkadas, p. 124.

<sup>33</sup>Id.

to these nuts is not as difficult to manage as a peanut allergy due to the pervasive use of peanuts in processed foods, it still requires strict elimination to be free from any reaction which means that patients diagnosed with such an allergy must be very diligent about reading labels on all of the foods that they eat.<sup>34</sup>

Lastly, there are an increasing number of people reported to have sensitivities to sesame seeds and oil as well as cottonseed oil. At least one death has been reported in Canada due to a sesame seed allergy.<sup>35</sup> Other symptoms include the usual culprits; asthma, nausea, vomiting, and angioedema.<sup>36</sup> The increased use of cottonseed protein flour in baked goods and cottonseed protein in cream substitutes and processed meats should cause patients with this allergy to read labels carefully as well.<sup>37</sup>

### C. Soy

Another of the more common food allergies is to soy, which is a type of legume, in its various forms, including soybeans, tofu, soy sauce, and miso.<sup>38</sup> Similar symptoms as discussed above occur with a soy allergy including gastroenteropathy, asthma, eczema, and anaphylaxis. One of the biggest dangers with soy is that soy formulas are often used as substitutes when a child is found to have an allergy to cow's milk.<sup>39</sup> Because soy formulas are no longer considered hypoallergenic, its use as an alternative is declining.<sup>40</sup> Hydrolyzed casein formulas are increasingly being used in their place.<sup>41</sup>

Like the peanut and the egg, soy is a cheap source of protein and is therefore increasingly being added to

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<sup>34</sup>Id.

<sup>35</sup>Id.

<sup>36</sup>Perkin, "Major Allergens," p. 57.

<sup>37</sup>Id.

<sup>38</sup>Id., p. 55.

<sup>39</sup>Id.

<sup>40</sup>Id.

<sup>41</sup>Zarkadas, p. 125.



processed foods as a supplement.<sup>42</sup> A soy allergy can be particularly difficult to manage if the patient has other food allergies no matter what the age. Soy is often considered a good alternative to other allergy inducing foods, such as milk, wheat, and egg, making an allergen free diet especially difficult for those with a soy allergy as well as a second allergy.<sup>43</sup>

Examples of processed foods which may contain soy, include, cereals, cheese substitutes, milk or cream replacements, sauces, and meats.<sup>44</sup>

#### D. Milk

Allergies to cow's milk have been recognized for hundreds of years. Both Hippocrates and Galen, reported on patients suffering from the ill effects of milk or milk products.<sup>45</sup> But despite this long held knowledge of the allergen causing effects of milk, many scientists and doctors are reluctant to diagnose the problem. On the other hand, some professionals over diagnose the problem, making patients forego milk unnecessarily.<sup>46</sup> Reactions to cow's milk have been on the rise since the beginning of the twentieth century and coincides with the increased used of cow's milk as a substitute for the breast feeding of infants. As women have grown more independent, they have relied on cow's milk to provide the nourishment to the children that they are not always able to provide.<sup>47</sup>

Cow's milk allergies usually become present very early in childhood, often within the first two or three months, depending of course on when cow's milk is introduced. The allergy is occasionally outgrown, but

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<sup>42</sup>Chiaramonte, p. 96.

<sup>43</sup>Perkin, "Major Allergens," p. 55.

<sup>44</sup>Perkin, Judy E., Ed. Food Allergies and Adverse Reactions. Appendix B, p. 249.

<sup>45</sup>Bahna, Sami L., M.D. and Douglas C. Heiner, M.D. Allergies to Milk. New York: Grune & Stratton, 1980, p. 1.

<sup>46</sup>Id.

<sup>47</sup>Id., p. 5.

often continues into adulthood.<sup>48</sup> There are really three different sensitivities to consider when dealing with cow's milk; milk allergy, milk intolerance, and lactose intolerance, but it is not necessary for our purposes to separate them.<sup>49</sup>

Milk sensitivities can manifest itself in a myriad of symptoms. Most patients complain of multiple symptoms, and the reaction often involves multiple systems of the body.<sup>50</sup> Gastrointestinal symptoms are the most common, with the patients most frequently experiencing vomiting, diarrhea, abdominal pain, and colic.<sup>51</sup> While these primary symptoms are uncomfortable and burdensome, it is the secondary effects which can do the most damage. The frequent vomiting and diarrhea leads to the malabsorption of nutrients and fat. Children suffering from the above symptoms due to a milk allergy can fail to thrive, have wasted limbs, and abdominal distension. These can all be signals of complete malnutrition of the patient.<sup>52</sup>

The respiratory system is another common victim of a cow's milk allergy. Persistent rhinorrhoea or nasal stuffiness, bronchitis, asthma, and wheezing, are all common symptoms.<sup>53</sup> The most dangerous respiratory effect is the possibility of Heiner's syndrome, where a child has "repeated attacks of pneumonia associated with pulmonary infiltrates, haemosiderosis, anaemia, and failure to thrive."<sup>54</sup>

Cow's milk allergy manifests itself in dermatologic symptoms as well with patients often suffering from dermatitis, eczema, and other rashes.<sup>55</sup>

Lastly, a milk allergy can cause neurological problems as well. In adults it is manifested as allergic tension-fatigue syndrome, which, as the name suggests, results in weakness, fatigue, fainting, and easy tiredness, but also in headaches, tension, anxiety, and apathy.<sup>56</sup> In children, the problem is usually seen as irritability and

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<sup>48</sup>Id., p. 7.

<sup>49</sup>Zarkadas, p. 125.

<sup>50</sup>Bahna, p. 45.

<sup>51</sup>Id.

<sup>52</sup>Gerrard, John W. "Cow's Milk and Breast Milk." *Food Allergy and Intolerance*. Eds. Jonathan Brostoff and Stephen J. Challacombe. London: Bailliere Tindall, 1987, p. 345-346.

<sup>53</sup>Id., p. 347.

<sup>54</sup>Id.

<sup>55</sup>Bahna, p. 62-64.

<sup>56</sup>Id., p. 67-68.

restlessness, which is normally not thought to be related to an adverse food reaction, but which often can be.<sup>57</sup>

Because milk allergies can result in so many varied symptoms, it is often very difficult to diagnose. It can be very difficult to link the symptoms together to get an accurate picture of a patient's problems. Looking back after the allergy has been discovered, it is easy to see all of the symptoms that affected the patient, but it is very challenging to diagnose a food allergy when a patient speaks of experiencing listlessness and general weakness. For this reason, doctors must keep their eyes open to the possibility of considering food allergies as a possible cause of their patients' problems. The diagnosis is made more difficult by the fact that symptoms often do not occur immediately and can take up to two days before onset.<sup>58</sup> This makes the connection between the food and the symptoms even more difficult to uncover. This delayed reaction also has problems for management because people exhibiting symptoms often cannot pinpoint the exact cause of them. This makes the likelihood of repeating a negative experience quite high.

Like the other allergies mentioned above, milk is also hard to completely eliminate from the diet. There are countless dairy foods, that people eat every day, but more difficult than that is eliminating milk and milk products from the processed foods that they eat.

#### E. Fish and Shellfish

"Hypersensitivity to fish is easier to diagnose than most food allergies owing to the immediacy of the reaction.

Most fish-sensitive individuals react with urticaria, angioedema, asthma, or a combination of these symptoms

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<sup>57</sup>Gerrard, p. 347.

<sup>58</sup>Bahna, p. 45.

within minutes of fish ingestion.”<sup>59</sup> As compared to the milk allergy examined above, it is easy to understand why the diagnosis of fish allergies is a simpler process. Allergies to fish are nearly always heat stable, meaning the patient will react regardless of whether the fish is cooked or not.<sup>60</sup> There is also a concern that fish allergens can act as an inhalant making someone with a fish allergy even more susceptible to an adverse reaction.<sup>61</sup>

The most widely studied allergy causing fish is the cod. The symptoms mostly consist of respiratory problems as mentioned above. It is believed that elimination of the food is the best treatment although some patients have responded to so called hyposensitization, where the patient is exposed to increasing levels of the allergen in order to build a tolerance to it.<sup>62</sup>

Both crustaceans and shellfish can also cause allergic reactions in people, the former more than the later, but both can cause problems.<sup>63</sup> These allergies, like the fish allergy discussed above, are often quick acting, making diagnosis relatively easy. Again, elimination from the diet is the best treatment for individuals suffering from this allergy.<sup>64</sup>

## F. Grains

There are countless allergies to different grains. Instead of describing all of them, it will be useful to discuss one of the more severe which encompasses many different grains to get a feel for just how damaging such an allergy can be.

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<sup>59</sup>Chiaromonte, p. 96.

<sup>60</sup>Id.

<sup>61</sup>Id.

<sup>62</sup>Aas, Kjell. “Fish Allergy and the Codfish Allergen Model.” Food Allergy and Intolerance. Eds. Jonathan Brostoff and Stephen J. Challacombe. London: Bailliere Tindall, 1987, p. 359.

<sup>63</sup>Zarkadas, p. 127.

<sup>64</sup>Id.

Celiac Disease is the clinical name of a digestive disorder that leaves its victim unable to digest wheat, barley, oats, and rye. Ingestion of the offending ingredients cause the villi of the small intestine (small finger-like projections in the intestines which aid in digestion) to flatten thereby leaving less room to digest food.<sup>65</sup> The result, over time, is malabsorption and malnutrition.<sup>66</sup> This is the usual chain of events, but by no means the only one. Many celiacs have these experiences and report symptoms of fatigue, vomiting, diarrhea, and abdominal pain, which culminate in malabsorption and drastic weight loss.<sup>67</sup> Others, however, only realized their allergy after suffering for years with a nutrient deficiency. It is not uncommon for diagnosed celiacs to report that their only past symptom was a history of anemia for example.<sup>68</sup>

The breadth of symptoms are similar to those with a cow's milk allergy. In fact, a milk allergy is often suspected in those that are celiacs because the first thing to go when the villi are damaged is the lactase containing cells which digest milk.<sup>69</sup> Most recovering celiacs must stay away from milk products until their intestines heal. This interrelationship also makes celiac disease especially difficult to diagnose. Many patients go years without a proper diagnosis because the symptoms are never found to be related. The key is the malabsorption which can cause so many other problems. Often celiacs are anemic, as mentioned above; some have low levels of vitamin K, which is responsible for blood coagulation; still others have such low levels of calcium that their bones fracture seemingly with no explanation.<sup>70</sup>

Most recently, celiac disease has been found to be related to migraines in a study published in the journal *Neurology*.<sup>71</sup> The study went on to state that a most important fact about celiac disease is that its symptoms

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<sup>65</sup>Barrett, Kim E. and Dean D. Metcalfe. "Immunologic Mechanisms in Food Allergy." *Food Allergy*. Eds. Lawrence T. Chiaramonte, Arlene T. Schneider, and Fima Lifshitz. New York: Marcel Dekker, Inc., 1988, pp. 35-36.

<sup>66</sup>Perkin, Judy E. "Adverse Reactions to Food Additives and Other Food Constituents," *Food Allergies and Adverse Reactions*. Ed. Judy E. Perkin. Gaithersburg, Maryland: Aspen Publishers, Inc., 1990, p. 151.

<sup>67</sup>Lowell, Jax Peters. *Against the Grain*. New York: Henry Holt and Company, 1995, pp. 11-13.

<sup>68</sup>Id.

<sup>69</sup>Perkin, "Adverse Reaction," p. 156.

<sup>70</sup>Lowell, pp. 11-13.

<sup>71</sup>Gorman, Christine. "Against the Grain: Some folks can't stomach the gluten found in cereals. It may be hurting their head as well," *Time*. February 26, 2001, p. 77.

can be unpredictable and can mimic those of other problems.<sup>72</sup>

Of greater concern may be the increased risk of lymphoma recognized in celiacs who continue to eat gluten.<sup>73</sup>

While the occasional mistake on a gluten free diet is expected, those that purposely continue to eat food containing gluten run the risk of either refractory sprue, or lymphoma.<sup>74</sup> While it seems obvious that people would not take this risk, many do unknowingly because they do not experience the gastrointestinal symptoms of the disease which warn them if they are ingesting gluten. For this reason, strict, life-long adherence to the diet upon diagnosis is a must.

Beyond the gastrointestinal symptoms, a gluten intolerance is also to blame for a skin condition called dermatitis herpetiformis (DH).<sup>75</sup> Most generally, those with DH, if examined, would show signs of intestinal damage, while the reverse is not necessarily the case. DH is characterized by itchy, globular blisters most often appearing on the knees and elbows. While treatment with medication has been shown to be successful in abating the symptoms of DH, the same can not be said of the gastrointestinal symptoms.<sup>76</sup> It is quite likely that those with DH who do not go on a gluten free diet, but instead choose only to use medication, continue to damage their intestines, perhaps without even knowing it.

Therefore, like all of the allergies mentioned above, the only safe and proven treatment for a gluten allergy is elimination of the offending food from the diet. The gluten free diet is among the most tricky. Like all of the above ones, the hardest part is dealing with processed and packaged foods. The allergy sufferer must rely on the ingredient label when deciding what is safe to eat.<sup>77</sup> But unlike some of the other foods, gluten can be much more invidious. It can be in vinegar, modified food starch, hydrolyzed vegetable protein, and

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<sup>72</sup>Id.

<sup>73</sup>Falchuk, p. 191.

<sup>74</sup>Id.

<sup>75</sup>Id.

<sup>76</sup>Id.

<sup>77</sup>Jax Peters Lowell lists the following as her “Basic Rule No. 2” in dealing with a gluten intolerance, “Read labels carefully. Never eat a meal or a packaged food if you don’t know what’s in it. If there’s no label, ask for it. If it’s not available, don’t risk it,” p. 20.

malt just to name a few of the unexpected sources.<sup>78</sup> The advice of some experts boils down to this, “the more processed the product, the more risk it contains... And, conversely, the fresher the food, the better your chances of being able to eat it.”<sup>79</sup>

This entire discussion, culminating in the above quote was designed to show just how burdensome having a food allergy can be. It is easy to say that those with a food allergy are lucky because their problem is identifiable and treatable. Their symptoms are not fatal, and they have no “disease” per say, but the reality is that managing a food allergy in today’s world of fast food and convenience is a huge undertaking.

Those suffering from a food sensitivity, must be wary of everything that goes into their mouth. It is a constant concern. While cooking all of their own food from scratch is certainly an option, is not a very realistic one. Most people rely on processed and pre-packaged foods at least to some extent, mostly out of convenience. While many of these foods are safe for those with a specific allergy, the only way of knowing is by reading the ingredient label in search of any offensive allergens. Anyone who has looked at an ingredient label on a processed food product lately knows that they are harder than they seem to decipher.

It is important that ingredient labels list, in the common name, any ingredients which could possibly contain allergens. Obviously, the safest thing for manufacturers to do would be to place a warning on the label to the effect that they cannot be certain that the food is free from allergy causing ingredients, but this is unnecessarily broad and limits people’s choices too severely. Some compromise should be met between the need for comprehensive labeling on the part of food allergy sufferers and the fear of manufacturers of liability. Of great concern is the possibility of cross contamination during production. The only remedy is safe production practices which protect the allergy sufferer.

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<sup>78</sup>Id., pp. 22-23.

<sup>79</sup>Id., p. 29.

### III. American Regulatory Scheme and Industry Response

Having shown the seriousness of food allergies, the remaining portion of this paper will focus on what the government and the food industry have done to address the need for proper ingredient labeling. The focus will be on the United States, but the paper will include a brief comparison to the regulatory scheme and industry response in Canada.

For much of its history, the Food and Drug Administration (“FDA”), which is entrusted with the oversight of food labeling in the United States, did not concern itself with the proper identification of allergens in food. In fact, for many years, labeling was optional, and only if it was undertaken by the manufacturer was it examined for accuracy.<sup>80</sup> This changed with the passage of the Federal Food Drug and Cosmetic Act of 1938. That Act stated that a food would be considered misbranded “unless the label bears (1) the common or usual name of the food, if any there by, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient...”<sup>81</sup> Since that time, the public has relied on the FDA to enforce this labeling requirement. While it may have been passed, due to the historical conditions, in response to concerns over food cleanliness and safety, it is currently relied on by allergy sufferers as a way to ensure that their food is properly labeled so as to avoid any possible adverse reactions.

Currently the FDA is responsible for enforcing the regulations concerning food labeling as outlined in Chapter 21 of the Code of Federal Regulations. The provisions are lengthy, but it is important to examine them closely to see exactly what is covered by the labeling laws and what is not. For even though the above proclamation sounds all encompassing, there are many things exempt from the strict labeling requirement, and it is these exceptions which can cause trouble for allergy sufferers.

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<sup>80</sup>FDA, “The Story of the Laws Behind the Labels” (visited Feb. 24, 2001) <<http://www.cfsan.fda.gov/~lrd/history1.html>>.

<sup>81</sup>Federal Food, Drug, and Cosmetic Act of 1938 §403 (i), 21 U.S.C. §§301 et seq.



The basic ingredient labeling provisions are laid out in the Code of Federal Regulations (“CFR”) beginning at §101.4, entitled “Food; designation of ingredients.” This provision requires all ingredients to be listed on the label of a food in descending order of predominance.<sup>82</sup> The name used for identifying the ingredient is supposed to be the specific and not a generic name.<sup>83</sup>

This appears to be excellent evidence of a comprehensive ingredient labeling scheme, but the exceptions begin from the start of the provision. The first section exempts from labeling all ingredients listed in §101.100.<sup>84</sup> The second provision lists other exemptions to the specific naming requirement, the biggest being that spices, artificial flavors, and natural flavors, as defined in §101.22, are allowed to be listed in their collective form rather than individually.<sup>85</sup> §101.4 also goes onto to list other exemptions to this strict labeling requirement without further reference to other parts of the regulations. It is necessary to consider each set of exceptions separately.

The first set laid out in §101.100, is quite broad in its scope. The first significant exemption is described as follows:

An assortment of different items of food, when variations in the items that make up different packages packed from such assortment normally occur in good packing practice and when such variations result in variations in the ingredients in different packages, with respect to any ingredient that is not common to all packages. Such exemption however, shall be on the condition that the label shall bear, in conjunction with the names of such ingredients as are common to all packages, a statement (in terms that are as informative as *practicable* and that are not misleading) indicating by name other ingredients which *may* be present. (*emphasis added*)<sup>86</sup>

On first glance, this provision seems very reasonable, but when read with an eye to the possible effects on an food allergy sufferer, it is more problematic. This provision allows manufacturers to vary slightly

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<sup>82</sup>21 C.F.R. §101.4(a)(1).

<sup>83</sup>21 C.F.R. §101.4(b).

<sup>84</sup>21 C.F.R. §101.4(a)(1).

<sup>85</sup>21 C.F.R. §101.4(b).

their production processes and ingredients used without having to account for it specifically in their product labels. This is one of many provisions in the code which legally lets manufacturers off by allowing them to use a “may contain” statement which covers all of their bases. The problem with such statements, as mentioned above and as will be discussed further below, is that such claims severely limit the choices of allergy sufferers. Because they cannot be sure which ingredients are used in any given batch of food, they must stay away from the food entirely for fear of a possible reaction.

Another provision in the same section of the code also creates a lot of “wobble room” for manufacturers. It states that “incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food” are not required to be listed on the label.<sup>87</sup> It goes on to list examples including “substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect.”<sup>88</sup> Processing aids are another huge category, exempting things added to the food during processing but not present in the final product and substances which migrate to the food from equipment or packaging.

The most obvious concern is the use of the term “insignificant levels.” For some allergy sufferers, there is no such thing, the mere inhalation of the offending food can cause a severe reaction and even death. This is even more dangerous than the “may contain” labels made possible by the previously discussed provision. At least with a “may contain” statement, a consumer can avoid the food, however unnecessarily. If trace amounts of an allergen are not listed though, it could be disastrous for an individual.

The second biggest group of exceptions is found in §101.22. There the regulations state that spices, artificial flavorings, and natural flavorings can be listed by those collective names on food labels.<sup>89</sup> It goes on to say

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<sup>87</sup>21 C.F.R. §101.100(a)(3).

<sup>88</sup>Id.

<sup>89</sup>21 C.F.R. §101.22(h)(1).

that incidental amounts of such things need not be placed on the label at all. Incidental is defined as those things falling into the exceptions examined above in 21 CFR 101.100(a)(3).<sup>90</sup>

This paper has not examined allergies to artificial ingredients, but it can indeed be problematic if the specific ingredients are not listed on the label. The natural flavorings dilemma is most relevant to the allergies examined by this paper. The Code defines natural flavorings as,

the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf, or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products there of, whose significant function in food is flavoring rather than nutritional.<sup>91</sup>

These obvious problems are for people with a milk, egg, or seafood allergy. If natural flavorings derived from these substances do not have to be listed, then the consumer with an allergy must avoid all such products containing “natural flavorings.” A less obvious example is that fermentation of products could be done with wheat, and yeast can be made with wheat as well, dooming the wheat allergic to the same fate of foregoing products with natural flavorings so as not to risk a reaction. While these are all things that do not even enter the mind of the average consumer, for those with food allergies, every label has to be scrutinized for such descriptions.

One last example in the code which shows how the exceptions are problematic for those with food allergies is also in §101.4. The section goes on to list various things which are deemed appropriately labeled if done so with words indicating that they may or may not be present, such as “or”, “and/or”, or “contains one or more of the following:”.<sup>92</sup> All of these things create doubt for those with allergies. Again, the product may

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<sup>90</sup>21 C.F.R. §101.22(h)(2).

<sup>92</sup>21 C.F.R. §101.4(b)(16-19).

not actually contain the offending ingredient, but if it is suspected that it might, then it must be avoided altogether.

On its website, the FDA gives some advice to food manufacturers in the form of a question and answer sheet about ingredient labeling. There it refers to another exception in §101.4. It states that, “listing alternative fat and oil ingredients (“and/or” labeling) is permitted only in the case of foods that contain relatively small quantities of added fat or oil ingredients (foods in which added fats or oils are not the predominant ingredient) and only if the manufacturer is unable to predict which fat or oil ingredient will be used.”<sup>93</sup> It goes on to give an example of an appropriate label, “Ingredients:... Vegetable Oil (contains one or more of the following: Corn Oil, Soybean Oil, or Safflower Oil)...”<sup>94</sup> The food given in the example would have to be avoided if someone had a soybean allergy.

All of these examples show that the labeling requirement, while perhaps adequate to protect the public from unsafe food, is wholly inadequate in dealing with possible allergens. There are so many exceptions that those with allergies end up having to forego countless products for fear of the unknown. The next logical question is whether or not something should be done about it, and if so, what.

Obviously, one solution would be to mandate the listing of every ingredient in the product, no matter how trivial. The problem with this alternative is that it could bog down the consumer in unnecessary information. Ingredient labels on processed foods already are lengthy, add to them every natural flavor and trace ingredient and the consumer may very well be overwhelmed. This alternative also has problems because it could lead to the revealing of valuable propriety secrets in the form of recipes and formulas.

Another solution would be to require manufacturers to state if their products contained any of the most common allergy inducing foods discussed in the first part of this paper (namely; peanuts, treenuts, milk,

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<sup>93</sup>21 C.F.R. §101.4(b)(14).

<sup>94</sup>FDA, “A Food Labeling Guide” (visited Feb. 24, 2001) <<http://vm.cfsan.fda.gov/~dms/flag-4.html>>.

soy, egg, wheat, and fish or shellfish). This solution would be much more user friendly as a consumer could quickly and easily identify if a particular food contained any allergens. The actual reactions of both the government and the food industry have been a mixture of these two approaches.

A recent article stated that,

Processors are under the gun to ensure that today's products contain what they say they do and, in the case of food allergies, don't contain what they don't disclose. And while food companies have made significant strides in dealing with the issue, considerable work remains to be done. Food allergen control, by all accounts, is a growth industry.<sup>95</sup>

While it may be safer for manufactures to use "may contain" statements on their products, they do so at the risk of alienating a growing segment of the consuming public, those with allergies. The effect can be larger than expected if you consider that some households which contain only one member with a food allergy forego a food completely either in support of the allergy sufferer, or simply because it is easier and safer. It could also be the case that if the person predominantly doing the grocery shopping for a family is an allergy sufferer, he or she will forego questionable products in favor of ones known to be safe.

While it is true that major companies have begun to invest a considerable amount of time, energy, and money into addressing problems of allergens in foods, industry wide, there is still a lot of progress to be made.<sup>96</sup> The biggest advance thus far has been the realization by food companies that by improving their manufacturing procedures, they can ensure that their products will be allergy free for their consumers. The key to an allergen control program is good manufacturing practices and a thorough sanitation program.<sup>97</sup> The problem however, is in convincing food producers that the extra effort is worth making. General Mills, a leader in allergen control, has gone so far as to commission

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<sup>96</sup>Id.

<sup>97</sup>Id.

an employee training video that features coworkers and their family members who suffer from food allergies. The point: an allergen-related food recall isn't just a public-relations black eye and a financial cost for manufacturers. It could result in death for a colleague or loved one.<sup>98</sup>

This was the basic point of the first part of this paper, and nearly any article on food allergen control for that matter, showing the audience, whoever that may be, how devastating a food allergy can be before you go on to address the issue of treatment or control of the problem. It is hard to convince people to address a problem without first educating them about the seriousness of it.

Once a company decides to focus on allergen control, there is a lot to consider. The manufacturers are realizing, by experience, that labels listing artificial flavorings or natural flavorings can be dangerous for allergy sufferers. An anecdote will help illustrate this point. Robert Humbert, manager of food safety at the Kellogg Company described what he considered to be the turning point in Kellogg's approach to allergen labeling. It appeared that doctors were recommending Kellogg's Rice Krispies Treats cereal as a good choice for those with milk allergies. However, shortly after the cereal was introduced, Kellogg began receiving countless calls about adverse reactions. Humbert then, "carefully reviewed the cereal's ingredients and found a butter flavoring that contributed less than one percent milk protein to the product. Kellogg had labeled the product as containing "natural and artificial flavors... which was legal labeling, but inadequate to protect the sensitive consumer."<sup>99</sup> He went on to say that Kellogg changed the label to list the butter flavor and sponsored a bulletin sent to members of the Food Allergy Network. He states that, "tracking allergens in flavorings is a real challenge due to the diversity of flavor ingredients and the proprietary nature of their formulas."<sup>100</sup>

As stated above, the first initial reaction of putting may contain statements on the labels of questionable

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<sup>99</sup> "Manufacturers Stress importance of Allergen Labeling," Food Labeling News. Vol. 5, No. 6, November 14, 1996, *available in* WESTLAW, 1996 WL 14383020.

<sup>100</sup>Id.

foods, is not an appropriate response. Anne Munoz-Furlong, founder and CEO of the Food Allergy Network, is concerned that such labels will severely limit the choices of those with food allergies. She cites an example, “where every one of the major allergens except fish and shellfish was covered on an ingredient panel with ‘This product may contain’ language... That could cause people to ignore ingredient panels altogether, and it raises questions about how thoroughly the manufacturer cleans its equipment.”<sup>101</sup> Such labels, done to cover all the bases of the manufacturer, leave the allergy sufferer without much choice in the supermarket. Fortunately, some major manufacturers have taken notice and are making strides.

General Mills, a leader in allergen control, agrees that “may contain” labels are counter productive. One of its doctors, Dr. Thomas Trautman, states that “food manufacturers absolutely must avoid the temptation to use labels, particularly ‘may contain’ labeling as an alternative to good manufacturing practices. He went on to say that “recent reactions to ingredients in flavors dictate that food manufacturers not only can, but absolutely should (label these ingredients) to make sure there are no levels of allergens in a product that are unlabeled.”<sup>102</sup> It is his belief that the FDA is not far from requiring food manufacturers to do this anyway. Of primary concern is the cleanliness of the production line. Most manufacturers do not have the ability to have separate facilities dedicated solely to producing allergen free food, so other alternatives have to be implemented. Campbell Soup Co.’s director of toxicology and analytical services, George Dunaif, suggests that any plan to address allergen control, must be a team effort. It cannot be done effectively by involving just one part of the company. The marketing department should be involved to help people understand the need for proper allergen control. The engineering department needs to be a primary player as well. As manufacturers have moved to focusing on allergens in their products, they have noticed that a big problem in addressing the issue is that many machines used for food production are not designed with allergen control in mind, meaning that they are difficult to clean completely. General Mills has gone so far as to install

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<sup>101</sup>Higgins, p. 78.

<sup>102</sup> “Manufacturers Stress Importance of Allergen Labeling,” 1996 WL 14383020.

doors into existing machinery to provide access for cleaning and visual inspection.<sup>103</sup> A better alternative would be to have equipment which was built with an eye to allergen control, and which would not have to be altered by the food manufacturer itself.

Other companies have gone even further. At the Austin Packaging Co., in Austin, Minnesota, they recently completed construction on a 7,500 sq. ft. allergen-controlled processing and packaging room. Tracy Bridgeman, Austin's technical services manager, stated that extensive thought had to go into designing the facility. She states, "Isolated personnel flow, supplies, product storage, and ingredient control are critical control points to preventing cross-contamination... Positive-pressure HEPA-filtered air is another key to preventing contamination."<sup>104</sup> To give a specific example of the lengths to which they are going to ensure allergen free foods, she states that "allergen ingredients such as peanut sauce are stored independently and under lock and key to further prevent possibilities of error. 'And there are only two keys to the ingredient storage lockers in the plant, both held by management.'"<sup>105</sup>

While all of these above programs help ensure that the initial product line is allergen free, or alternatively, appropriately labeled as containing an allergen, there is another concern which arises when manufacturers change their formulas to include allergens. It is necessarily the case that after searching for a product that is safe to eat, whether it be ketchup, mayonnaise, or a salad dressing, a consumer with an allergy will continually buy that same product. All allergy sufferers are warned to read the labels of everything they buy every time they shop, but in the real world, this does not happen.<sup>106</sup> Many people have a hard time finding time to grocery shop anyway without the added time needed to read all the labels on their chosen products. This is particularly the case, if the consumer has read the label a few times, each time to be reassured that the product is safe. Steve Taylor, a food allergy researcher at the University of Nebraska, suggests that

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<sup>103</sup>Higgins, p. 78.

<sup>104</sup>"Allergen Awareness," Food Engineering. May, 1999, p. 18, *available in* LEXIS, News Library, Food Engineering & Ingredients File.

<sup>105</sup>*Id.*

<sup>106</sup>Lowell, p. 28.



manufacturers who change their formulas to include an allergen where previously there was none make such changes obvious to their consumers.<sup>107</sup>

It seems clear that the industry has made significant strides in dealing with food allergies on its own out of concern for its consumers and also the desire to avoid liability and keep customers. The larger companies have a great advantage in doing this, however. Smaller companies may not take the necessary steps absent some government intervention.

While the FDA has not changed the regulations to reflect the need for mandatory listing of allergens on food labels, it has adopted a policy of recalling foods containing allergens that are not appropriately marked. In June of 1996, the FDA issued an Allergy Warning Letter to Manufacturers entitled, "Label Declaration of Allergenic Substances in Foods." Written by Fred R. Shank, Director of the Center for Food Safety and Applied Nutrition, the advisory letter announced that it was receiving complaints of adverse reactions to manufactured foods. It stated that, "These exposures occurred because the presence of the allergenic substance in the food was not declared on the food label."<sup>108</sup>

It is the FDA's position that the foods were not appropriately labeled because of manufacturers' misinterpretations of the exceptions to complete ingredient labeling set out in the regulations, specifically in the aforementioned 21 CFR 101.100(a)(3) and 21 CFR 101.22(h)(1).<sup>109</sup>

In its discussion of the exceptions in 21 CFR 101.100(a)(3) the FDA called attention to the fact that the regulation only exempts ingredients which are present at an insignificant level. The FDA stated its position clearly, that if the ingredient is an allergen, is it unlikely that it could ever be at an insignificant level,

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<sup>107</sup>"Manufacturers Stress Importance of Allergen Labeling," 1996 WL 14383020

<sup>108</sup>FDA, "FDA Allergy Warning Letter: Notice to Manufacturers, June 10, 1996," (visited Mar. 29, 2001) <<http://www.cfsan.fda.gov/~lrd/allerg7.html>>.

<sup>109</sup>*Id.*

“because evidence suggests that some allergenic substances can cause serous allergic responses in some individuals upon ingestion of very small amounts of the substance.”<sup>110</sup>

Similarly, the Administration recognizes that exceptions for natural and artificial flavorings and spices can pose problems for allergy sufferers as well. The letter points to the fact that in the past, the FDA has required ingredients covered by this exemption to be declared because they posed a risk to individuals citing FD&C Yellow No. 5 as an example.<sup>111</sup>

The letter goes on to state that the FDA is considering whether or not it needs to clarify the regulations to reflect this policy or whether the current law addresses the problem. It advises manufacturers that precautionary labeling (“may contain” labels) should not be used in lieu of good manufacturing policies, it should only be used as a last resort, when it is truly impracticable to determine if an allergen might be present in a food.<sup>112</sup>

The biggest challenge, which the FDA recognizes, is determining which allergens to include in the labeling requirements and which ones are okay to ignore. The letter states that while the FDA has not adopted any official list or definition of allergens, it has provided guidance in a different policy statement to the effect that “milk, eggs, fish, crustacea, mollusks, tree nuts, wheat, and legumes (particularly peanuts and soybeans)” are the foods most commonly associated with adverse reactions.<sup>113</sup>

In a very recent (January 2001) posting to the FDA website, entitled “Food Allergen Monitoring,” the Administration states that ninety percent of food allergic reactions are caused by the eight common foods listed above.<sup>114</sup> This document uses even stronger language when admonishing the use of “may contain” labeling. It states that, “Precautionary labeling (“may contain”) can not be used in lieu of Good Manufacturing

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<sup>110</sup>Id.

<sup>111</sup>Id.

<sup>112</sup>Id.

<sup>113</sup>57 Fed. Reg. 22984 at 22987.

<sup>114</sup>FDA, “Food Allergen Monitoring,” (visited Mar. 29, 2001) <<http://www.cfsan.fda.gov/~dms/alrgfact.html>>.

Practice.”<sup>115</sup> In the past four years the FDA has shifted from discouraging, to forbidding the use of “may contain” labels absent a showing of good reason for it.

It seems as though the FDA has realized that the regulations contain loopholes for those who live with allergies and it has tried to address them, not only with letters and advisories like those mentioned above, but also in practice by issuing more recalls and press releases. The FDA has three classes of recalls for use with varying levels of danger depending on the product involved. Class I is reserved for those things which could pose a serious risk of injury or death to consumers. In recent years, the Administration has increasingly issued Class I recalls because of improperly labeled foods containing allergens.<sup>116</sup>

All of these things, the improvement of the manufacturers in addressing the problem of allergens, and the government’s increased interest in protecting the public from allergens, show that the “ingredients” are there for a sound federal policy dealing with food labeling. Just a few more steps would move the FDA by leaps and bounds towards fully protecting allergy sufferers. While the FDA has resisted changing the regulations to reflect the problem of allergens being improperly labeled, I think that it would help tremendously to have a clear statement in the regulations requiring manufacturers to declare the presence of allergens in their products regardless of the amount that may be present. I believe also that it would be beneficial for the FDA to officially adopt a list of allergens the presence of which manufacturers must declare on their food labels. This list could be updated from time to time to reflect the most current progress in the diagnosis and treatment of food allergies. While this is not an easy undertaking that can be taken lightly, I would argue that given the seriousness of food allergies, as highlighted in the beginning of this paper, it is worth the effort. Even if only a small percentage of the population is affected by food allergies, it warrants the attention of our government. It is not our practice in this country to protect only majority groups from possible health and safety dangers. In fact, it is in the case of things which affect only a small percentage of

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<sup>115</sup>Id.

<sup>116</sup>“Recalls for Undeclared Food Allergens Apparently Risking, FDA Official Says,” Food Labeling News. Vol. 5, No. 37, June 19, 1997, *available in* WESTLAW, 1997 WL 9737630.

the population that we most need the government's help. It needs to take a leadership role in this important issue in order for real change to take place.

#### IV. Canadian Regulatory Scheme and Industry Response

Not surprisingly, the response to the problem of food allergies and ingredient labeling in Canada has been quite similar. In 1997, the Canadian Government established the Canadian Food Inspection Agency (CFIA), which is responsible for the inspection and enforcement services formally performed by four different government agencies.<sup>117</sup> The CFIA's jurisdiction includes enforcing the labeling requirements on prepackaged food. In the short time that it has been in existence, the CFIA has taken on the challenge of ensuring that the foods Canadians buy are allergen free, or appropriately labeled as containing an allergen.

In March of 1998, the CFIA issued a letter to all manufacturers urging them to be more aware of their manufacturing and labeling policies so as to ensure that customers could be fully informed as to what they were eating.<sup>118</sup> The letter listed the most common food allergens, mentioned above numerous times; peanuts, tree nuts, sesame seeds, milk, eggs, fish, crustaceans, and shellfish, soy, wheat, and sulphites. The letter states,

the CFIA urges you to ensure that the above foods are included in the ingredient list on your labels when present as ingredients or components. To further assist consumers in making safe food choices, the CFIA encourages you to identify the plant source of ingredients, such as plant proteins, starches, modified starches and lecithin (e.g. hydrolysed soy protein, wheat starch, modified wheat starch, soy lecithin).

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<sup>117</sup>CFIA, "The Canadian Food Inspection Agency: Contributing to the Quality of Canadian Life," (visited on Feb. 26, 2001.) <<http://www.cfia-acia.agr.ca/english/corpaffr/publications/prog/agence.shtml>>.

<sup>118</sup>CFIA, "Labelling of Foods Causing Allergies and Sensitivities," (visited on Mar. 26, 2001) <<http://www.dfia-acia.agr.ca/english/bureau/inform/19980331be.shtml>>.

The Agency realizes, that there are many reasons why an allergen may not be labeled on a food product. Some are the fault or responsibility of the manufacturer, such as carry-over of an allergen due to incomplete cleaning of equipment, or incorrect labeling, but another reason is because, like the US regulations, the Canadian ones leave loopholes in the ingredient labeling rules which allow some potential allergens to be left off of the label.<sup>119</sup> The agency also recognizes both the value and downside to using precautionary labeling as a way to avoid possible adverse reactions to foods. It states that the “policy allows the food industry to voluntarily label products that may inadvertently contain substances capable of causing severe adverse reactions,” however, “Precautionary labeling must be truthful and must not take the place of good manufacturing practices.”<sup>120</sup>

It will be informative to examine the key regulations which govern ingredient labeling in Canada, to see how they compare with the FDA’s policies. The most important provisions are C.R.C., C. 870, §§ B.01.008 – B.01.011.

§B.01.008 is the most basic provision calling for the listing of all ingredients on food labels subject to some specific exemptions for things like individual servings of packaged foods and things packaged and sold on the same premises. This section also states that components of foods (ingredients of ingredients) are to be listed on the label as well.<sup>121</sup>

The next section goes on to list some exceptions to the component labeling requirement. § B.01.009 lists many different exceptions, but the most interesting, for the purposes of this paper, are ones such as starches or modified starches and hydrolysed plant protein.<sup>122</sup> Both of these substances, as discussed more fully be-

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<sup>119</sup>CFIA, “Labelling of Foods Causing Allergies And Sensitivities,” (visited on Feb. 26, 2001) <<http://www.cfia-acia.agr.ca/english/corpaffr/foodfacts/allergense.shtml>>.

<sup>120</sup>Id.

<sup>121</sup>C.R.C., C. 870, s. B.01.008.

<sup>122</sup>C.R.C., C. 870, s. B.01.009.

low, can contain allergens. This same section also contains exceptions for spices, seasonings, and flavorings, which simply can be listed by those names without disclosing the individual ingredients.<sup>123</sup> This is further reiterated in the next section which lists the common names for foods which are to be used on ingredient labels.<sup>124</sup> One last example of a problem in the regulations is in §B.01.011 which allows manufacturers to vary the ingredients used in a food product by using a label that informs the customer that the food may or may not contain certain ingredients.<sup>125</sup> All of these regulations mirror those in the United States, as do the resulting problems.

An article published in 1999 (and cited above numerous times in support of the seriousness of food allergies and the symptoms involved) entitled, “Common Allergenic Foods and Their Labelling in Canada – A Review,” deals intelligently with the loopholes caused by the Canadian regulations. Nearly two thirds of the article is devoted to examining the most common allergens discussed above and how elimination of the offending food from the diet is the only sure method of preventing an adverse reaction. This naturally leads to the question of ingredient labeling because those labels hold the key to successful elimination of the allergen.<sup>126</sup>

The biggest problem with the Canadian labeling regulations, according to the authors, is that it allows the use of class names and unspecific common names on food labels.<sup>127</sup> The class names include the use of things such as flavors, colors, seasonings, and spices. The authors state, “Such foods, particularly seasonings and flavors, often contain ingredients such as wheat, milk, egg derivatives, etc.”<sup>128</sup> The authors go on to state that,

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<sup>123</sup>Id.

<sup>124</sup>C.R.C., C. 870, s. B.01.010.

<sup>125</sup>C.R.C., C. 870, s. B.01.011.

<sup>126</sup>Zarkadas, p. 131.

<sup>127</sup>Id.

<sup>128</sup>Id.

Although such names may give flexibility to the manufacturer, they severely limit the choice of foods that can be purchased by individuals with adverse reactions, since many avoid all foods identifying only “seasoning” or “flavoring” on the label because of their desire to be safe rather than sorry.<sup>129</sup>

The use of these vague terms can be dangerous to the allergy sufferer who has to look not only at the printed ingredients but potentially hidden sources of an allergen.

The article goes on to address the issue of unspecific common names, the two most dangerous being hydrolyzed plant proteins and food starches, as mentioned above. The authors correctly point out that hydrolyzed plant proteins do have to have their source listed if they are manufactured by enzymatic hydrolysis, but if not, then they can just use this common name.<sup>130</sup> The dilemma for allergy sufferers is that these plant proteins could come from soy, wheat, corn, or even peanuts. Without knowing the source of the protein, it is not safe for any allergy sufferer to consume such foods.<sup>131</sup>

A similar problem occurs with the starches. Many labels say “modified food starch” without identifying what kind of starch it is. As with the hydrolyzed plant proteins, they could be from wheat or corn. Without proper labeling, someone with a gluten allergy for instance, would have to forego the food altogether.<sup>132</sup> The article goes on to state that manufacturers are starting to take notice of the problem, but concludes with some specific recommendations.

The authors suggest that the eight foods discussed above, always appear on labels in their common name. They would also like to see the plant source of starches and hydrolyzed plant proteins, as well as lecithins identified. Lastly, they urge food manufacturers to develop allergen prevention plans to help manage the risk to allergy sufferers of unintentional ingestions of an allergen.<sup>133</sup>

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<sup>130</sup>Id. See also C.R.C., C. 870, s. B.01.010, which states this requirement.

<sup>131</sup>Id.

<sup>132</sup>Id., p. 132.

<sup>133</sup>Id., p. 134.

It appears that the Canadian regulatory scheme has made about as much progress as the FDA has in addressing the need for the proper labeling of allergens in prepackaged foods. Both countries have started to realize the need for a more proactive stance to protect allergy sufferers not only from mistaken ingestion, but also from being “over-protected” by precautionary labeling. As for the industry response, the Canadian manufacturers have started to respond to the challenge as well.

The Anaphylaxis Foundation of Canada (“AFC”) recently awarded Tiffany Gate Foods, Inc., a Toronto based company, with its “Partner in Anaphylaxis Safety” award.<sup>134</sup> The award is meant to honor those companies that meet high standards of allergen prevention in particular and food safety in general. Some of the criteria include implementing policies concerning the management of allergens, establishing programs to respond to consumer and regulatory inquiries, identifying risks in the production process, establishing an allergy management plan, and managing diligently an ingredient labeling policy.<sup>135</sup> But beyond taking measures to ensure the safety of the food sold to the general public, Canada is the home of many food manufacturers which have developed to cater specifically to those with food allergies.

A good example of such a company is Kingsmill Foods. Kingsmill is Canada’s leading manufacturer of foods for people with special dietary needs.<sup>136</sup> The company offers “a line of special dietary foods for people with food allergies, lactose intolerance, celiac disease, kidney disease, metabolic disorder, and a swallowing disorder known as dysphagia.”<sup>137</sup> The President of the company, Dorian Kingsmill says that her company strives to give people suffering from the above problems the luxury of choice in their diet, something that is

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<sup>134</sup>“Tiffany Gate Foods formally recognized as a leader in allergen management and prevention,” Canada News Wire. March 13, 2001, *available in* LEXIS, Canadian News Library, Canadian Publications File.

<sup>135</sup>*Id.*

<sup>136</sup>“Canadians’ Demand for “Special” Foods is Key to Success for Kingsmill Foods,” Canada News Wire. June 7, 1999, *available in* LEXIS, Canadian News Library, Canadian Publications File.

<sup>137</sup>*Id.*



often missing for allergy sufferers.<sup>138</sup>

## V. Conclusion

This brief look at the Canada's response to the problem of unidentified allergens in prepackaged foods, is encouraging in that it appears that the United States through the FDA is taking the lead in this area. But, that is also a big responsibility. The world is watching what the United States does in this area. Indeed, that is another of the problems with ingredient labeling, the lack of any strict international standards. Recent news from Australia and New Zealand seems to indicate that they are on the way to requiring food labels to detail allergenic ingredients, no matter how slight their presence.<sup>139</sup> But by and large, the world waits, as in many arenas, to see what the United States will do first.

It is clear that any new regulatory scheme will face opposition from manufacturers as over broad and too burdensome, but it seems as though the time has come. The United States should step up to the plate and pass a regulation requiring the inclusion of allergens on ingredient labels regardless of the amount of allergen in the food. This regulation would put some teeth into the FDA's current policy of doing this already. This one step would make a huge difference in the lives of allergy sufferers in the United States of course, but also likely around the world. They could buy more products safe in the knowledge that they will not make them sick. This regulation would have to be joined by a continued effort on the part of manufacturers to

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<sup>138</sup>Id.

<sup>139</sup>Pritchard, Chris. "Australia Gets Into Designer Labels," Medical Post, November 28, 2000, p. 31, *available in* LEXIS, Canadian News Library, Canadian Publications File.

practice good manufacturing policies and reduce the risk of allergen contamination in their products. There is still a lot of danger out there for the allergy sufferer, going to eat at a restaurant is an obvious one, but it is unlikely that the FDA can control that at least for now. Most experts agree with Fred Shank, Director of the Center for Food Safety and Applied Nutrition who says, “I feel for the patient, but [imposing allergen rules for restaurants] goes a lot farther than what the FDA can do.”<sup>140</sup> For now, the allergy sufferer should be happy with the direction in which the FDA is moving. The current policies are an important step towards ensuring that all allergy sufferers feel safe with the food they buy in stores and prepare at home.

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<sup>140</sup> “FDA Asks Food Processors For Help In Addressing Undeclared Allergens In Food,” Food Labeling News. Vol. 5, No. 17, January 30, 1997, *available in* WESTLAW, 1997 WL 9737231.