

---

---

COMMENT

---

---

---

---

MAY CONTAIN: ALLERGEN LABELING REGULATIONS

---

---

SARAH BESNOFF<sup>†</sup>

INTRODUCTION .....	1466
I. HISTORY OF ALLERGEN-LABELING LAWS AND REGULATIONS .....	1472
II. CASCADING PROBLEMS: NO THRESHOLDS, NO GMPs, AND NO ADVISORY LABELING .....	1476
A. <i>No Thresholds</i> .....	1476
B. <i>No GMPs</i> .....	1478
C. <i>No Advisory Labels</i> .....	1480
D. <i>Cascading Problems Lead to Uninformed Consumers</i> .....	1482
1. <i>Advisory Labels Are Currently Meaningless</i> .....	1483
2. <i>Food Producers Are Permitted to Opt Out of Protecting Food-Allergic Consumers</i> .....	1484
III. CONSUMER-FOCUSED SUGGESTIONS FOR THE FDA REGARDING CONTAMINATION LABELING .....	1486
A. <i>The FDA Should Establish Thresholds for Major Allergens</i> .....	1486
B. <i>The FDA Should Incorporate Thresholds into Amended GMP Regulations and Increase Enforcement Efforts</i> .....	1488
1. <i>Goal #1: Detecting Cross-Contact</i> .....	1489
2. <i>Goal #2: Preventing Cross-Contact</i> .....	1489

---

<sup>†</sup> Comments Editor, Volume 162, *University of Pennsylvania Law Review*. J.D., 2014, University of Pennsylvania Law School; M.P.A., 2011, Fels Institute of Government, University of Pennsylvania; B.A., 2009, Barnard College. I am grateful to Kirsten Boreen, Stephanie Moran, Tian Wen, and the editors of the *Law Review* for their support and guidance. I thank Larry Besnoff, Teresa Gavigan, Eric Stahl, and Harper Seldin for their thoughtful feedback. I also thank Professor Peter Grossi for his advice and assistance with this Comment.

As someone with peanut, soy, nut, and chickpea allergies, I am grateful to the *Law Review* for the opportunity to expose this issue to a wider audience.

C. <i>Advisory Labeling Should Be Standardized and Should Reflect Thresholds and GMPs</i> .....	1491
CONCLUSION.....	1492

## INTRODUCTION

Nausea; hives; swelling of eyes, nose, and throat; lung failure;<sup>1</sup> and possibly death<sup>2</sup>—these are the symptoms food allergy<sup>3</sup> sufferers can endure if they consume their respective food allergen.<sup>4</sup> Food allergies affect between

---

<sup>1</sup> These symptoms reflect the wide spectrum of potential reactions a person with food allergies can suffer when exposed to an allergen depending on that person's level of sensitivity. See Ray Formanek Jr., *Food Allergies: When Food Becomes the Enemy*, FDA CONSUMER MAG., July–Aug. 2001, available at [http://permanent.access.gpo.gov/lps1609/www.fda.gov/fdac/features/2001/401\\_food.html](http://permanent.access.gpo.gov/lps1609/www.fda.gov/fdac/features/2001/401_food.html) (listing common symptoms of food allergies).

<sup>2</sup> See generally Hugh A. Sampson et al., *Fatal and Near-Fatal Anaphylactic Reactions to Food in Children and Adolescents*, 327 NEW ENG. J. MED. 380 (1992) (analyzing six fatal cases of allergic reactions to food); John W. Yunginger, *Lethal Food Allergy in Children*, 327 NEW ENG. J. MED. 421 (1992) (concluding that the vast majority of the fatal cases cited by Sampson et al. occurred in public places or schools); John W. Yunginger et al., *Fatal Food-Induced Anaphylaxis*, 260 JAMA 1450 (1988) (identifying and analyzing seven cases of fatal food allergy reactions).

<sup>3</sup> For the purposes of this Comment, I define “food allergy” as an adverse reaction of immediate hypersensitivity to food due to a specific immune response. I rely primarily on the definition proposed by the National Institute of Allergy and Infectious Diseases (NIAID). NIAID defines a food allergy as “an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food.” NAT’L INST. OF ALLERGY & INFECTIOUS DISEASES, GUIDELINES FOR THE DIAGNOSIS AND MANAGEMENT OF FOOD ALLERGY IN THE UNITED STATES: SUMMARY OF THE NIAID-SPONSORED EXPERT PANEL REPORT § 2.1.1 (2010), available at <http://www.niaid.nih.gov/topics/foodAllergy/clinical/Documents/FAGuidelinesExecSummary.pdf> [hereinafter NIAID REPORT]; *What Is Food Allergy?*, NAT’L INST. ALLERGY & INFECTIOUS DISEASES (Nov. 8, 2010), <http://www.niaid.nih.gov/topics/foodAllergy/understanding/Pages/whatIsIt.aspx> (“Food allergy is an abnormal response to a food, triggered by the body’s immune system. . . . The binding of IgE antibodies to specific molecules in a food triggers the immune response.”). I do not focus on the separate issues of food intolerances or delayed hypersensitivity reactions. For a great summary contrasting these three, see Laura E. Derr, *When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004*, 61 FOOD & DRUG L.J. 65, 67-69 (2006) (explaining the differences between food intolerances (e.g., lactose intolerance), immediate hypersensitivity (e.g., food allergies), and delayed hypersensitivity reactions (e.g., celiac disease)).

<sup>4</sup> Food allergens are generally defined as “those specific components of food or ingredients within food (typically proteins . . . ) that are recognized by allergen-specific immune cells and elicit specific immunologic reactions, resulting in characteristic symptoms.” NIAID REPORT, *supra* note 3, § 2.1.1; see also Henry Metzger, *Two Approaches to Peanut Allergy*, 348 NEW ENG. J. MED. 1046, 1046 (2003) (“[T]he fundamental basis of the mechanism of allergic reactions [is as follows]: a serum component (now known to be allergen-specific IgE) that is present in an allergic person but not in a nonallergic person combines with a receptor on mast cells of basophils (IgE receptor I). The reaction of the bound IgE with the specific allergen triggers the release of potent mediators such as the vasodilator histamine.”).

2%-9% of the U.S. population.<sup>5</sup> Each year, roughly 30,000 individuals require emergency room treatment, and roughly 150 individuals die from allergic reactions to food.<sup>6</sup>

Even minimal exposure to an allergen can cause an allergic reaction in some individuals. Currently, there is no known cure.<sup>7</sup> Despite some recent successes in medical trials of alternative treatments,<sup>8</sup> the primary option for

---

<sup>5</sup> The percentage of allergic persons in the United States fluctuates across different studies. General consensus places the percentages at around 2% of adults and 5% of children. *See* Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), Pub. L. No. 108-282, § 202(1)(A), 118 Stat. 905, 906 (codified at 21 U.S.C. § 343 (2012)) (stating that approximately two percent of adults and about five percent of infants and young children suffer from food allergies); NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, FOOD ALLERGY: AN OVERVIEW 3 (July 2012), available at <http://www.niaid.nih.gov/topics/foodallergy/documents/foodallergy.pdf> (“[A]most 1 in 20 young children under the age of 5 years and almost 1 in 25 adults are allergic to at least one food.”); THE THRESHOLD WORKING GRP., FDA, APPROACHES TO ESTABLISH THRESHOLDS FOR MAJOR FOOD ALLERGENS AND FOR GLUTEN IN FOOD 19 (2006) [hereinafter THRESHOLD WORKING GRP.], available at <http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/UCM192048.pdf> (estimating that “up to 6% of children and 4% of the total population have IgE-mediated food allergies”); Derr, *supra* note 3, at 70 (“While food allergies were thought to affect two to four percent of children and as few as one percent of adults as recently as ten years ago, the estimated prevalence of food allergies among both children and adults has more than doubled in the past five years.” (footnote omitted)); Ruchi S. Gupta et al., *The Prevalence, Severity, and Distribution of Childhood Food Allergy in the United States*, 128 PEDIATRICS e9, e11 (2011) (reporting that 8% of children have food allergies); Gideon Lack, *Food Allergy*, 359 NEW ENG. J. MED. 1252, 1252 (2008) (stating that approximately 6%-8% of children and less than 3% of adults have IgE-mediated food allergies); Katie Thomas, *Tiny Lifesaver for a Growing Worry*, N.Y. TIMES, Sept. 8, 2012, at B1 (citing a recent study finding that about one in thirteen children have a food allergy). *But see* Food Allergies, ASTHMA & ALLERGY FOUND. AM. (2005), <http://www.aafa.org/display.cfm?id=9&sub=20&cont=286> (finding that only “1 percent to 2 percent of adults have true food allergies”).

<sup>6</sup> *See* 21 U.S.C. § 343 note; *see also* FDA, FOOD ALLERGIES: WHAT YOU NEED TO KNOW 2 (2007), available at <http://www.fda.gov/downloads/Food/ResourcesForYou/Consumers/UCM079428.pdf> (stating that food allergies are responsible for “30,000 emergency room visits[,] . . . 2,000 hospitalizations[,] . . . [and] 150 deaths” every year); Donald Y.M. Leung et al., *Effect of Anti-IgE Therapy in Patients with Peanut Allergy*, 348 NEW ENG. J. MED. 986, 987 (2003) (reporting that 50 to 100 peanut-allergic persons in the United States die every year from unintended ingestion); Hugh A. Sampson, *Peanut Allergy*, 346 NEW ENG. J. MED. 1294, 1294 (2002) (“Food allergy accounts for about 30,000 anaphylactic reactions, 2000 hospitalizations, and 200 deaths each year in the United States.”); *Life Is No Picnic for Food Allergy Sufferers*, NAT'L INST. ALLERGY & INFECTIOUS DISEASE (July 22, 2010), <http://www.niaid.nih.gov/topics/foodAllergy/research/Pages/noPicnic.aspx> (reporting that 100 to 200 people in the United States die each year from severe food allergy-related reactions).

<sup>7</sup> *See* FALCPA § 202(2)(B) (citing the lack of a cure for food allergies to support Food and Drug Administration (FDA) regulations on labeling).

<sup>8</sup> *See* Katherine Anagnostou et al., *Assessing the Efficacy of Oral Immunotherapy for the Desensitization of Peanut Allergy in Children (STOP II): A Phase 2 Randomised Controlled Trial*, THE LANCET (2014) (corrected proof at 5), available at [http://dx.doi.org/10.1016/S0140-6736\(13\)62301-6](http://dx.doi.org/10.1016/S0140-6736(13)62301-6) (studying the impact of oral immunotherapy (the daily ingestion of a small amount of peanut protein) and reporting an 84% success rate in desensitizing peanut-allergic children to 800 mg protein of

those suffering from food allergies is still complete avoidance of the allergens themselves.<sup>9</sup>

To avoid allergens successfully, food allergy sufferers must be able to trust information provided by food producers and manufacturers.<sup>10</sup> The average individual does not produce his or her own food; instead, nearly everyone purchases food from grocery stores, farmers' markets, and other commercial suppliers and rely on food labels to determine whether a product is safe for consumption.<sup>11</sup> For food allergy sufferers, the ingredient labels on these packaged foods are lifelines to ensure their safety.<sup>12</sup>

In an effort to protect food allergy sufferers, Congress passed the Food Allergen Labeling and Consumer Protection Act (FALCPA) in 2004.<sup>13</sup> The

peanuts (roughly 5 peanuts)); A. Wesley Burks et al., *Oral Immunotherapy for Treatment of Egg Allergy in Children*, 367 NEW ENG. J. MED. 233, 234, 237 (2012) (testing an alternative therapy to "total avoidance" using a double-blind, randomized, placebo-controlled study, and finding that 28% of egg-allergic children who received oral immunotherapy (a clinically significant subset) sustained unresponsiveness to eggs after twenty-five months of therapy); Leung et al., *supra* note 6, at 988-92 (demonstrating that dosages of TNX-901, an IgE antibody, increased the threshold sensitivity of peanut-allergy sufferers); Metzger, *supra* note 4, at 1046-48 (detailing two distinct approaches to treatment of peanut allergies—genetically modified allergens and anti-IgE antibody therapy); Paloma Poza-R. Glez et al., *MIP-1 $\alpha$ , MCP-1, and Desensitization in Anaphylaxis from Cow's Milk*, 367 NEW ENG. J. MED. 282, 282-83 (2012) (reporting successful results of a protocol of desensitization wherein twelve children with an allergy to cow's milk protein were able to drink a glass of milk per day two years after undergoing therapy).

<sup>9</sup> See Jonathan B. Roses, *Food Allergen Law and the Food Allergen Labeling and Consumer Protection Act of 2004: Falling Short of True Protection for Food Allergy Sufferers*, 66 FOOD & DRUG L.J. 225, 225 (2011) ("There is no cure for these allergies, so the approximately 11 million American food allergy sufferers have no choice but to avoid the allergens present in food."); see also Lack, *supra* note 5, at 1255, 1258 (noting that the "cornerstone of the management of food allergies is avoidance of the relevant food allergens" and that other proposed treatments for food allergies come with "high attendant costs" and require additional study); *Life Is No Picnic for Food Allergy Sufferers*, *supra* note 6 ("The only ways to manage food allergies, however, are to avoid the foods that cause reactions and to treat the allergic reactions caused by food exposure.").

<sup>10</sup> In a public comment at an FDA public meeting on modernizing good manufacturing processes for cross-contact reduction, Dr. Julia Bradsher, then-CEO of the Food Allergy and Anaphylaxis Network argued, "[C]onsumers with food allergies . . . rely heavily upon manufacturers to ensure that proper preventive controls are in place, which ensure their safety. They must also rely on accurate ingredient statements of packaged food products to identify those products that contain their allergens." FDA, PUB. MTG. ON THE FOOD SAFETY MODERNIZATION ACT: FOCUS ON PREVENTATIVE CONTROLS FOR FACILITIES 48-49 (Apr. 20, 2011), available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM253612.pdf>.

<sup>11</sup> See generally H.R. REP. NO. 108-608 (2004), reprinted in 2004 U.S.C.C.A.N. 830, 837 (noting that the FDA regulates approximately 300,000 food labels).

<sup>12</sup> See ASTHMA & ALLERGY FOUND. OF AM., REPORT OF THE FOOD ALLERGEN LABELING SURVEY 2 (2009), available at <http://www.aafa.org/pdfs/Allergen%20Labeling%20Report%20Final%202009.pdf> (reporting that in a survey of over 2500 people who have, or have a child who has, food allergies, 90% "always" read the ingredient list on food packaging and over 90% would "never" consume a product that listed an allergen in the ingredients section of the label).

<sup>13</sup> Pub. L. No. 108-282, 118 Stat. 905 (codified at 21 U.S.C. § 343 (2012)).

Act required, for the first time,<sup>14</sup> producers of commercial food products to indicate on a label whether the product contained any of the eight major allergens.<sup>15</sup>

The food allergy community<sup>16</sup> heralded the creation of this legislation.<sup>17</sup> However, the Act left one important concern for food allergy sufferers untouched: advisory label warnings. An advisory label warning is an addition to a food product's ingredient label that alerts consumers to the possibility of contamination, or "cross-contact," with an allergen.<sup>18</sup> Some food allergy sufferers can have allergic reactions to very small amounts of allergens, including food products that were only in cross-contact with allergens.<sup>19</sup>

---

<sup>14</sup> Prior to FALCPA's passage in 2004, food producers were not required to inspect or label their foods for allergens. In a 1999 study conducted by the FDA, the FDA found that twenty-five percent of sampled baked goods in Minnesota and Wisconsin failed to list peanuts or eggs as ingredients on their food labels, despite the presence of these allergens in the foods. *Id.* § 202(3)(A).

<sup>15</sup> *Id.* § 203(a). These eight major food groups—milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans—account for ninety percent of food allergies. *Id.* § 202(2)(A); see generally FOOD ALLERGIES: WHAT YOU NEED TO KNOW, *supra* note 6, at 1 (discussing major food allergens).

<sup>16</sup> Food allergy sufferers and parents of food allergic children have created a powerful advocacy group, Food Allergy Research & Education (FARE), an organization founded in 2008 from a merger of the former Food Allergy & Anaphylaxis Network (FAAN), a membership organization providing information and support, and the Food Allergy Initiative (FAI), the world's largest private source of funding for food allergy research. See generally *History*, FARE, <http://www.foodallergy.org/about/history> (last visited Apr. 18, 2014) (providing a history of the merger between FAAN and FAI). The organization advocates for legislation and regulations that benefit food allergy sufferers and provides scientific research grants for innovative approaches to treating food allergies. See generally *About Fare*, FARE, <http://www.foodallergy.org/about> (last visited Apr. 18, 2014) (describing the organization's objectives).

<sup>17</sup> "This legislation will make that task easier for the 11 million Americans who have food allergies and their family and friends who are reading labels on their behalf." Press Release, Food Allergy & Anaphylaxis Network, Food Allergen Labeling and Consumer Protection Act (FALCPA) Awaits President Bush's Signature (July 20, 2006), <http://www.prnewswire.com/news-releases/food-allergen-labeling-and-consumer-protection-act-falcpa-awaits-president-bushs-signature-71339657.html> (quoting Anne Munoz-Furlong, Founder of FAAN).

<sup>18</sup> Advisory labels typically appear just below the ingredient list on a food package and use language such as "May Contain," "Processed in a Facility That Processes," or "Allergen Warning."

<sup>19</sup> See THRESHOLD WORKING GRP., *supra* note 5, at 21 (citing three studies showing that cross-contact caused several instances of consumers' allergic reactions); Sampson, *supra* note 6, at 1296 ("[I]nadvertent exposure as a result of peanut contamination of equipment used in the manufacture of various products, inadequate food labeling, cross-contamination of food during cooking in restaurants (e.g., the use of the same pan to cook foods containing peanuts and food without peanuts), and unanticipated exposures (e.g., the inhalation of peanut dust in airplanes) result in an allergic reaction every three to five years in the average patient with peanut allergy." (footnotes omitted)); see also Marie Plicka, *Mr. Peanut Goes to Court: Accommodating an Individual's Peanut Allergy in Schools and Day Care Centers Under the Americans with Disabilities Act*, 14 J.L. &

“Cross-contact” indicates that a “residue or trace amount of an allergen [has] unintentionally crosse[d] over into a product” whose main ingredients do not contain that allergen.<sup>20</sup> Cross-contact can occur when multiple products are manufactured on the same processing line due to “ineffective cleaning, or from the generation of significant dust containing the allergen” during the labeling, storage, or production processes.<sup>21</sup>

Despite FALCPA’s major strides forward for allergen labeling requirements,<sup>22</sup> it has failed to create standards for advisory labeling. FALCPA contains no specifications regarding how to list cross-contact warnings, no requirements about how food producers should measure cross-contact or report any discovered risk of cross-contact, and no limitations on what a company can include in its advisory labeling.<sup>23</sup> As such, a cursory perusal of any neighborhood grocery will show a wide variety of warning labels, from no warning to “May Contain . . .” to “This product was processed on machinery . . .” to “We are unable to guarantee . . .” None of these warnings explain how this risk of cross-contact was measured (if at all), where in the production process this potential contamination may have occurred, or whether this perceived risk of cross-contact is the result of testing, speculation, or, worse, a nervous legal department.

The FDA has yet to enact regulations on advisory labeling. The FDA has not mandated facility inspections or promulgated guidance requirements or final rules for testing cross-contact. A continuing roadblock for effective regulation is that the amount of an allergen that an allergic person

---

HEALTH 87, 90 (1999–2000) (“As little as half a peanut can cause a fatal reaction for severely allergic individuals.”).

A startling example of how a minuscule allergen amount can still cause an anaphylactic reaction can be found in passive transmission in blood transfusions. See Joannes F.M. Jacobs et al., *Anaphylaxis from Passive Transfer of Peanut Allergen in a Blood Product*, 364 NEW ENG. J. MED. 1981, 1981-82 (2011) (presenting a case where a peanut-allergic, six-year-old boy had an anaphylactic reaction after receiving a blood transfusion from five donors, three of whom had eaten several handfuls of peanuts the evening before they donated blood).

<sup>20</sup> FOOD ALLERGY RESEARCH & RES. PROGRAM, COMPONENTS OF AN EFFECTIVE ALLERGEN CONTROL PLAN: A FRAMEWORK FOR FOOD PROCESSORS (2008) [hereinafter ALLERGEN CONTROL PLAN], available at <http://www.foodallergy.org/document.doc?id=146>.

<sup>21</sup> *Id.* (discussing the logistics of cross-contact).

<sup>22</sup> Specifically, FALCPA required manufacturers to list all known major allergens in product ingredient labels for the first time. 21 U.S.C. § 343(w) (2012); see also *id.* § 321(qq) (defining “major allergens”). FALCPA also required the FDA to prepare reports on the issue of cross-contact and to inspect facilities more for cross-contact problems. FALCPA, Pub. L. No. 108-282, § 204, 118 Stat. 905, 909 (2004) (requiring the Secretary of Health and Human Services to submit a report to the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce analyzing, among other things, “the ways in which foods, during manufacturing and processing, are unintentionally contaminated with major food allergens”).

<sup>23</sup> See generally 21 U.S.C. § 343.

will react to is difficult to quantify. Allergists call the amount of an allergen that will cause an allergic reaction the lowest observed adverse effect level (LOAEL) or “threshold level.”<sup>24</sup> Any exposure below that level will not cause an allergic reaction, while any amount above it likely will. In 2008, the FDA’s Threshold Working Group released a report in which it proposed four different methods for determining thresholds.<sup>25</sup> It concluded that the “application of each is limited by the availability of appropriate data” and only tenuously endorsed moving forward on one method specifically.<sup>26</sup>

Without thresholds, the FDA is limited in its ability to set measurable requirements for good manufacturing practices (GMPs) to prevent cross-contact.<sup>27</sup>

---

<sup>24</sup> THRESHOLD WORKING GRP., *supra* note 5, at 13 (explaining allergen thresholds). The “gold standard” for testing an individual’s level of sensitivity to a food allergen is a “double-blind, placebo-controlled food challenge (DBPCFC)” where every thirty minutes a food-allergic person is given an escalating dose of either a placebo or an allergen until an objective sign of allergic reaction occurs. *Id.* at 21-22. The Threshold Working Group prepared an extensive summary of over thirty food-challenge studies in its Report. *Id.* at 54 tbl.IV-5; 89-100 app. 2.

Prior to sharing the summary of the range of the smallest amounts of allergens observed to cause allergic reactions, it should be noted that these food-challenge studies tested different populations and employed different methodologies, including, but not limited to, the use of different definitions of “allergic reaction”—some allowing subjective symptoms, others requiring objective signs. *Id.* at 89-100 app. 2. As such, this summary conflates studies that may not be perfectly compared. Moreover, these studies were used primarily for diagnosis and not actual testing of the absolute lowest amount of an allergen a food-allergic person could withstand prior to developing an allergic reaction. *Id.* at 22. Therefore, the studies may reflect higher amounts of allergens than would actually cause an allergic person to react because the tests stopped at the lowest level observed that *did* cause a reaction and *not* the lowest level that did *not* cause a reaction. *Id.* I provide this summary not as evidence of scientific fact, but rather to demonstrate what was reported by the Threshold Working Group:

- Eggs: whole raw (0.13-0.65 mg protein); whole dried (0.42-250 mg protein); whole pasteurized (2.9 mg protein); raw white (0.2-20 mg protein); dried white (1500 mg); cooked white (10 mg protein)
- Peanuts: roasted (0.1 mg protein); peanut flour (0.12 mg protein); ground (0.25-125 mg protein); raw (25 mg protein); peanut butter (6-100 mg protein)
- Milk: dried nonfat (140-280 mg protein); whole (0.6-180 mg protein); dried (187 mg protein); formula (1.5-75 mg protein); lactose-free (0.36 mg protein)
- Soy: formula (21.8-522 mg protein)
- Tree nuts: hazelnut raw (1-16 mg protein); hazelnut roasted (32 mg protein); hazelnut ground (2775 mg protein)
- Fish: cooked (50 mg fish); minced (65-200 mg fish); cod (5 mg fish); mackerel (500 mg fish); herring (5 mg fish); plaice (6000 mg fish)
- Wheat: flour, raw and cooked (15 mg protein)

*Id.* at 89-100 app. 2.

<sup>25</sup> See *infra* note 61 and accompanying text.

<sup>26</sup> THRESHOLD WORKING GRP., *supra* note 5, at 52. For a critique of each of the four methods, see *infra* note 62 and accompanying text.

<sup>27</sup> For the purposes of this Comment, I use the phrase “good manufacturing practices” or “GMPs” to refer specifically to GMPs intended to avoid and/or reduce cross-contact with allergens.

With no clear definition of cross-contact, companies have no guidance for their advisory labeling about whether a perceived, but probably untested, cross-contact risk actually creates a cross-contact problem. Companies are instead incentivized to be overinclusive on their advisory labels, while remaining unmotivated to transform their practices to avoid cross-contact.

Food-allergic consumers deserve to have these problems addressed by the FDA. The FDA should set threshold amounts for each of the major allergens, mandate a high standard for GMPs to avoid cross-contact, inspect facilities more aggressively for cross-contact, and stipulate exact requirements for advisory labeling.

This Comment proceeds in three Parts. Part I addresses the history of allergen labeling laws and regulations, focusing particularly on the immediate history preceding the passage of FALCPA in 2004 and the progress made since. Part II addresses what I title the “cascading problems of advisory labeling” whereby the failure to define threshold levels leads to an inability to define GMPs to avoid cross-contact, resulting in labeling laws that neither quantify nor standardize how companies should warn consumers about their products’ cross-contact with allergens. Finally, Part III provides consumer-focused suggestions for the FDA on how to better protect the interests of food-allergic consumers. Throughout this Comment, I seek to present the perspective of consumers with allergies, rather than that of food producers. The Comment concludes with suggestions for follow-up research that could better address the concerns of food producers.

## I. HISTORY OF ALLERGEN-LABELING LAWS AND REGULATIONS

Over the past century, Congress has passed several statutes requiring food producers to share an increasing amount of information with consumers about the contents of their food products. In 1906, Congress passed the first statute regulating the labeling of food ingredients as the Federal Food and Drugs Act of 1906 (the Wiley Act).<sup>28</sup> In 1938, the Federal Food, Drug, and Cosmetic Act (FFDCA)<sup>29</sup> established the FDA. In 1966, Congress passed the Fair Packaging and Labeling Act (FPLA), which requires the labeling of ingredients on all food products.<sup>30</sup> In 1990, Congress passed the Nutrition Labeling and Education Act (NLEA), which amended the FFDCA to

---

<sup>28</sup> 21 U.S.C. §§ 1–15 (1934) (repealed 1938).

<sup>29</sup> *Id.* 301–399 (2012).

<sup>30</sup> 15 U.S.C. §§ 1451–1461 (2012).



require food producers to include nutrition labels and to list all ingredients on standardized food products.<sup>31</sup>

The NLEA led to the enactment of a host of FDA regulations about ingredient labeling and opened up a new set of questions regarding the labeling of allergens. In 1996, the FDA released a Notice Letter to food producers clarifying that known food allergens could not be exempted from ingredient declaration under FDA exceptions to the NLEA.<sup>32</sup> First, an FDA regulation exempted any “incidental additive[s]” that are present in a food at “insignificant levels” from the NLEA requirement to list all ingredients.<sup>33</sup> However, the Notice Letter clarified that allergens are never present at “insignificant levels” because “evidence suggests that some allergenic substances can cause serious allergic responses in some individuals upon ingestion of very small amounts of the substance” and “an amount of a substance that may cause an adverse reaction is not insignificant.”<sup>34</sup> Second, the Notice Letter encouraged food producers to voluntarily include all allergens in their ingredient labels.<sup>35</sup> The Notice Letter marked the first time the FDA addressed the growing trend of labeling products with “May Contain” advisory-labeling warnings.<sup>36</sup> The FDA stated that these advisory warnings should not be used in lieu of adherence to GMPs.<sup>37</sup>

In 2001, the FDA released a report titled “Guidance on Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients,” which addressed GMPs for avoiding cross-contact at the production, receiving, processing, final testing, and labeling phases of

---

<sup>31</sup> 21 U.S.C. §§ 301–343 (2012).

<sup>32</sup> See CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, LABEL DECLARATION OF ALLERGENIC SUBSTANCES IN FOODS; NOTICE TO MANUFACTURERS (1996) [hereinafter FDA WARNING LTR.], available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocuments/RegulatoryInformation/Allergens/ucm106546.htm> (“FDA asks manufacturers to examine their product formulations for ingredients and processing aids that contain known allergens that they may have considered to be exempt . . . and to declare the presence of such ingredients in the ingredient statement.”).

<sup>33</sup> *Id.* (citing 21 C.F.R. § 101.100(a)(3) (2013)).

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* It should be noted that despite the letter, there was already a regulation stating that spices, flavorings, and colorings could be declared collectively, without specification as to allergen content. 21 C.F.R. § 101.22(h)(1) (2013) (“Spice, natural flavor, and artificial flavor may be declared as ‘spice’, ‘natural flavor’, or ‘artificial flavor’, or any combination thereof, as the case may be.”).

<sup>36</sup> FDA WARNING LTR., *supra* note 32 (“The agency is aware that some manufacturers are voluntarily labeling their products with statements such as ‘may contain (insert name of allergenic ingredient).’”).

<sup>37</sup> *Id.* (“The agency urges manufacturers to take all steps necessary to eliminate cross contamination and to ensure the absence of the identified food.”).

development.<sup>38</sup> Rather than providing specific methods, requirements, or testing procedures, however, the guidelines listed a series of questions that food producers should ask themselves in their self-evaluations of cross-contact risks.<sup>39</sup> The guidelines also provided recommendations to food producers on language to use in advisory labeling, including specific language options.<sup>40</sup>

In 2004, Congress passed FALCPA, which amended the FFDCA.<sup>41</sup> FALCPA mandates that all food labels clearly state, in plain language, whether the food product contains any “major food allergens”<sup>42</sup> by labeling it with a “Contains” warning followed by the name of the source of the food allergen after or adjacent to the list of ingredients.<sup>43</sup>

FALCPA did not amend the FFDCA to add any advisory labeling requirements regarding cross-contact. However, FALCPA did address the issue of cross-contact in two ways. First, FALCPA required the Secretary of Health and Human Services to conduct inspections of facilities in which foods are manufactured, processed, packed, or held.<sup>44</sup> The purpose of these inspections was two-fold: (1) to ensure that food producers are following GMPs to “reduce or eliminate cross-contact” and (2) to “ensure that major

---

<sup>38</sup> FDA, GUIDANCE ON INSPECTIONS OF FIRMS PRODUCING FOOD PRODUCTS SUSCEPTIBLE TO CONTAMINATION WITH ALLERGENIC INGREDIENTS (2001) [hereinafter GUIDANCE ON INSPECTIONS], available at <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074944.htm>; see also Guidance on Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients; Availability, 66 Fed. Reg. 42,869, 42,869 (Aug. 15, 2001) (“This guidance will assist FDA investigators and inspectors in evaluating conditions that may result in the introduction of undeclared allergens in food.”).

<sup>39</sup> GUIDANCE ON INSPECTIONS, *supra* note 38.

<sup>40</sup> See *id.* (suggesting language for advisory labeling like “may contain (allergen)” or “this product was processed on machinery that was used to process products containing (allergen)”).

<sup>41</sup> Pub. L. No. 108-282, 118 Stat. 905 (codified at 21 U.S.C. § 343(2012)).

<sup>42</sup> FALCPA defines “major food allergen” as any food ingredient that contains protein derived from milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, or soybeans. *Id.* § 202(2)(A). The FDA defined these eight food products as major allergens even prior to the passage of FALCPA. In 1992, the FDA released a policy notice addressing the growing prevalence of genetically modified food, including a section on the potential problem of “hidden” allergens (e.g., if a peanut protein is used to grow corn, corn may become allergenic to peanut-allergy sufferers). Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,987 (May 29, 1992). This policy notice marked the first time in the Federal Register that the FDA cited a list of common allergens, including “milk, eggs, fish, crustacea, molluscs, tree nuts, wheat, and legumes.” *Id.*

<sup>43</sup> FALCPA § 203(a) (requiring the identification of food allergen sources on food label ingredient lists); see also H.R. REP. NO. 108-608 (2004), reprinted in 2004 U.S.C.A.N. 830 (outlining support for this change in legislation); FDA, REGULATORY PROCEDURES MANUAL § 2-2-5 (2012), available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074340.pdf> (explaining how FALCPA amended the FFDCA).

<sup>44</sup> FALCPA § 205.

food allergens are properly labeled on foods.”<sup>45</sup> FALCPA also required the FDA to submit a report including an analysis of the frequency of unintentional contamination during manufacturing and processing, recommendations for GMPs to avoid cross-contact, how the FDA inspections required by FALCPA have helped prevent cross-contact, and suggestions for advisory labeling.<sup>46</sup> The FDA addressed this requirement as three separate questions: (1) whether to establish thresholds for major allergens; (2) whether to change GMPs to address cross-contact; and (3) whether to standardize threshold labeling.

In 2011, President Barack Obama signed into law the FDA Food Safety Modernization Act (FSMA), amending the FFDCFA to establish the foundation of a modernized, prevention-based food safety system.<sup>47</sup> Of relevance to food-allergy sufferers, the Act required food operators to “identify and evaluate” the presence of allergens,<sup>48</sup> to “implement preventive controls to significantly minimize or prevent” the hazard of allergens<sup>49</sup> by creating a “food allergen control plan,”<sup>50</sup> to monitor the effectiveness of these controls,<sup>51</sup> to take “corrective actions” if the methods are ineffective, and to verify and keep records of these efforts.<sup>52</sup> Congress primarily left the details of these requirements to the FDA and its rulemaking process.<sup>53</sup> Starting in 2013, the FDA has begun the promulgation of rules to clarify these requirements.<sup>54</sup>

As I discuss in the next Part, the FDA has taken steps regarding each of these issues by creating working groups, releasing draft reports and recommendations, proposing rules, and establishing notice and comment periods. However, as of May 2014, no final rules have been promulgated relating to thresholds, GMPs to prevent cross-contact, or advisory labeling.

---

<sup>45</sup> *Id.*

<sup>46</sup> *Id.* § 204; *see also* H.R. REP. NO. 108-608, *reprinted in* 2004 U.S.C.C.A.N. 830, 846 (addressing these requirements).

<sup>47</sup> Pub. L. No. 111-353, 124 Stat. 3885 (2011).

<sup>48</sup> *Id.* § 103(b).

<sup>49</sup> *Id.* § 103(a).

<sup>50</sup> *Id.* § 103(o).

<sup>51</sup> *Id.* § 103(d).

<sup>52</sup> *Id.* § 103(d)-(f).

<sup>53</sup> *Id.* § 418.

<sup>54</sup> The FDA's response will be discussed further *infra* Section II.B.

## II. CASCADING PROBLEMS: NO THRESHOLDS, NO GMPs, AND NO ADVISORY LABELING

FALCPA failed to provide leadership on the issue of cross-contact, leaving future policy determinations to the FDA. Unfortunately, the FDA has not set thresholds for food allergens, updated GMP regulations to include prevention of cross-contact, or provided regulations about advisory labeling. As a result, food producers are left to define GMPs in a vacuum and to create advisory labels without any oversight. This lack of clear standards disempowers the food-allergic consumer. Because the FDA has not established threshold levels for allergens, all cross-contact GMPs are developed individually at each company, leading to haphazard results. Labels are similarly disjointed across different food products because companies have discretion in deciding what to include on their advisory labels.

Under this system, some food products do not contain advisory labels about cross-contact with major allergens, despite having a high probability of contamination. In contrast, some food products with a low probability of cross-contact with major allergens feature advisory warnings for all eight major allergens. Both of these approaches are consistent with FALCPA and current FDA regulations. However, consumers are left confused by the meanings of different advisory labels, and food producers are not incentivized to improve their cross-contact GMPs or to clarify their advisory labeling practices. FALCPA's failure to define thresholds creates a cascading effect, allowing food producers to define cross-contact risk however they choose.

### A. *No Thresholds*

In FALCPA, Congress passed the question of thresholds on to the Secretary of Health and Human Services, requiring the Secretary to prepare a report on thresholds and cross-contact.<sup>55</sup> The FDA's Threshold Working Group solicited comments from consumers,<sup>56</sup> produced a draft report,<sup>57</sup>

---

<sup>55</sup> FALCPA § 204.

<sup>56</sup> See Food Advisory Committee; Notice of Meeting, 70 Fed. Reg. 29,528 (May 23, 2005) (announcing creation of committee and soliciting requests for comment).

<sup>57</sup> See Draft Report of the Threshold Working Group, Center for Food Safety and Applied Nutrition: Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food; Availability; Request for Comments and for Scientific Data and Information, 70 Fed. Reg. 35,258, 35,258 (June 17, 2005) [hereinafter Threshold Working Group Draft] (explaining that the draft report "describes a number of areas in which the working group concluded that the body of scientific data relating to food allergen thresholds is incomplete").

conducted a public meeting,<sup>58</sup> and eventually released a final report.<sup>59</sup> The stated goal of the Working Group was to develop a “sound analytical framework” for setting thresholds.<sup>60</sup>

The Working Group’s final report analyzed four strategies for determining thresholds and concluded that each had drawbacks.<sup>61</sup> The report held that the risk assessment–based approach was the strongest, most transparent way to establish thresholds for major allergens.<sup>62</sup> In a quantitative risk assessment model, the threshold would be determined by estimating the cumulative probabilities of allergic reactions to different levels of allergen exposure, and any accompanying uncertainty based on statistical models.<sup>63</sup> In 2006, the same year that the Threshold Working Group released its final report, an FDA Working Group on the labeling of soy lecithin published a report stating that it was impossible to determine a threshold for soy,<sup>64</sup> one of the eight major allergens.

---

<sup>58</sup> See 70 Fed. Reg. 29,528 (providing notice of public meeting on the issue of allergen thresholds).

<sup>59</sup> See generally THRESHOLD WORKING GRP., *supra* note 5.

<sup>60</sup> See Threshold Working Group Draft, *supra* note 57, at 35,258 (explaining that understanding thresholds would be “useful in addressing food allergen cross-contact and the use of advisory labeling”).

<sup>61</sup> See THRESHOLD WORKING GRP., *supra* note 5, at 42–52. The Report outlined the following four approaches: (1) an analytical methods-based approach where “thresholds are determined by the sensitivity of the analytical method(s) that can be used to verify compliance”; (2) a safety assessment–based approach where thresholds are set based on an acceptable daily intake; (3) a risk assessment–based approach requiring “hazard identification, exposure assessment, hazard characterization (dose–response), and risk characterization”; (4) a statute-derived approach where thresholds are established “by extrapolating from an exemption established by Congress for another purpose.” *Id.* at 42–65.

<sup>61</sup> *Id.* at 52–58. The report critiques the use of each of the four methods it proposes: (1) the thresholds of the analytical methods–based approach “should be replaced by thresholds established using another approach as quickly as possible”; (2) the safety assessment–based approach may not allow for establishment of LOAELs for each individual allergen and would require an “uncertainty factor” and periodic reevaluation; (3) the risk assessment–based approach—the “strongest” model—does not have data “sufficient to meet the requirements of th[e] approach”; and (4) the statute-derived approach “should be used only on an interim basis.” *Id.* at 3.

<sup>62</sup> *Id.* at 56 (“The quantitative risk assessment-based approach is the most scientifically rigorous approach and provides the most insight into both the level of protection and the degree of uncertainty associated with an exposure level.”).

<sup>63</sup> *Id.* at 43–45 (describing the complex methodology of risk assessments).

<sup>64</sup> CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, GUIDANCE FOR INDUSTRY GUIDANCE ON THE LABELING OF CERTAIN USES OF LECITHIN DERIVED FROM SOY UNDER SECTION 403(W) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT 4, *available at* 2006 WL 1358755 (Apr. 1, 2006) (“Absent a consensus on a LOAEL for soy protein and on levels of exposure to soy protein . . . it is not possible to state unequivocally the risk, if any, that there may be to soy-allergic persons who consume foods [with soy].”).

However, the FDA seems to be moving in the direction of incorporating these recommendations into regulations. On December 14, 2012, the FDA released a request for comments about establishing thresholds for allergens.<sup>65</sup> During the extended<sup>66</sup> commenting period, the FDA received over 400 comments.<sup>67</sup> The FDA looks to be on the precipice of adding a threshold requirement for major allergens. This Comment hopes to add to the chorus of comments calling for the FDA to establish these thresholds.

### B. *No GMPs*

FALCPA required the FDA to provide a report on how food producers could minimize cross-contact.<sup>68</sup> To fulfill this requirement, the FDA relied on a pre-FALCPA already ongoing study. In late 2002, the FDA's Center for Food Safety and Applied Nutrition formed a Food Current Good Manufacturing Practice (CGMP) Modernization Working Group to modernize existing GMP protocols, which had not been updated since 1986.<sup>69</sup> The goals for modernization included the creation of CGMPs to avoid cross-contact.<sup>70</sup> After two public comment periods,<sup>71</sup> three public

---

<sup>65</sup> Request for Comments and Information on Initiating a Risk Assessment for Establishing Food Allergen Thresholds; Establishment of Docket, 77 Fed. Reg. 74,485 (Dec. 14, 2012).

<sup>66</sup> See Request for Comments and Information on Initiating a Risk Assessment for Establishing Food Allergen Thresholds; Establishment of Docket; Extension of Comment Period, 78 Fed. Reg. 7785 (Feb. 4, 2013) (extending the comment period by roughly three months).

<sup>67</sup> See *Establishments of Dockets: Risk Assessment for Establishing Food Allergen Thresholds; Request for Comments*, REGULATIONS.GOV (Dec. 14, 2012), <http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-0711-0001> (listing 284 comments filed in the first open commenting period); *Request for Comments and Information on Initiating a Risk Assessment for Establishing Food Allergen Thresholds; Establishment of Docket; Extension of Comment Period*, REGULATIONS.GOV (Feb. 4, 2013), <http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-0711-0009> (listing 121 additional comments received during the extended commenting period).

<sup>68</sup> Pub. L. No. 108-282, § 204, 118 Stat. 905, 909 (codified at 21 U.S.C. § 343 (2012)).

<sup>69</sup> Compare Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, 21 C.F.R. §§ 110.10-.93 (2013), with Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food, 21 C.F.R. §§ 110.10-.93 (1986).

<sup>70</sup> It should be noted that the FDA had been looking into amending its GMPs to address cross-contact with allergens for almost a decade prior to the passage of FALCPA. In October of 1998, the FDA formed the "Food Allergen Partnership" with the Minnesota Department of Agriculture (MDA) and the Wisconsin Department of Agriculture, Trade and Consumer Protection (WDATCP) to investigate ways to prevent cross-contact. The Report found that changes to regulations were necessary because, according to research from 1998 in Minnesota and Wisconsin, less than fifty percent of inspected firms used any procedures to control cross-contamination with undeclared allergen and ninety-six percent of firms did not have any testing to verify that cleaning procedures were eliminating allergen residuals. See *Food Allergen Partnership*, FDA (Jan. 2001), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/cm106779.htm> [hereinafter *Food Allergen Partnership*].

meetings, and years of independent research, the Working Group published its report in 2005.<sup>72</sup> The Working Group suggested that existing GMP protocols<sup>73</sup> should be amended to include a requirement that any food processor who works with a major allergen develop an allergen control plan for its facility that addresses training, segregation of food allergens, validated cleaning procedures, prevention of cross-contact, product label review, and supplier control programs.<sup>74</sup>

Following the passage of the FSMA<sup>75</sup> on April 20, 2011, the FDA held a public meeting titled “FDA Food Safety Modernization Act: Focus on Preventive Controls for Facilities” to kickstart the process of promulgating rules to add clarity, definition, and substance to the FSMA.<sup>76</sup> On January 16, 2013, the FDA proposed rules for the FSMA’s requirements of “[a] written food safety plan; [h]azard analysis; [p]reventative controls for hazards that are reasonably likely to occur; [m]onitoring; corrective actions; [v]erification; and [a]ssociated records.”<sup>77</sup> The proposed rules incorporated the CGMP Modernization Group’s suggestion to require food producers to create and implement “a written food allergen control plan for food processing establishments that handle major food allergens.”<sup>78</sup> The proposed language of the rules read:

---

<sup>71</sup> See Food; Current Good Manufacturing Practice Regulations; Public Meetings, 69 Fed. Reg. 29,220, 29,220-21 (May 21, 2004) (providing notice of three public meetings to discuss revisions to the CGMPs, including addressing the “principal contributors to the presence of undeclared allergens in food . . . [including] labeling errors or cross-contamination”); Food; Current Good Manufacturing Practice Regulations; Public Meetings, 69 Fed. Reg. 40,312, 40,312 (July 2, 2004) (rescheduling the three meetings announced on May 21, 2004).

<sup>72</sup> FOOD CGMP MODERNIZATION WORKING GRP., CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, FOOD CGMP MODERNIZATION—A FOCUS ON FOOD SAFETY (2005), available at <http://www.fda.gov/ohrms/dockets/dockets/04n0230/04n-0230-rpt0001-vol4.pdf>.

<sup>73</sup> See 21 C.F.R. § 110 (2013) (addressing general provisions regarding GMPs as well as facilities, equipment, and processes).

<sup>74</sup> FOOD CGMP MODERNIZATION WORKING GRP., *supra* note 72, at 35-36.

<sup>75</sup> FSMA, Pub. L. No. 111-353, 124 Stat. 3885 (2011).

<sup>76</sup> FDA, PUBLIC MEETING ON THE FOOD SAFETY MODERNIZATION ACT: FOCUS ON PREVENTATIVE CONTROLS FOR FACILITIES (Apr. 20, 2011), available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM253612.pdf>. At the meeting, Julia Bradsher, serving then as the Chief Executive Officer of the Food Allergy and Anaphylaxis Network, encouraged the FDA to “address the evaluation of allergens as a food hazard and the need for preventative controls for allergens in its implementations.” *Id.* at 49.

<sup>77</sup> Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventative Controls for Human Food, 78 Fed. Reg. 3646, 3648 (Jan. 16, 2013). The Rule was “corrected” in March of 2013, but nothing substantive was changed. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventative Controls for Human Food; Correction, 78 Fed. Reg. 17,142 (Mar. 20, 2013).

<sup>78</sup> 78 Fed. Reg. 3646, 3651.

- (2) *Food allergen controls.* Food allergen controls must include those procedures, practices, and processes employed for:
- (i) Ensuring protection of food from cross-contact, including during storage and use; and
  - (ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.<sup>79</sup>

The proposed rules provide examples for the types of procedures that would ensure reduction of cross-contact, including using physical or temporal barriers to separate allergens during food production and ensuring that food labels correctly declare all of the food allergens present in the food produced.<sup>80</sup>

Taken together, the proposed changes to the language of the GMPs clarify that “protection against contamination also requires protection against cross-contact.”<sup>81</sup> The commenting period for this proposed rule was extended four times;<sup>82</sup> the FDA has announced that they will extend the period again through June 2014.<sup>83</sup> Given the extensions to the commenting period, as of May 2014, the FDA has yet to promulgate a final rule.

### C. *No Advisory Labels*

Neither FALCPA nor the FDA regulates advisory labeling. In this regulatory void, companies tend to take one of three approaches to advisory labeling: (1) place no advisory label;<sup>84</sup> (2) place an advisory label listing any

---

<sup>79</sup> *Id.* at 3806.

<sup>80</sup> *Id.* at 3755.

<sup>81</sup> *Id.* at 3718.

<sup>82</sup> Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Extension of Comment Period for Information Collection Provisions, 78 Fed. Reg. 11,611 (Feb. 19, 2013); Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Extension of Comment Periods, 78 Fed. Reg. 24,691 (Apr. 26, 2013); Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Extension of Comment Periods, 78 Fed. Reg. 48,636 (Aug. 9, 2013); Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Extension of Comment Periods, 78 Fed. Reg. 69,604 (Nov. 20, 2013).

<sup>83</sup> *Update on Proposed Rules Under the FDA Food Safety Modernization Act*, FDA (March 19, 2014), <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm389696.htm> (“FDA will soon announce a 90-day extension of the comment period for both documents to June 30, 2014.”).

<sup>84</sup> See FDA, HAVE FOOD ALLERGIES? READ THE LABEL 2 (2011) [hereinafter HAVE FOOD ALLERGIES?], available at <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM254727.pdf> (“Be aware that the ‘may contain’ statement is voluntary [and] . . . ‘[y]ou still need to read the ingredient list to see if the product contains your allergen.’”).



allergen that could possibly come in cross-contact with the food product during the manufacturing, packaging, labeling, or holding processes; or (3) place an advisory label against all eight major allergens to counter any potential product liability. What to include, what to leave out, and what qualifies as “cross-contact” are all open questions. Each individual company determines for each individual food product what should be placed on an advisory label. As such, consumers see a wide variety of labels that each mean different things to different food producers, but that mean nothing to the consumer. Moreover, as food producers are trending toward listing all eight major allergens in order to avoid any liability, advisory labels risk becoming completely superfluous.<sup>85</sup>

The state of advisory labels is so confusing that the FDA has released advisory media pieces to explain the various possible meanings behind advisory labels.<sup>86</sup> In addition, following the passage of FALCPA, the FDA released a series of four non-binding guidance letters to the food production industry clarifying the requirements in FALCPA. The first letter explained that FALCPA allows two options for declaring major allergens, either within the ingredient list or following the ingredient list with “a separate ‘contains’ statement.”<sup>87</sup> In the guidance letter’s second version<sup>88</sup> and reiterated in its third<sup>89</sup> and fourth versions,<sup>90</sup> the FDA established that FALCPA

---

<sup>85</sup> See Derr, *supra* note 3, at 88 (“Over-use of advisory labeling also can perversely cause people to ignore the warnings altogether. Because of the proliferation of ‘may contain’ statements . . . the integrity of all precautionary labels [is] being questioned by consumers.” (internal quotation marks omitted) (second alteration in original)).

<sup>86</sup> See, e.g., HAVE FOOD ALLERGIES?, *supra* note 84. This piece explains to consumers the difference between “Contains” and “May Contain,” how the “May Contain” label can indicate that the manufacturer uses the same equipment to make different products, and that “[e]ven after cleaning this equipment, a small amount of an allergen (such as peanuts) that was used to make one product (such as cookies) may become part of another product (such as crackers),” leading to the cracker’s label stating “May Contain Peanuts.” *Id.* at 2.

<sup>87</sup> *Id.* at 1 (clarifying the options available to manufacturers when labeling their products).

<sup>88</sup> See CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, FINAL GUIDANCE FOR INDUSTRY: QUESTIONS AND ANSWERS REGARDING FOOD ALLERGENS, INCLUDING THE FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT OF 2004 (EDITION 2) (2005) [hereinafter 2005 ALLERGEN GUIDANCE EDITION 2].

<sup>89</sup> CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, FINAL GUIDANCE FOR INDUSTRY: QUESTIONS AND ANSWERS REGARDING FOOD ALLERGENS, INCLUDING THE FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT OF 2004 (EDITION 3) (2006) [hereinafter 2006 ALLERGEN GUIDANCE EDITION 3].

<sup>90</sup> CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, GUIDANCE FOR INDUSTRY: QUESTIONS AND ANSWERS REGARDING FOOD ALLERGENS, INCLUDING THE FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT OF 2004 (EDITION 4); FINAL GUIDANCE (2006) [hereinafter 2006 ALLERGEN GUIDANCE EDITION 4], available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM301394.pdf> (answering major questions from the food

does not require advisory labeling about cross-contact.<sup>91</sup> The fourth edition guidance letter also clarified that “FALCPA does not require FDA to establish a threshold level for any food allergen.”<sup>92</sup> Finally, the letter established that “major food allergens that are unintentionally added to a food as the result of cross-contact” are not subject to FALCPA’s labeling requirements.<sup>93</sup>

The guidance letters did acknowledge that FALCPA required the FDA to gather data about consumer opinions regarding the lack of advisory guidelines.<sup>94</sup> In 2008, the FDA acted on this requirement and announced a Notice of Public Hearing on the use of food allergen advisory labeling.<sup>95</sup> While the administrative record for this hearing closed in 2009, the FDA has done nothing more than release a Consumer Update since then.<sup>96</sup> Without more guidance, consumers remain unable to identify the actual risks associated with consumption of a product that contains an advisory warning.

#### D. Cascading Problems Lead to Uninformed Consumers

This cascade of problems has led to an uninformed consumer base. Food allergen advocacy organizations and researchers have long noted that the failure to standardize advisory labels has resulted in labels lacking the necessary utility for customers.<sup>97</sup> For example, a 2000 Food Allergy and

---

industry surrounding the language of warnings and food covered by FALCPA and reiterating the answers to the questions about contamination from the first three editions).

<sup>91</sup> *Id.* at 5 (“FALCPA does not address the use of advisory labeling, including statements describing the potential presence of unintentional ingredients in food products resulting from the food manufacturing process . . . . In earlier guidance, FDA advised that advisory labeling such as ‘may contain [allergen]’ should not be used as a substitute for adherence to current Good Manufacturing Practices (cGMPs).”).

<sup>92</sup> *Id.* (“It is not unlikely, however, that FDA will at some point need to consider a threshold level for one or more food allergens in the context of reviewing a petition or a notification submitted to request that an ingredient be exempt from FALCPA’s labeling requirements.”).

<sup>93</sup> *Id.* at 6.

<sup>94</sup> *Id.* at 5 (“FALCPA does require FDA to submit a report to Congress, a part of which assesses the use of, and consumer preferences about, advisory labeling.”).

<sup>95</sup> See Food Labeling; Current Trends in the Use of Allergen Advisory Labeling: Its Use, Effectiveness, and Consumer Perception; Public Hearing; Request for Comments, 73 Fed. Reg. 46,302 (Aug. 8, 2008) (announcing a public hearing on allergen labeling of foods and requesting public comments).

<sup>96</sup> See *Food Allergies: Reducing the Risks*, FDA (Jan. 23, 2009), <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm089307.htm> (providing the FDA’s limited guidance regarding food allergen labeling, despite having held an administrative hearing).

<sup>97</sup> See ALLERGEN CONTROL PLAN, *supra* note 20, at 2 (“[T]here has been a proliferation of the use of precautionary allergen statements, which range in wording from ‘May Contain’ and ‘Processed in a Facility’, to ‘Made on Shared Equipment’. This increase has limited consumer food

Anaphylaxis Network (FAAN) survey found that “[o]f the 550 individuals who participated in the 2000 FAAN food labels survey, ninety-eight percent said the information on food labels was not enough to allow them to make effective safety decisions.”<sup>98</sup> Similarly, a 2009 Asthma and Allergy Foundation of America survey of food allergy sufferers and parents of children with food allergies found that 95% of the roughly 2500 participants believed that advisory warnings were necessary, but 89.4% reported dissatisfaction with current advisory labels.<sup>99</sup>

The current regime creates two major hurdles for food-allergic consumers that stifle the very purpose of FALCPA: (1) advisory labeling has left consumers confused and ill-equipped to manage risk and (2) food producers are allowed the opportunity to opt out of protecting food-allergic consumers.

### 1. Advisory Labels Are Currently Meaningless

When a box of crackers says “May Contain Milk,” what does that mean? Are the crackers processed on the same factory line as a milk-containing product or processed in the same factory but on a different line? The former option likely causes a greater risk of contamination than the latter. However, the confusion goes beyond just that clarification.

Consider the former option. The cracker is made on the same line, but is it (a) made on the same day or (b) made on a different day to avoid contamination? Either way, does the company (c) clean the line in between the different productions or (d) never clean the line? Even if the crackers are made on a different line, (e) does the factory ever check that line for dust from the allergens another line or (f) never check for cross-contact on the separate lines? More generally, does the company ever test for allergens? What amount of exposure exists? What amount of the allergen protein is present? What has the consumer actually learned from this label?

The problem of overinclusive labeling reflects the inherent conflict between the stated purpose of FALCPA to ensure “that the food source from which a major food allergen is derived is clearly labeled in plain English”<sup>100</sup> and Congress’s decision to leave contamination labeling to food producers’

---

choices. Alarming, food-allergic consumers, especially teens, are beginning to ignore precautionary statements, and taking risks regarding the food they choose to eat.”).

<sup>98</sup> Derr, *supra* note 3, at 82.

<sup>99</sup> See ASTHMA & ALLERGY FOUND. OF AM., *supra* note 12, at 3.

<sup>100</sup> H.R. REP. NO. 108-608 (2004), reprinted in 2004 U.S.C.C.A.N. 830, 831-32; see also S. REP. NO. 108-226 (2004), at 4 (“Use of plain English in food labels to identify the presence of the eight major food allergens will make the food label much more useful to consumers with food allergies.”).

discretion.<sup>101</sup> As this hypothetical demonstrates, food products' FALCPA-compliant labels may not always be so clear.<sup>102</sup>

## 2. Food Producers Are Permitted to Opt Out of Protecting Food-Allergic Consumers

Consider the following hypothetical: A food producer (Jupiter) makes a peanut cookie and a plain, peanut-free cookie in the same facility. Cross-contact GMPs—including extensive cleaning procedures, dedicated production lines for peanut versus peanut-free products, and air filtration systems<sup>103</sup>—could eliminate the risk of cross-contact of the peanut cookie production with the peanut-free cookie production. However, the FDA does not mandate these practices,<sup>104</sup> so Jupiter debates whether to implement them. Jupiter compares the cost of implementing these protections

---

<sup>101</sup> The Senate Report on FALCPA specifically addressed that “[f]ood allergens sometimes inadvertently find their way into a food because of a firm’s production practices,” causing a product to contain an allergen not included as an ingredient on the label. S. REP. NO. 108-226, at 3-4. However, despite this acknowledgment of risk, the report determined that “it may not be possible to eliminate the possibility of cross-contact [by] following good manufacturing practice” and the “use of advisory labeling” “may be appropriate.” *Id.* Tacitly acknowledging the disconnect between the ingredient labeling requirements of FALCPA and the unregulated practice of contamination labeling, the Report concluded that “‘cross-contact’ deserve[d] further study by both FDA and the food industry.” *Id.* at 4.

<sup>102</sup> For additional hypotheticals on how consumers interact with unregulated advisory labeling, see *Roses*, *supra* note 9, at 239-40 (outlining multiple examples where a “FALCPA-compliant” label would likely mislead, or ill-inform, food-allergic consumers and arguing that “a consumer who was initially diligent in confirming the lack of an ingredient in a product may be at risk following the addition of an allergen to the product” where the unregulated advisory label remained unchanged following the addition). See also Food Allergy Research & Educ., Comment on the Food and Drug Administration (FDA) Notice: Request[sic] for Comments and Information on Initiating a Risk Assessment for Establishing Food Allergen Thresholds; Establishment of Docket; Extension of Comment Period, REGULATIONS.GOV (May 21, 2013), <http://www.regulations.gov/?tr=y&cauid=12679480#!documentDetail;D=FDA-2012-N-0711-0059> [hereinafter FARE Threshold Comment] (“FARE asserts that the large number of different cautionary label statements presently used is confusing to the food allergy community, and therefore misleading.”). The FARE Threshold Comment cited various studies, including Mariah M. Pieretti et al., *Audit of Manufactured Products: Use of Allergen Advisory Labels and Identification of Labeling Ambiguities*, 124 J. ALLERGY & CLINICAL IMMUNOLOGY 337, 337-41 (2009), which identifies advisory labeling ambiguities and limitations of FALCPA-compliant labels. *Id.*

<sup>103</sup> For a greater discussion of procedures that would reduce or eliminate the risk of cross-contact see *infra* subsection III.B.2.

<sup>104</sup> The FDA’s proposed rule regulating the FSMA provisions would require that food producers create “food allergen control plans,” which might include some of these procedures. See *supra* notes 75-83 and accompanying text. Under current GMP guidelines, there is not a requirement to use these procedures. See generally *supra* Section II.B.

against another option: disclaiming liability on an advisory label.<sup>105</sup> Disclaiming liability through overinclusive labeling is likely cheaper than preventing liability through GMPs.<sup>106</sup> Thus, Jupiter includes an advisory label on its plain cookies stating, “May Contain Peanuts, Tree Nuts, Milk, Wheat, Soy, Egg, and Shellfish.” The main ingredients label does not list any of these allergens. Jupiter does not test if its plain cookies actually contain any of the allergens warned against on its advisory label.

The label may not reflect the true probability of exposure. Studies testing for detectable levels of allergens in food products with advisory warnings have found that contamination varies widely across different products using the same advisory labeling language.<sup>107</sup> These studies underscore that many

---

<sup>105</sup> “Liability” in this context refers to the potential for a lawsuit by a food-allergic consumer who suffered an allergic reaction to a food that did not warn of the potential for allergen exposure. For a survey of the causes of action available to food-allergic persons in these situations, see Roses, *supra* note 9, at 231-35, 237 (describing the available causes of action—including failure to warn, manufacturing or product defect, implied warranty of fitness of foods, and infliction of emotional distress—and their varying levels of success).

<sup>106</sup> For the purposes of this Comment, a comprehensive economic analysis comparing over-inclusive advisory labeling and practices CGMPs was not performed. This statement is based on assumptions developed from a comparison of the projected cost of compliance with various labeling requirements and the estimated cost of compliance with the new proposed rules for CGMPs. For the cost of labeling, the Congressional Budget Office’s estimated that FALCPA’s food allergen labeling requirements, including the “administrative, printing, analytical, and label inventory costs associated with this mandate[,] would total less than \$75 million through fiscal year 2006, and would be *negligible in later years*.” H.R. REP. NO. 108-608 (2004), *reprinted in* 2004 U.S.C.C.A.N. 830, 837 (emphasis added). For voluntary label changes to reflect the presence of gluten, the FDA estimated that the average estimated cost for relabeling during a twelve month period was \$7,101 per label for branded products. FDA, FOOD LABELING; GLUTEN-FREE LABELING OF FOODS: FINAL REGULATORY IMPACT ANALYSIS 29, *available at* <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM363530.pdf>. In contrast to this “negligible” amount, the FDA estimated that the total costs for food allergen controls under the proposed new rules for CGMPs would be “the sum of the costs of the developing procedures for allergen use and storage to prevent cross-contact (including written procedures and training), reviewing that the appropriate label has been applied to the appropriate product, and the costs of writing up label control procedures,” totaling annual costs \$5,143,240 (food producers with less than 20 employees), \$6,148,350 (food producers with 20-99 employees), \$4,775,474 (food producers with 100-499 employees), and \$370,708 (food producers with 500 or more employees). FDA, CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD 93 (2013), *available at* <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM334117.pdf>.

<sup>107</sup> See, e.g., Matthew P. Crotty & Steve L. Taylor, *Letter to the Editor: Risks Associated with Foods Having Advisory Milk Labeling*, 125 J. ALLERGY & CLINICAL IMMUNOLOGY 935, 935 (2010) (testing for detectable milk residue in food products that did not list “milk” as an ingredient but did provide an advisory warning against “milk” and finding that “detectable milk residues were found in 60.7% (17/28) of products with ‘may contain’ labels[,] . . . 33.3% (10/30) of products with ‘shared equipment’ labels[,] . . . and 28.6% (6/21) of products with ‘shared facility’ labels”); Lara S. Ford et al., *Letter to the Editor: Food Allergen Advisory Labeling and Product Contamination with Egg, Milk, and Peanut*, 126 J. ALLERGY & CLINICAL IMMUNOLOGY 384, 384-85 (2010)

producers do not develop food production processes that eliminate contamination. Granted, elimination of allergen contamination may not be possible for some food producers, particularly smaller businesses. However, for other food producers, like the hypothetical Jupiter, the possibility of reducing or eliminating contamination may be in reach, but may be deemed less attractive than the cheaper alternative of using advisory labeling. While the FDA has previously stated that advisory warnings should not be used in place of attempting to limit cross-contact with allergens,<sup>108</sup> the FDA's failure to regulate advisory labeling allows, and even incentivizes, food producers to opt out of attempting to correct, prevent, or even detect allergen contamination.

### III. CONSUMER-FOCUSED SUGGESTIONS FOR THE FDA REGARDING CONTAMINATION LABELING

The FDA can make advisory labeling more helpful to consumers. The suggestions in this Part address the many problems that begin with failure to identify thresholds and end with poorly informed consumers. First, the FDA should establish thresholds for all major allergens. Second, the FDA should establish GMPs to reduce cross-contact that specifically test for these thresholds. Third, labels should be standardized both in language and content to reflect the thresholds and GMPs that the FDA develops.

#### A. *The FDA Should Establish Thresholds for Major Allergens*

The final report by the Threshold Working Group proposed various paths through which the FDA could determine proper thresholds.<sup>109</sup> The FDA should follow the Group's suggestion and utilize the risk assessment-based

---

(finding, in the largest study to date on this issue, egg in 1.8% of products with egg-advisory statements and 2.6% of products with no allergen declared; milk in 10.2% of products with milk-advisory statements and 3.0% of products with no allergen declared; and peanut in 4.5% of products with advisory statements and 0% of products with no allergen declared); Susan L. Hefle et al., *Consumer Attitudes and Risks Associated with Packaged Foods Having Advisory Labeling Regarding the Presence of Peanuts*, 120 J. ALLERGY & CLINICAL IMMUNOLOGY 171, 173 (2007) ("Of the 179 packages with allergy advisory statements, 13 products had detectable levels of peanut in one or both lots, including 2 of 51 products with a 'may contain' statement, 3 of 57 products with a 'shared equipment' statement, 7 of 68 products with a 'shared facility' statement, and 1 of 3 products with a unique allergy advisory statement.").

<sup>108</sup> FDA WARNING LTR., *supra* note 32 ("FDA advises that, because adhering to good manufacturing practice (GMP) is essential for effective reduction of adverse reactions, such precautionary labeling should not be used in lieu of adherence to GMP.").

<sup>109</sup> THRESHOLD WORKING GROUP, *supra* note 5, at 3-4.

approach to setting thresholds.<sup>110</sup> While the Threshold Working Group noted that there were no options that would provide perfect scientific certainty,<sup>111</sup> this approach would be most effective in determining what would cause the average allergy sufferer to sustain an allergic reaction.<sup>112</sup>

While food-allergy sufferers' reactions to different amounts of allergens vary, this standard is better than no standard. Food producers would be able to employ GMPs and actually test the efficacy of those procedures against an established standard. The food producers could test and measure for allergen contamination above the threshold level once a baseline threshold has been developed.

With any threshold, there is the possibility that the level will not be set low enough for any individual allergy sufferer. Particularly with a statistical model like the risk assessment–based approach in place, there will be a minority of allergy sufferers who sustain reactions to food that has been contaminated below the thresholds. As such, the FDA should be encouraged to establish a conservative estimate from the risk assessment–based approach. In any event, the perfect should not be the enemy of the good; any definite threshold is better than no threshold.<sup>113</sup>

---

<sup>110</sup> *Id.* at 56 (asserting that the risk-assessment approach is the most scientifically rigorous and citing data suggesting that the approach shows promise).

<sup>111</sup> *Id.* at 48 (“Based on currently available data, the Threshold Working Group was unable to identify any scientifically-based studies that indicate that the standard 10-fold uncertainty factor used in safety assessments for inter-individual variability is not adequate to account for variation within the sensitive population [allergy sufferers].”).

<sup>112</sup> *Id.* at 43-44.

<sup>113</sup> Disagreeing with this adage, FARE submitted a public comment to the FDA in May 2013, arguing that thresholds should not be established until “(1) reliable scientific data that clearly identifies a quantity of the allergen that is so small that it will not cause an allergic reaction in even the most sensitive individuals, and (2) a reliable analytical method for determining compliance with the threshold that can be easily used by food companies and FDA.” FARE Threshold Comment, *supra* note 102. To support their position, FARE relied on the results of a February 2013 survey of 5578 of their members—primarily parents or caregivers of children with food allergies and adults with food allergies—revealing that the majority of consumers were unaware of the definition of thresholds and would not change their purchasing behaviors based on the use of thresholds. *Id.*

This Comment argues that the second goal suggested by FARE is necessary, *see infra* Sections III.B–C, and that the aim of the first goal should be a guiding principle in establishing thresholds. However, this Comment asserts that the second goal necessarily flows from establishing thresholds, not the other way around. In addition, the first goal is unnecessarily idealistic. For example, a recent study in the *Journal of Allergy & Clinical Immunology* suggested “reference doses for 11 commonly allergenic foods to guide a rational approach by manufacturers based on all publically available valid oral food challenge data” to be used as Voluntary Incidental Trace Allergen Labeling (VITAL) 2.0 thresholds now recommended in Australia (analogous to using LOELs for advisory labeling in the United States). Katrina J. Allen et al., *Allergen Reference Doses for Precautionary Labeling (VITAL 2.0): Clinical Implications*, 131 *J. ALLERGY & CLINICAL IMMUNOLOGY* 156, 156-64 (2013) (“[T]he eliciting dose for an allergic reaction in 1% of the population

B. *The FDA Should Incorporate Thresholds into Amended GMP Regulations and Increase Enforcement Efforts*

Along with the establishment of thresholds, the FDA should amend its 1986 GMPs to add prevention measures that require testing for cross-contact. For the food-allergic consumer, the 2013 proposed rules to modernize the GMPs are encouraging. These rules should be adopted. However, even if these cross-contact rules were to take effect, they lack crucial components: accountability and enforcement. For both the proposed cross-contact requirements, the FDA proposes twin escape hatches for food producers. Neither “validation of the adequacy of the food allergen cross-contact controls” nor “validation of the adequacy of the food allergen labeling controls” is required.<sup>114</sup> The FDA “tentatively concludes” that it cannot require food producers to validate that these manufacturing or labeling checkpoints are working because these “types of controls generally are not evaluated through scientific studies or by the collection of technical information.”<sup>115</sup>

New regulations should serve two main goals. The first is *detecting* cross-contact. A glaring issue with the status quo is that there is no requirement for food producers to test, discover, or record issues of cross-contact. A continuing problem with the proposed rules is that there is no requirement to test and validate the success or failure of GMPs to prevent cross-contact. The second is *preventing* cross-contact. The GMPs move toward that goal, though it is likely a larger, more difficult goal to accomplish.

These two goals can work in sequence but can also be at odds. For the former, there should be a metric by which to measure cross-contact. For the latter, a regulatory scheme that prizes only detection and not minimization may allow a company to diligently detect and report cross-contact without consequence. However, a focus exclusively on reducing cross-contact may present unrealistic cost hurdles to the average food producer.

A balance of these two goals seems appropriate. We should pursue a system of detection for the purpose of reduction while implementing reduction realistically.

---

estimated for the following were 0.2 mg of protein for peanut, 0.1 mg for cow’s milk, 0.03 mg for egg, and 0.1 mg for hazelnut.”). This study’s results may not meet the standard set from the first goal, but would certainly (1) encompass the allergic sensitivities of the vast majority of the food allergic population, (2) provide a standard for establishing more concrete GMPs, and (3) add clarity to advisory labels. These three aims should be the prerequisites for establishing thresholds.

<sup>114</sup> 78 Fed. Reg. 3646, 3755 (Jan. 16, 2013).

<sup>115</sup> *Id.* The FDA declares that a food producer has sufficiently followed the cross-contact regulations if the producer “monitor[s]” that the procedures against cross-contact in production and labeling are being followed. *Id.*



### 1. Goal #1: Detecting Cross-Contact

The first goal of modernizing GMPs should be to create a standardized process by which food producers and the FDA test, measure, and report cross-contamination. The proposed rules for GMPs address the need for monitoring and detection. However, I argue that a further goal should be the measurement and validation of GMPs. The addition of threshold requirements to these procedures would create a need for greater product testing to determine whether the allergen is in cross-contact despite the practice of GMPs. It takes an intensive, scientific process to determine the presence of allergens;<sup>116</sup> however, there are also many producers of affordable commercial kits to analyze contamination of the major allergens.<sup>117</sup>

There are also multiple approaches to administer this testing: (1) the FDA could engage in scheduled or random tests of the facilities themselves; (2) the FDA could mandate that food producers self-report the presence of cross-contact allergens above the established threshold to the FDA; or (3) the FDA could require some combination of the two. To implement the first approach, food producers should create allergen leadership teams. These teams would be responsible for assessing the risk of cross-contact for all food products. The leadership team at each company would be required to develop an allergen-testing plan. Testing should lead to self-reporting by the company, including timely requests to change labels if additional allergen contaminants are found.

Each of these approaches would need to be analyzed further. In addition, the FDA might have to employ different procedures for large and small food producers.

### 2. Goal #2: Preventing Cross-Contact

The second goal is to actually prevent cross-contact. First, I explore an idealized concept of “prevention.” Second, I propose more realistic steps toward achieving this goal.

From an allergic-person’s perspective, an allergen plan would ideally establish and implement any and all policies that could help reduce the potential for cross-contact. In a perfect world, such processes would eliminate all risk of cross-contact. Any allergen that is not an ingredient would simply not be present in the food product. The allergen would not be used

---

<sup>116</sup> See THRESHOLD WORKING GROUP, *supra* note 5, at 28-29 (explaining the factors that make it difficult to detect and measure food allergens).

<sup>117</sup> *Id.* at 28 (referencing a study by the FDA and AOAC that found that three commercial peanut testing kits correctly allocated the test samples at the target level).

in the same manufacturing facility. If an allergen was processed in the same facility, food producers would dedicate separate lines to foods that contain allergens and foods that do not. If allergens were processed on the same lines, processing, packaging, and other steps in the process would be performed on different days of the week. Increased sanitation and testing for cleanliness would be required between allergen-free and allergen processes.

Taking it a step further, an ideal allergen plan would ban food producers from releasing food products that pose contamination risks. An allergen would either be listed as an ingredient or would not be a contamination risk at all.

This may not be a realistic vision. Yet, there are things that can be done to provide a reduction in cross-contact that would be a step in the right direction.

In 2001, the Food Allergen Partnership released suggestions for minimizing allergen exposure and cross-contact. In a comment analyzing the Food Allergen Partnership's suggestions, Laura Derr summarized that they require:

[D]edicating certain production lines to foods containing a specific type of allergen, scheduling the processing of allergen-containing foods on separate days of the week than products that do not contain allergens, running allergen-containing products on lines after allergen-free products have been run, heightening sanitation processes, verifying sanitation before running nonallergenic products, increasing employee training about allergens, appropriately labeling food articles that previously have been processed and are being reworked into new products, and making improvements to equipment and system designs.<sup>118</sup>

The Food Allergy Research & Resource Program provides a sample "Allergen Control Plan" to food processors that can serve as a model for complying with GMPs mandated by the FDA.<sup>119</sup> The program advocates an Allergen Control Plan that consists of five steps: (1) creating a leadership team composed of key leaders from different relevant departments; (2) conducting a risk assessment to determine which allergens could potentially contaminate; (3) developing an "allergen map" to understand "where allergenic ingredients and foods exist in the plant and where they are introduced in the process"; (4) developing an Allergen Control Plan specific

---

<sup>118</sup> Derr, *supra* note 3, at 86 (citing Food Allergen Partnership, *supra* note 70).

<sup>119</sup> ALLERGEN CONTROL PLAN, *supra* note 20.

to each processing facility; and (5) creating an iterative process of review and redevelopment of the plan.<sup>120</sup>

The Modernization Working Group argued that food processors should develop an allergen control plan for their facilities that addresses training, segregation of food allergens, validated cleaning procedures, prevention of cross-contact, product label review, and supplier control programs.<sup>121</sup> The FDA showed support for the Group's recommendation by incorporating a requirement of a "food allergen control plan" into the proposed GMP modernization rules.<sup>122</sup>

Implementation of these policies would reduce the risk of contamination, moving toward the ideal goal of total prevention.

*C. Advisory Labeling Should Be Standardized and Should Reflect Thresholds and GMPs*

The FDA should require that advisory labels reflect these thresholds and GMPs. The FDA has a difficult task of give-and-take when developing advisory labeling, as it wants to warn consumers who may have adverse reactions to a particular level of contaminant, but at the same time it does not want to scare away—or worse, deliberately mislead—consumers who are not allergic to that level of contaminant. From a consumer perspective, what do the advisory labels need to accomplish? Based on my personal experiences as a food-allergic consumer and my research on public comments provided to the FDA on this issue, the following is a Food-Allergic Consumers' Advisory Labeling Wish List:

- Advisory label warns of major allergens that may be present in the food product above established LOAELs. Relevant LOAEL is listed on the packaging. Suggested language: "Cross-contact risks for [ALLERGEN] at [LOAEL amount]."

---

<sup>120</sup> *Id.*

<sup>121</sup> See FOOD CGMP MODERNIZATION WORKING GROUP, *supra* note 72, at 35-36.

<sup>122</sup> See 78 Fed. Reg. 3646, 3651 (Jan. 16, 2013) (explaining that the CGMP Working Group report presented seven opportunities for GMP modernization including "requiring the creation and implementation of a written food allergen control plan for food processing establishments that handle major food allergens"); 78 Fed. Reg. at 3693 (describing how the CGMP Working Group considered public comments when recommending "that food processing establishments that handle any of the major food allergens be required to develop and adopt a food allergen control plan that addresses . . . [p]revention of cross-contact during processing") (alteration in original) (citation omitted); 78 Fed. Reg. at 3741 ("Proposed § 117.135(d)(2) also is consistent with the recommendations in the CGMP Working Group Report . . . that food processing establishments that produce foods containing a major food allergen be required to have a food allergen control plan.").

- Advisory label does not warn about major allergens that are not present in the food above established LOAELs. Label does not overwarn to avoid practicing any GMPs.
- Advisory label warns only about cross-contact risks. Allergens that qualify as “ingredients” are properly listed in the ingredients list.
- Advisory label reflects cross-contact risks of major allergens that could not be removed by GMPs. Advisory label reflects food producer’s good-faith effort to keep the cross-contact risk as low as possible.
- Testing for cross-contact is conducted regularly and labels are updated expeditiously to reflect any changes.
- Advisory labels are included on every food product, including products with no cross-contact risk. Suggested language: “No cross-contact risk with eight major allergens.”

To meet the demands of this wish list, thresholds would need to be set and GMPs would need to be updated. Consumers will also need to know what their individual LOAEL is. Allergy sufferers can meet with their doctors to do undergo an oral challenge to determine if their LOAEL is below the standard set by the FDA.

The ideal label would thus provide standardized language that appropriately warns consumers of the risks of allergic reaction.

#### CONCLUSION

The food allergy community deserves continued action to reform advisory labeling. The current state of advisory labels results in uncertainty among the consuming public. In addition, as a note for future study, the approach advocated in this Comment may solidify a consumer’s right to sue companies for allergic reactions to products, and at the same time, protect companies that have followed GMPs and appropriately listed cross-contact risks on their labels.

At the moment, those protections do not exist on either side. Because of the voluntary nature of the current precautionary warnings, companies use them to disclaim liability. The problem for consumers, of course, is that the same warning could require a little or a lot of care on their part to avoid cross-contact. As such, many warnings are not persuasive as they currently stand, yet companies can rightfully argue in court that they appropriately attempted to warn consumers to refrain from consuming their product. On the other side of the coin, companies that are diligent and attempt to prevent cross-contact are equally as liable as companies that do nothing,

since GMPs are so vaguely defined, and consumers can make a strong case for strict scrutiny if they prevail first on a failure-to-warn claim.

Under this new system, both sides would understand what the promises are and what they are agreeing to when selling or consuming a product. The FDA has gathered the information it needs, and it is now time for action. The FDA should establish thresholds, amend and improve its GMPs to prevent cross-contact, and regulate advisory labeling.