

7-30-2018

The Global Status of Food Allergen Labeling Laws

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Recommended Citation

Baker, Reed (2018) "The Global Status of Food Allergen Labeling Laws," *California Western Law Review*. Vol. 54 : No. 2 , Article 4.

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THE GLOBAL STATUS OF FOOD ALLERGEN LABELING LAWS

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I. INTRODUCTION

She “tried to read the ingredients” before she took a bite,¹ but they were difficult to read and absent of any allergy warnings.² Moments later, Georgina Hickman—twenty-four and in perfect health—began struggling to breathe.³ Her boyfriend called an ambulance to no avail.⁴ Georgina died shortly thereafter.⁵ Her cause of death: allergic reaction to peanuts.⁶

The amount of food allergic individuals is increasing at an exponential rate.⁷ This medical phenomenon is not restricted to the United States; food allergies are skyrocketing all over the world.⁸ Doctors, researchers, and allergy organizations alike are viewing this increase as a global health issue.⁹ To make matters worse, there is no cure for food allergies.¹⁰ This leaves an allergic consumer one option

1. Emma Lake, *DEADLY ALLERGY Nursery School Worker, 24, Died after Eating a Single Crisp with Peanut Flavouring*, THE SUN (July 29, 2017, 11:21 AM), <https://www.thesun.co.uk/news/4125981/nursery-worker-georgina-hickman-died-allergic-reaction-crisps-peanut/>.

2. Mario Zaccaro, *Peanut Flavouring Led to Georgina Hickman Death*, S. DAILY ECHO (July 25, 2017), http://www.dailyecho.co.uk/news/15433473.Peanut_flavouring_led_to_womans_death/.

3. *See id.*

4. *Id.*

5. *Id.*

6. *Id.*

7. *See Severe Allergic Reactions to Food are Increasing; In Adults as Well as Children*, WBUR (Aug. 25, 2017, 3:57 PM), <http://www.wbur.org/hereandnow/2017/08/24/severe-food-allergies> (confirming the rise of food allergic individuals through numerous studies, which found an increase in the amount of people having to visit hospitals for allergic reactions).

8. *See Mimi L. K. Tang & Raymond J. Mullins, Food Allergy: Is Prevalence Increasing?*, INTERNAL MED. J. 256, 257–58 (2017).

9. *Cf. Susan L. Prescott et al., A Global Survey of Changing Patterns of Food Allergy Burden in Children*, WORLD ALLERGY ORG. J., Dec. 4, 2013, at 9, 10 (determining, in 2013, that a global health issue was inevitable due to an expected increase in food allergies over the next ten years).

10. Imke Reese et al., *Allergen and Allergy Risk Assessment, Allergen Management, and Gaps in the European Food Information Regulation*, 24 ALLERGO J. INT'L 180, 181 (2015) (“Causal treatments offering the prospect of a cure for food allergies are still lacking today.”).

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when it comes to addressing his or her specific allergen: strict avoidance.¹¹

As a result of being condemned to lifelong avoidance of their trigger food, allergic consumers must carefully check labels and thoroughly read the ingredient list of every prepackaged food product they consume. Because consuming a trigger food can result in severe allergic reaction symptoms, such as hives, swelling of throat, and even death, food allergic individuals are left with no choice but to rely on the accuracy and transparency of product labels.¹² Global legislation has recognized the allergic consumer's reliance on labels by enacting label requirements for the most commonly recognized food allergens.

This comment introduces and dissects the various labeling laws enacted by legislative bodies. Part II provides a general background on food allergies, the severity of allergic reactions to food, the economic burden of having a food allergy, and the prevalence of allergic consumers in different regions around the world. Part III begins with a historical background of how various governing bodies enacted their respective labeling laws and ends with a snapshot of these countries' existing regulations. Part IV addresses the current status of precautionary allergen labeling laws in various jurisdictions; particularly, Part IV focuses on the countries which regulate food labels and those which do not. Part V addresses contemporary issues arising from current allergen labeling laws and precautionary allergen labeling; specifically, it addresses the need for a global framework for food labels, and the universal confusion associated with precautionary allergen labels. Finally, Part VI recommends the United States follow in the European Union's footsteps by enacting legislation applying allergen labeling laws to non-prepackaged foods. Additionally, Part VI calls for the United States to adopt Switzerland and South Africa's precautionary allergen labeling policies.

11. *Id.*; see also *Food Allergy FAQs*, AM. C. OF ALLERGY, ASTHMA & IMMUNOLOGY, <http://acaai.org/allergies/types/food-allergy> (last visited Mar. 16, 2018) (acknowledging avoidance of a respective allergen is the only way to avoid an allergic reaction).

12. See *What is an Allergic Reaction?*, WEBMD, <https://www.webmd.com/allergies/allergic-reaction-causes#1> (last visited May 16, 2018).

II. BACKGROUND

Food allergies burden individuals in a number of ways, whether it be through physical symptoms, psychological stress, or financial costs. Alarming, food allergies are on the rise across the globe. Now more than ever, it is important to understand these burdens and how we can begin to minimize them.

A. Food Allergies in General

A food allergy occurs when the human immune system reacts negatively to certain food proteins.¹³ The food related immune sensitivity of greatest public concern is known as an IgE-mediated immediate reaction.¹⁴ This comment speaks specifically to individuals who have IgE-mediated food reactions because these individuals are the most dependent on ingredients lists and food labels.¹⁵ An IgE-mediated reaction is the most serious allergic reaction someone can have because it results in a rapid onset of severe health symptoms, including hives, dizziness, difficulty breathing, swelling of the throat, and anaphylaxis.¹⁶ Anaphylaxis is the life-threatening symptom of allergic reactions, and if left untreated can result in death.¹⁷

13. Joshua A. Boyce et al., *Guidelines for the Diagnosis and Management of Food Allergy in the United States: Summary of the NIAID-Sponsored Expert Panel Report*, 126 J. ALLERGY CLINICAL IMMUNOLOGY 61, 63 (2010) (“A food allergy is defined as an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food.”).

14. Stephen M. Gendel, *Comparison of International Food Allergen Labeling Regulations*, 63 REG. TOXICOLOGY & PHARMACOLOGY, 279, 279 (2012).

15. *Id.* at 279–80.

16. *Allergies and Food Safety*, U.S. DEP’T OF AGRIC., <https://www.fsis.usda.gov/wps/portal/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/allergies-and-food-safety> (last modified Dec. 1, 2015) [hereinafter U.S. DEP’T OF AGRIC.].

17. EUROPEAN ACAD. OF ALLERGY & CLINICAL IMMUNOLOGY, *FOOD ALLERGY & ANAPHYLAXIS PUBLIC DECLARATION 7* (2013) [hereinafter EAACI PUBLIC DECLARATION], <http://www.eaaci.org/attachments/FoodAllergy&AnaphylaxisPublicDeclarationCombined.pdf>.

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Anaphylaxis holds no prejudices and can be fatal to any person regardless of age or health.¹⁸ For instance, Elijah Silvera was only three-years-old when he died after being fed grilled cheese at preschool; he was allergic to milk.¹⁹ Anthony Lyson, was a healthy eighteen year-old who suddenly died after eating a PowerBar containing his respective allergen: tree nuts.²⁰ Nissan Hayuni was a thirty-three year-old newlywed who died from anaphylaxis on his honeymoon flight from Spain to Miami after eating an in-cabin meal.²¹ Khoo Siew Hong was sixty when she died at the hands of her shellfish allergy after eating two prawns.²² These are not isolated instances; fatalities from anaphylaxis have become widespread.

Food allergies do not solely manifest physical symptoms; they have severe psychological effects as well. Food allergic individuals frequently suffer from stress, frustration, and social embarrassment.²³ Imagine, the little girl whose milk allergy is so severe that her mother will not allow her to attend sleepovers; the frequent-flyer with the peanut allergy responsible for the stewardess's in-flight announcement stating they "cannot serve snacks on today's flight because a customer has a peanut allergy;" the businessman with the wheat allergy who has to play twenty-questions with the waiter at a work luncheon; or the law student with the tree nut allergy who cannot try the new Thai restaurant with her friends because she cannot afford the risk of a potentially staggering hospital bill. Furthermore, allergic consumers must maintain constant vigilance when it comes to the ignorance of others because non-allergic individuals do not usually comprehend how severe and dangerous food allergies can be.²⁴

Scenarios like the ones mentioned are far too common given the sheer amount of food allergic individuals. Up to 5 percent of adults and 8 percent of children suffer from food allergies worldwide,²⁵ with over

18. See generally Lisa Rutter, *Remembering Those We Have Lost to Food Allergies*, NO NUTS MOMS GROUP (July 22, 2017), <https://nonutsmomsgroup.weebly.com/blog/remembering-those-we-have-lost-to-food-allergies>.

19. *Id.*

20. *Id.*

21. *Id.*

22. *Id.*

23. *Id.*

24. *Id.*

25. Gendel, *supra* note 14, at 279.

160 foods currently known to cause an allergic reaction.²⁶ However, of these 160 or so foods, only 8 of them are responsible for 90 percent of allergic reactions.²⁷ These eight foods are considered the “major food allergens.”²⁸ They include: milk, eggs, fish (bass, flounder, cod), shellfish (crab, lobster, shrimp), tree nuts (almonds, pecans, walnuts), peanuts, wheat, and soy.²⁹

B. The Economic Burden of Food Allergies

The United States and Europe have conducted comprehensive studies that provide a look into the economic impact of food allergies. In 2007, Virginia Commonwealth University’s study determined the direct and indirect medical costs associated with food allergies and anaphylaxis in the United States.³⁰ Direct medical costs included inpatient visits, emergency room visits, outpatient visits, ambulance trips, and the use of Epinephrine Auto-Injectors (Epi-Pens).³¹ Indirect medical costs included morbidity and mortality figures.³² The study found the direct medical costs amounted to \$225 million and indirect costs amounted to \$115 million, placing the total economic healthcare burden of food allergies and anaphylaxis in the United States at \$340 million for the year 2007.³³

Europe conducted a similar study in 2011.³⁴ The study concluded that (1) people with food allergies have higher annual healthcare costs than people without food allergies, and (2) there is a positive relationship between the severity of the allergic reaction and the cost of

26. U.S. DEP’T. OF AGRIC., *supra* note 16.

27. *Id.*

28. *Id.*

29. *Id.*

30. Dipen A. Patel et al., *Estimating the Economic Burden of Food-Induced Allergic Reactions and Anaphylaxis in the United States*, 128 J. ALLERGY CLINICAL IMMUNOLOGY 110, 110 (2011).

31. *Id.* at 111 (reporting that an Epi-Pen is a lifesaving medicine intended for use immediately after consuming an allergen to prevent the rapid onset of anaphylaxis).

32. *Id.* at 111–12.

33. *Id.* at 110.

34. See Margaret Fox et al., *Health Sector Costs of Self-Reported Food Allergy in Europe: A Patient-Based Cost of Illness Study*, 23 EUR. J. OF PUB. HEALTH 757 (2013).

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care.³⁵ Specifically, adults in Europe with food allergies average I\$2016³⁶ per year in health care costs versus adults without food allergies averaging I\$1089.³⁷

However, in the United States, the full economic impact—not just the healthcare burden—facing caregivers with children having food allergies is an estimated \$24.8 billion annually.³⁸ To determine this figure, researchers analyzed lost labor productivity value and opportunity costs in addition to direct and out-of-pocket medical expenses.³⁹ This number equates to approximately \$4200 per year per child with a food allergy.⁴⁰

C. Prevalence of Food Allergies

The prevalence and severity of certain food allergens vary per geographic region. For example, the most common food allergies of adults in continental Europe are peanuts, tree nuts, vegetables, and fruit, whereas children in the same area are commonly allergic to peanuts, cow's milk, and eggs.⁴¹ In contrast with continental Europeans, Scandinavians⁴² are more commonly allergic to shellfish and cod.⁴³

35. *Id.* at 761.

36. The database for this study used the International Dollar, I\$, in estimating unit service costs. *Id.* at 758 (“The I\$ is an average unit of cost derived by adjusting exchange rates between the US dollar and the local currency to compare values of different currencies based on purchasing power parity and the average commodity prices within each country.”); *see also* *What is an “International Dollar”?*, THE WORLD BANK, <https://datahelpdesk.worldbank.org/knowledgebase/articles/114944-what-is-an-international-dollar> (last visited May 16, 2018) (“An international dollar would buy in the cited country a comparable amount of goods and services a U.S. dollar would buy in the United States.”).

37. Fox, *supra* note 34, at 757.

38. Ruchi Gupta et al., *The Economic Impact of Childhood Food Allergy in the United States*, 167 JAMA PEDIATRICS 1026, 1026 (2013).

39. *Id.*

40. *Id.* at 1030.

41. EAACI PUBLIC DECLARATION, *supra* note 17, at 11.

42. Amanda Briney, *An Introduction to the 5 Scandinavian Countries*, THOUGHTCO., <https://www.thoughtco.com/countries-of-scandinavia-1434588> (last updated Mar. 8, 2018) (listing Norway, Sweden, Finland, Denmark, and Iceland as the five Scandinavian Countries).

43. EAACI PUBLIC DECLARATION, *supra* note 17, at 11.

Studies like these continue to demonstrate a correlation between geographic location and specific allergen prevalence.

Scientists have concocted numerous theories on how to determine the precise number of people with food allergies and whether that number is increasing.⁴⁴ Ultimately, scientists have used the health care burden as a cost-effective method to determine this information.⁴⁵ This involves examining hospital data to compare the amount of people currently being admitted for food allergies against the amount of people admitted at different points in time.⁴⁶ As an alternative, researchers can look at insurance claims data to determine if there has been a rise in the amount of food allergy claims.⁴⁷ However, one of the most frequently used and prevalent studies evaluates hospital intake data to determine if there has been an increase in patients admitted for either food allergies or anaphylaxis.⁴⁸

1. *The United States*

It is estimated that 15 million people in the United States have a food allergy: 9 million adults and 6 million children.⁴⁹ This number equates to 4 percent of adults and 8 percent of children.⁵⁰ FAIR Health, a national and independent nonprofit, recently examined the amount of private healthcare insurance claims made for food allergies.⁵¹ Its results indicated anaphylactic reactions in the United States increased by an astounding 377 percent from 2007 to 2016.⁵² Specifically, peanuts and tree nuts were the guiltiest culprits, with reactions increasing by 445

44. Prescott et al., *supra* note 9.

45. See, e.g., *id.*

46. Tang & Mullins, *supra* note 8, at 258.

47. FAIR HEALTH, FOOD ALLERGY IN THE UNITED STATES: RECENT TRENDS AND COSTS 2 n.1 (2017) [hereinafter FAIR HEALTH], <https://s3.amazonaws.com/media2.fairhealth.org/whitepaper/asset/Food%20Allergy%20White%20Paper%20Final.compressed.pdf>.

48. Tang & Mullins, *supra* note 8, at 257.

49. *Fact Sheet: Food Allergy Facts and Statistics for the U.S.*, FOOD ALLERGY RES. & EDUC., <https://www.foodallergy.org/sites/default/files/migrated-files/file/facts-stats.pdf> (last visited May 16, 2018).

50. *Id.*

51. FAIR HEALTH, *supra* note 47, at 2, 33.

52. *Id.* at 2.

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and 603 percent, respectively.⁵³ American children also experienced increases in food allergies. From 1997 to 2011, “the prevalence of food allergy in children increased 50 percent,” and, “[b]etween 1997 and 2008, the prevalence of peanut or tree nut allergy appears to have more than tripled.”⁵⁴

2. *The European Union*

Over 17 million people have a food allergy in Europe (3.5 million are under twenty-five years-old), and the number is increasing.⁵⁵ Children are the demographic in the European Union (“EU”)⁵⁶ experiencing the sharpest rise in food allergies.⁵⁷ The European Academy of Allergy and Clinical Immunology (“EAACI”) reported that children hospitalized for allergic reactions increased seven-fold from 2003 to 2013.⁵⁸ The EAACI responded to this alarming increase by launching a public awareness campaign directed towards EU policy-makers.⁵⁹ The campaign urged European legislators to enact laws setting clear food labeling guidelines.⁶⁰ The campaign’s “clear guidelines” initiative sought food products containing allergens or their derivatives to be labeled in a clear, non-confusing way.⁶¹ The campaign also sought to enact a law requiring products containing allergens to indicate such on their labels in a different typeset than other ingredients.⁶²

53. *Id.* at 14.

54. *Food Allergy Facts and Statistics for the U.S.*, FOOD ALLERGY RES. & EDUC., <https://www.foodallergy.org/sites/default/files/2018-04/FARE-Food-Allergy-Facts-Statistics.pdf> (last visited May 16, 2018).

55. EAACI PUBLIC DECLARATION, *supra* note 17, at 5.

56. *See generally The 28 Member Countries of the EU*, EUR. UNION, https://europa.eu/european-union/about-eu/countries_en (last visited May 16, 2018) (listing members of the European Union as Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom).

57. EAACI PUBLIC DECLARATION, *supra* note 17, at 5.

58. *Id.* at app.

59. *Id.* at 5.

60. *Id.*

61. *Id.* at app.

62. *Id.*

3. *The United Kingdom*

In the United Kingdom (UK), approximately 2 million people have been diagnosed with an allergy to at least one type of food.⁶³ This figure works out to approximately 1–2 percent of adults and 5–8 percent of children.⁶⁴ The UK, like so many other places in the world, is experiencing an uptick in food allergies.⁶⁵ One study found food allergy hospitalizations increased 500 percent from 1990 to 2006,⁶⁶ and another found hospital admissions for anaphylaxis doubled between 1998 and 2012.⁶⁷

4. *Australia and New Zealand*

Two percent of adults and between 4 and 8 percent of children have food allergies in Australia.⁶⁸ A recent study of the food allergies affecting Australian children “reported the highest prevalence of food allergy internationally.”⁶⁹ Additionally, Australian hospitals have experienced their highest rise in anaphylaxis hospitalizations, with the number of patients admitted increasing four-fold.⁷⁰

63. STEVE WEARNE, FOOD STANDARDS AGENCY, FOOD ALLERGY AND INTOLERANCE PROGRAM § 2.1 (2017), <https://www.food.gov.uk/sites/default/files/media/document/fsa170306.pdf>.

64. *Id.*

65. Tang & Mullins, *supra* note 8, at 258.

66. Caroline Hadley, *Food Allergies on the Rise? Determining the Prevalence of Food Allergies, and How Quickly it is Increasing, is the First Step in Tackling the Problem*, 7 EMBO Rep. 1080, 1080 (2006).

67. Tang & Mullins, *supra* note 8, at 258.

68. AUSTRALASIAN SOC’Y OF CLINICAL IMMUNOLOGY & ALLERGY, INFORMATION FOR PATIENTS, CONSUMERS AND CARERS: FOOD ALLERGY 2 (2016), https://www.allergy.org.au/images/pcc/ASCIA_PCC_Food_Allergy_2016.pdf.

69. *See Prevalence of Food Allergies in Australia Remain Remarkably High*, AM. ACAD. OF ALLERGY ASTHMA & IMMUNOLOGY (May 14, 2017), <https://www.aaaai.org/global/latest-research-summaries/Current-JACI-research/food-allergy-australia>.

70. Tang & Mullins, *supra* note 8, at 258.

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5. *China*

In China, 1–2 percent of adults and 5 percent of children have a food allergy.⁷¹ According to the Population Reference Bureau, China had a population of 1.357 billion people in 2013,⁷² which means tens of millions of people have a food allergy in China. China has experienced an increase in food allergies as well.⁷³ From 1999 to 2009, food allergies doubled from 3.5 to 7.7 percent.⁷⁴ Children in China have higher allergy prevalence rates than adults, and the Population Reference Bureau indicates between 3.8 and 7.7 percent of infants in China have food allergies.⁷⁵

III. HISTORY AND CURRENT STATUS OF FOOD
ALLERGEN LABELING LAWS

A multitude of countries deem food allergies a public health issue due to the vast amount of allergic consumers coupled with over 200 foods capable of causing an allergic reaction.⁷⁶ In response, lawmakers around the world created legislation regulating the way food producers label products containing certain allergens.⁷⁷ While there is no global framework for food allergen labeling, there is a multi-governmental body that provides its member countries with guidelines for how food allergens should be labeled on products.⁷⁸ In 1963, the World Health Organization and the Food and Agricultural Organization collaborated to form the Codex Alimentarius Commission (Codex).⁷⁹ Codex's

71. Zhou Wenting, *Allergens to be Listed on Food Labels*, CHINA DAILY (Dec. 21, 2011, 09:39), http://www.chinadaily.com.cn/china/2011-12/21/content_14298531.htm.

72. POPULATION REFERENCE BUREAU, 2013 WORLD POPULATION DATA SHEET 2 (2013), http://www.prb.org/pdf13/2013-population-data-sheet_eng.pdf.

73. Prescott et al., *supra* note 9, at 6.

74. *Id.*

75. *Id.*

76. Gendel, *supra* note 14, at 280.

77. *Id.*

78. *Codex Alimentarius Commission*, U.S. DEP'T OF AGRIC., <https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius/Codex+Alimentarius+Commission> (last modified Aug. 7, 2017).

79. *Codex Alimentarius International Food Standards [“CAIFS”]: About Codex*, FOOD & AGRIC. ORG. OF THE U.N. & WORLD HEALTH ORG., <http://www>.

mission is to protect the health of consumers and promote fair practices in food trade,⁸⁰ and it is recognized as the international organization that provides food safety standards.⁸¹ As of May 2018, 188 countries and one organization (the EU) are members of the Codex.⁸²

The World Health Organization tasked Codex with developing food safety guidelines,⁸³ e.g., which food allergens to include on the label, and how to get that allergen to stand out. In response, Codex developed the Codex General Standard for the Labeling of Prepackaged Food (“Standard”).⁸⁴ The Standard lists peanuts, tree nuts, soybeans, milk, eggs, fish, crustaceans, cereals containing gluten, and sulfites in concentrations of more than ten milligrams per kilogram (10mg/kg) as the ingredients food manufacturers should declare on labels.⁸⁵ Codex chose these foods because they are known to cause hypersensitivity.⁸⁶

Codex’s member countries are not required to follow the Standard.⁸⁷ Rather, Codex strives to provide legislative bodies with guidelines to consult when constructing their own regulatory framework.⁸⁸ Because following the Standard is optional for a Codex member, many countries’ labeling laws differ.

A. Allergen Labeling Laws in the United States

In 1938, the United States recognized “the need to protect sensitive consumers” through its enactment of the Food, Drug, and Cosmetics

fao.org/fao-who-codexalimentarius/about-codex/en/#c453333 (last visited May 16, 2018) [hereinafter *CAIFS: About Codex*].

80. *Id.*

81. Gendel, *supra* note 14, at 280.

82. *CAIFS: Members*, FOOD & AGRIC. ORG. OF THE U.N. & WORLD HEALTH ORG., <http://www.fao.org/fao-who-codexalimentarius/about-codex/members/en/> (last visited May 16, 2018).

83. *Id.*

84. Gendel, *supra* note 14, at 280.

85. Codex Comm’n on Food Labeling, Gen. Standard for the Labeling of Prepackaged Foods, Food & Agric. Org. of the U.N. [FAO] & World Health Org. [WHO] § 4.2.1.4 (rev. 1991).

86. *Id.*

87. *CAIFS: Codex Texts*, FOOD & AGRIC. ORG. OF THE U.N. & WORLD HEALTH ORG., <http://www.fao.org/fao-who-codexalimentarius/codex-texts/en/> (last visited May 16, 2018).

88. *See id.*; *see also CAIFS: About Codex, supra* note 79.

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Act (FDCA).⁸⁹ By enacting the FDCA, the United States became the first country in the world to regulate food labels being sold within its borders.⁹⁰ The FDCA required food products to have ingredient lists⁹¹ so that food allergic consumers would know whether the product contained their respective allergen.⁹²

The FDCA required food product labels to include, among other things, the name of the food, its ingredients, and its net quantity of contents.⁹³ While these requirements may seem basic today, they revolutionized the amount of information available to consumers from a label.⁹⁴ However, the FDCA failed in its primary purpose of informing and protecting allergic consumers⁹⁵ by allowing standardized foods to not disclose their ingredients.⁹⁶ Furthermore, the FDCA proves unsuccessful because it does not address the labeling of “subingredients” such as spices and flavorings.⁹⁷

Despite its simplicity, the FDCA remained virtually unchanged for seventy years.⁹⁸ In 2004, Congress rectified some of the inadequacies of the FDCA by enacting the Food Allergen Labeling and Consumer Protection Act (“FALCPA”).⁹⁹ The FALCPA established heightened requirements for food manufacturers by demanding products containing common allergens disclose allergens in distinguishable font of a certain size.¹⁰⁰ Additionally, “Contains” must precede the allergen so that the label reads, “Contains [allergen].”¹⁰¹ This statement must be

89. Gendel, *supra* note 14, at 280.

90. 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, 96 (2006).

91. *See* Gendel, *supra* note 14, at 280.

92. Derr, *supra* note 90, at 164.

93. *Id.* at 96.

94. *See generally id.* at 164.

95. *Id.*

96. *Id.* at 97.

97. *Id.*

98. *Id.* at 96.

99. *Id.* at 113.

100. 21 U.S.C. § 343(w)(1) (2012).

101. *Id.*

separate and distinct from the full ingredient list so that the reader can easily find it.¹⁰²

The FALCPA subjects eight “major food allergens” to its requirements:¹⁰³ milk, eggs, fish, crustacean shellfish (crab, lobster, shrimp), tree nuts (almonds, walnuts, pecans), wheat, peanuts, and soybeans.¹⁰⁴ These eight foods were singled out as causing 90 percent of all food allergies.¹⁰⁵ However, Congress failed to clarify whether that figure meant those eight foods cause 90 percent of allergic reactions, or whether 90 percent of food allergic individuals are allergic to one (or more) of those eight foods.¹⁰⁶ The FALCPA also addressed the “subingredient” issue by subjecting foods containing any type of protein derived from one of the eight major allergens to the FALCPA’s requirements.¹⁰⁷

B. Allergen Labeling Laws in the European Union

In 1995, the EU began to address the need for specific allergen labeling,¹⁰⁸ by commissioning the Scientific Committee on Food to conduct a study determining which allergenic foods present the most danger to allergic consumers.¹⁰⁹ Eight years later in 2003, the European Parliament amended its food labeling regulations to include allergen labeling requirements, in what is now the Food Information Regulation (FIR).¹¹⁰ Again, the EU commissioned the Scientific Committee on Food, this time to decide the foods applicable to the FIR. Due to the Committee’s findings, the European Parliament subjected twelve

102. *Id.*

103. *Id.*

104. 21 U.S.C. § 321(qq)(1) (2012).

105. Food Allergen Labeling and Consumer Protection Act, Pub. L. No. 108-282, § 202(2)(A), 118 Stat. 905, 906 (2004) (codified as amended at 21 U.S.C. 343).

106. Gendel, *supra* note 14, at 280.

107. 21 U.S.C. § 321(qq)(2) (though this requirement exempts certain highly refined oils and certain ingredients exempt under § 343(w)).

108. Gendel, *supra* note 14, at 280.

109. *Id.*

110. Council Directive 2003/89, annex IIIa, 2003 O.J. (L 308) 15 (EC) [hereinafter Council Directive 2003/89] (amending Council Directive 2000/13, 2000 O.J. (L 109) 29 (EC)). Both Directives were repealed and replaced for consistency purposes with Council Regulation 1169/2011, 2011 O.J. (L 304) 18 (EU).

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common food allergens to the requirements of FIR, thereby taking a more liberal stance than the United States.¹¹¹ These foods were cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, cow's milk, nuts,¹¹² celery, mustard, sesame, and sulfites present at over 10mg/kg.¹¹³

A unique characteristic of the FIR is it requires prepackaged foods to indicate whether allergens are contained in foods with unfamiliar names.¹¹⁴ For example, the food lysozyme contains egg, so once the FIR became enacted, all foods containing lysozyme had to communicate the fact that it contains egg—"Lysozyme (contains egg)."¹¹⁵ By requiring manufacturers to indicate whether allergens are present in either direct or derivative ingredients of prepackaged food, the FIR eliminated many of the problems arising from unlabeled hidden allergens.¹¹⁶

In 2011, the EU repealed and replaced the FIR¹¹⁷ in an effort to simplify the law, ensure legal certainty, reduce the administrative costs, and provide citizens with "clear, comprehensible and legible" food labels.¹¹⁸ First, mollusks and lupin were added to the original twelve regulated food allergens.¹¹⁹ Second, the allergen label must be clearly distinguishable, i.e., the font, background color, or style of a written

111. Council Directive 2003/89, *supra* note 110, at 18.

112. For example, nuts consist of almond, hazelnut, walnut, cashew, pecan, brazil, pistachio, macadamia, and Queensland. *Id.*

113. *Id.*

114. Gendel, *supra* note 14, at 282.

115. See Vincenzo Fierro et al., *Food Labeling Issues in Patients with Severe Food Allergies: Solving a Hamlet-Like Doubt*, 17 ALLERGY & CLINICAL IMMUNOLOGY 204, 205 (2017).

116. *Id.*

117. See generally Council Regulation 1169/2011, 2011 O.J. (L 304) 18, 19 (EU) [hereinafter Council Regulation 1169/2011] (repealing and replacing Council Directive 2000/13, 2000 O.J. (L 109) 29 (EC) and amendments thereto, effective Dec. 13, 2014).

118. EURO COMMERCE, GUIDANCE ON THE PROVISION OF FOOD INFORMATION TO CONSUMERS 1 (2013) [hereinafter EURO COMMERCE], http://www.fooddrinkeurope.eu/uploads/publications_documents/FDE_Guidance_WEB.pdf.

119. Council Regulation 1169/2011, *supra* note 117, at annex II; see also EURO COMMERCE, *supra* note 118, at 75.

allergen must differ from other ingredients.¹²⁰ Third, the FIR now requires the word “Contains” to precede the allergen on the label; for example, if a product contains peanuts, its label must state, “Contains Peanuts.”¹²¹ Fourth, the Committee must continually update the list of allergens subject to its labelling requirements.¹²²

Most importantly, the FIRS’s fifth amendment subjected non-prepackaged food to the FIR’s requirements.¹²³ The EU expanded the FIR to non-prepackaged foods after a study discovered 70 percent of severe allergic reactions occurred after eating non-prepackaged foods.¹²⁴ The extensive benefits of the amendment can be demonstrated in the following two examples. Imagine your neighborhood bakery; shelves aligned with a myriad of cookies, cakes, and pastries. A carrot cake which contains pecans sits on the bottom shelf. Pre-amendment, the sign in front of the cake would denote nothing more than its kind: Carrot. However, post-amendment, the sign must now read, “Carrot Cake, contains pecans.” In another scenario, visualize the menu of a generic breakfast restaurant. When looking at the pancake section, you are used to simply seeing “Buttermilk, Blueberry, Chocolate Chip, etc.” Now—easily identifiable and in conformance with the other 2011 FIR amendments—the section must include “Contains milk and eggs.” These two examples demonstrate the broad reach the FIR’s fifth amendment has on the entire EU food industry. Furthermore, it is the first of its kind; no other jurisdiction in the entire world applies its allergen labeling laws to non-prepackaged foods.

C. Allergen Labeling Laws in the United Kingdom

The United Kingdom’s (“UK”) allergen labeling laws mirror the EU’s FIR.¹²⁵ The Food Labeling (Amendment) (England) (No. 2) Regulations in 2004 were the UK’s first actual labeling regulations, which came from the country’s Food Standards Agency.¹²⁶ These

120. EURO COMMERCE, *supra* note 118, at 69.

121. See EAACI PUBLIC DECLARATION, *supra* note 17, at 21.

122. *Id.*

123. *Id.*

124. See *id.*

125. See The Food Labeling (Amendment) (England) (No. 2) Regulations 2004, SI 2824, intro.

126. *Id.*

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regulations enforced the 2003 EU Directive throughout England as they relate to allergen labeling laws.¹²⁷ However, just like the 2003 Directive, the 2004 English Regulation was revoked by the Food Information Regulations 2014, which implemented the EU's 2011 labeling amendments discussed above.¹²⁸ Like the EU, England's allergen labeling laws apply to both prepackaged and non-prepackaged foods¹²⁹

Like England, both Scotland and Wales follow the FIR; Scotland has its Food Information (Scotland) Regulations 2014,¹³⁰ while Wales has its Food Information (Wales) Regulations 2014.¹³¹ In sum, the three sections of the UK discussed above—England, Scotland, and Wales—all have nearly identical allergen labeling laws.

D. Allergen Labeling Laws in Australia and New Zealand

Australia and New Zealand's allergen labeling laws are found in the Australia New Zealand Food Standards Code ("Food Standards Code").¹³² Australia and New Zealand require prepackaged food labels to inform consumers if the food contains any of the following twelve allergens: peanuts, tree nuts, milk, eggs, sesame seeds, fish, shellfish, soy, wheat, lupins, or added sulfites over 10mg/kg.¹³³ The Food Standards Code requires these twelve allergens be written on labels of foods if they are either a direct ingredient or subingredient of the food.¹³⁴

127. *Id.* at Explanatory Note ¶ 1.

128. The Food Information Regulations 2014, SI 1855, sched. 6, pt. 1 (Eng.).

129. *Id.* ¶ 5(2).

130. See *Labeling and Composition Standards*, FOOD STANDARDS SCOT., <http://www.foodstandards.gov.scot/business-and-industry/safety-and-regulation/labelling> (last visited Dec. 7, 2017) (citing The Food Information (Scotland) Regulations 2014, (ASP 312)).

131. The Food Information (Wales) Regulations 2014, W.S.I. 2303 (W. 227).

132. Austl. N.Z. Food & Standards Code, *Standard 1.2.3 – Information Requirements – Warning Statements, Advisory Statements and Declarations*, F2017C00418 (May 25, 2017), <https://www.legislation.gov.au/Details/F2017C00418>.

133. *Id.* § 1.2.3–4.

134. *Allergen Labeling*, FOOD STANDARDS AUSTL. N.Z. (May 2017), <http://www.foodstandards.gov.au/consumer/labelling/Pages/Allergen-labelling.aspx>.

Although Australia and New Zealand do not subject non-prepackaged foods to allergen labeling requirements, they do regulate the amount of ingredient information food manufacturers must provide food caterers. A food caterer is a person, establishment, restaurant, or other company, who sells or offers food for immediate consumption.¹³⁵ The food manufacturer is required to provide the caterer with allergen information in conformance with the Food Standard Code's regulations.¹³⁶ For example, if a bakery delivers muffins every morning to a coffee cart, they must provide the coffee cart accurate allergen information, regardless of whether the muffin is prepackaged or not. In other words, food retailers in Australia are legally required to possess knowledge to help a customer choose an allergen-free menu item.¹³⁷

E. Allergen Labeling Laws in China

China implemented its first allergen labeling laws in 2012.¹³⁸ The China National Standard has two governing rules as it relates to labeling requirements: the General Rule for the Labeling of Prepackaged Foods, and the General Rule for Nutrition Labeling of Prepackaged Foods.¹³⁹ The General Rule for the Labeling of Prepackaged Foods identifies peanuts, soybeans, wheat, shellfish, fish, eggs, milk, and tree nuts as the

135. Austl. N.Z. Food & Standards Code, *Standard 1.2.1 – Requirements to Have Labels or Otherwise Provide Information*, §1.2.1—3, F2017C00718 (Sept. 7, 2017), <https://www.legislation.gov.au/Details/F2017C00718>.

136. *Id.* § 1.2.1–6.

137. *Declaring Allergens*, DEP'T OF PRIMARY INDUSTRIES FOOD AUTHORITY, <http://www.foodauthority.nsw.gov.au/foodsafetyandyou/food-labelling/labels-and-the-law/declaring-allergens> (last visited Apr. 21, 2018).

138. Wenting, *supra* note 71.

139. Guojia Shipin anquan guojia biao zhun yu baozhuang shipin yingyang biaoqian tongze GB 7718-2011 (食品安全国家标准 预包装食品营养标签通则 GB 7718-2011) [National Food Safety Standards General Rules for the Labeling of Prepackaged Food GB 7718-2011] (promulgated by Ministry of Health, Apr. 20, 2011, effective Apr. 20, 2012) (China), *translated in* USDA FOREIGN AGRIC. SERV., GAIN REPORT NUMBER CH110030 (May 25, 2011) [hereinafter GB 7718-2011]; Guojia Shipin anquan guojia biao zhun yu baozhuang shipin yingyang biaoqian tongze GB 28050-2011 (食品安全国家标准 预包装食品营养标签通则 GB 28050-2011) [National Food Safety Standards General Rules for the Labeling of Prepackaged Food GB 28050-2011] (promulgated by Ministry of Health, Oct. 12, 2011, effective Jan. 1, 2013) (China), *translated in* USDA FOREIGN AGRIC. SERV., GAIN REPORT NUMBER CH13001 (Jan. 9, 2013); Fierro et al., *supra* note 115, at 206.

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most problematic allergens,¹⁴⁰ notably, the same foods the United States deems “major allergens.” This Chinese standard only applies to prepackaged foods.¹⁴¹ It does not apply to food sold for immediate consumption as required in the EU, nor does it apply to manufacturers providing food to caterers as required in Australia and New Zealand.

The National Institute of Nutrition and Food Safety under the Chinese Center for Disease Control and Prevention noted China used the same statistics as the United States when it enacted FALCPA because it did not have its own reliable food allergy statistics.¹⁴² Some theorize the only reason China enacted allergen labeling laws is because it exports such a high volume of food to countries that do require allergen labeling.¹⁴³

F. Allergen Labeling Laws in Other Countries

Allergen labeling laws that regulate the way allergens are included on a prepackaged food’s label are not exclusive to the five countries discussed above. There are many other countries, both developed and developing, that regulate the way food allergens are disclosed. For instance, Canada’s Food and Drug Regulations list twelve types of food as priority allergens.¹⁴⁴ Canada’s allergen labeling laws are reflected in both the Food and Drugs Act and the Consumer Packaging and Labeling Act.¹⁴⁵ In 1994, Canada became the first country to regulate

140. GB 7718-2011, *supra* note 139.

141. *Id.*

142. Wenting, *supra* note 71.

143. Katrina J. Allen et al., *Precautionary Labelling of Foods for Allergen Content: Are We Ready for a Global Framework?*, WORLD ALLERGY ORG. J., Apr. 2014, at 1, 2.

144. *Common Food Allergens*, GOV’T OF CAN., <https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-allergies-intolerances/food-allergies.html> (last visited Dec. 7, 2017) (listing eggs, milk, mustard, peanuts, crustaceans, mollusks, fish, sesame, soy, tree nuts, wheat, and sulfites as priority allergens).

145. *See Allergen Labeling*, GOV’T OF CAN., <https://www.canada.ca/en/health-canada/services/food-allergies-intolerances/avoiding-allergens-food/allergen-labelling.html> (last updated Jan. 12, 2012) [hereinafter GOV’T OF CAN.] (discussing food producers’ twofold violation—of the Food and Drugs Act as well as the Consumer Packaging and Labeling Act—for failure to declare allergenic components).

the labels of prepackaged foods containing allergens.¹⁴⁶ In 2012, Canada amended its food allergy regulations, requiring priority allergens to be clearly and unambiguously labeled on products.¹⁴⁷ For example, milk must be labeled as milk, nothing else.¹⁴⁸ It cannot be labeled as “casein,” which is another term for milk.¹⁴⁹ With these new laws, Canada enabled its consumers to make accurate and informed choices regarding the foods they choose to eat.¹⁵⁰

Switzerland and Ukraine have their own allergen labeling laws given they are both located outside of the EU. However, the two countries subject the same fourteen allergens as the EU to their allergen labeling requirements.¹⁵¹ Switzerland’s laws are found in the Ordinance of the Federal Department of Home Affairs on Food Labeling and Advertising of Foods.¹⁵² Ukraine’s laws are found in the Technical Regulations on Rules for Marking of Food Products.¹⁵³

Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Mexico, Nicaragua, and Venezuela are the countries in Central and South America with allergen labeling laws.¹⁵⁴ Argentina’s allergen labeling requirements are found in the Argentine Food Code.¹⁵⁵ The country requires the same fourteen allergens as the EU to be listed on prepackaged foods.¹⁵⁶

Bolivia, Colombia, Costa Rica, Cuba, Nicaragua, and Venezuela require prepackaged food labels to indicate if the food contains any of the eight major allergens recognized by FALCPA.¹⁵⁷ The countries also

146. Fierro et al., *supra* note 115, at 206.

147. *Food Labeling*, FOOD ALLERGY CAN., <http://foodallergyCanada.ca/allergy-safety/food-labelling/> (last visited Dec. 7, 2017).

148. *Id.*

149. *Id.*

150. *Id.*

151. Gendel, *supra* note 14, at 281.

152. *Id.*

153. *Id.*

154. Allen et al., *supra* note 143, at 2.

155. Gendel, *supra* note 14, at 281.

156. *Id.*

157. INST. OF AGRIC. & NAT. RES.: FOOD ALLERGY RESEARCH & RES. PROGRAM, *Food Allergens-International Regulatory Chart*, U. OF NEB.-LINCOLN, <https://farrp.unl.edu/IRChart> (last visited Dec. 7, 2017).

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require the disclosure of cereals containing gluten and sulfites.¹⁵⁸ Mexico differs from these countries by not recognizing wheat as an allergen.¹⁵⁹

Brazil's allergen labeling laws went into effect in July 2016.¹⁶⁰ Brazil requires eighteen different allergens to be included on prepackaged food labels if the food contains the allergen as an ingredient.¹⁶¹ However, Brazil's list of eighteen allergens is the largest in South America because it counts tree nuts like walnuts, pecans, pistachios, and macadamia nuts as individual allergens, rather than clumping them together in the category of tree nuts.¹⁶²

In 1996, Chile enacted its allergen labeling laws,¹⁶³ which are found in the country's Food Health Regulations.¹⁶⁴ Chile adopts the same wording found in the Codex.¹⁶⁵ Chile is not the only country to enforce the language developed by the Codex; other countries that have adopted the Codex standards include Barbados, the Grenadines, Papua New Guinea, the Philippines, and St. Vincent.¹⁶⁶

China is not the only country in Asia with allergen labeling laws. Hong Kong, Japan, Kuwait, Malaysia, Singapore, and South Korea also have laws in place.¹⁶⁷ Similarly, Japan enacted the Food Allergen Labeling Regulation in the Food Sanitation Act in 2002, requiring seven foods be disclosed during all stages of production of prepackaged

158. *Id.*

159. *Id.*

160. FOOD ALLERGY RESEARCH & EDUC., TRAVELING TO BRAZIL WITH FOOD ALLERGIES (2016) [hereinafter TRAVELING TO BRAZIL], <https://www.Foodallergy.org/sites/default/files/migrated-files/file/Travel-Tips-Brazil.pdf>.

161. *Id.*

162. *Id.*

163. Law No. 977/1996, Aprueba Reglamento Sanitario de los Alimentos Approves Food Sanitary Regulations], Agosto 6, 1996, DIARIO OFICIAL [D.O.] (Chile) (amended 2016).

164. Law No. 13 Modifica Decreto Supremo No. 977/1996, Reglamento Sanitario de Los Alimentos [Decree No. 13 Amending Supreme Decree No. 977/1996, Food Sanitary Regulations], Abril 16, 2015, DIARIO OFICIAL [D.O.] (Chile).

165. *See* Gendel, *supra* note 14, at 281.

166. *Id.*

167. Fierro et al., *supra* note 115, at 208.

foods.¹⁶⁸ These foods were egg, milk, wheat, buckwheat, shrimp, crab, and peanut.¹⁶⁹ While Japan's list of recognized food allergens ballooned to twenty-seven as of 2013, the original seven foods remain the only allergens subject to mandatory disclosure.¹⁷⁰

The Japanese Government merely recommends disclosing the presence of the other twenty foods.¹⁷¹ Japan cites three reasons for not including these twenty foods in the mandatory disclosure category.¹⁷² First, there are much fewer reported allergic reactions to these foods compared to the original seven foods.¹⁷³ Second, there have been hardly any serious allergic reactions reported as a result of consuming these foods.¹⁷⁴ Third, no scientific studies exist indicating that requiring these foods to be included as allergens on prepackaged food labels would result in less allergic reactions.¹⁷⁵

In 2012, South Korea implemented allergen labeling laws in both the Ministry of Food and Drug Safety's Food Sanitation Act, and in the Korean Food and Drug Administration's Food Labeling Standards.¹⁷⁶ South Korea subjects twenty-one foods to its allergen labeling regulations.¹⁷⁷ It also requires these twenty-one foods be listed on their own separate labels next to the non-allergenic ingredients.¹⁷⁸ The allergens must further be labeled with a different background color

168. Masahiro Shoji & Hiroshi Akiyama, *Food Allergen Labeling Regulation and its Implementation in Japan*, Morinaga Inst. of Biological Sci., Inc., slides 10–11, <https://www.slideshare.net/Adrienna/japan-food-allergen-labeling-regulation> (last visited Dec. 7, 2107).

169. *Id.* slide 11.

170. Letter from Int'l Org. of the Flavor Indus., to Organization Members, on Food Allergen Labeling in Japan (Oct. 2, 2013), <https://farrp.unl.edu/77c3494f-6568-42f3-b62c-f97d21eb2586.pdf>.

171. *Id.*

172. *Id.*

173. *Id.*

174. *Id.*

175. *Id.*

176. Gendel, *supra* note 14, at 281.

177. *South Korean Food Labeling System*, S. KOR. MINISTRY OF FOOD & DRUG SAFETY, <http://www.mfds.go.kr/eng/index.do?nMenuCode=118> (last visited Mar. 19, 2018) [hereinafter S. KOR. MINISTRY OF FOOD & DRUG SAFETY] (listing these foods as abalone, beef, buckwheat, chicken, clams, crab, eggs, mackerel, milk, mussels, oysters, peaches, peanuts, pork, shrimp, soybeans, squid, sulfuric acid, tomato, walnuts, and wheat).

178. *Id.*

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from the other ingredients.¹⁷⁹ The Korean Food Labeling Standards require the specific quantity of an ingredient be listed on the food label unless the food is an allergen.¹⁸⁰ Except for sulfuric acid, the Food Labeling Standards require foods containing any of the stated allergens to be reported on the label, regardless of quantity.¹⁸¹

IV. PRECAUTIONARY ALLERGEN LABELING

Precautionary allergen labeling (PAL) is another major segment of allergen labeling. While regulations exist across the globe for labeling the presence of known food allergens on prepackaged foods, PALs remain another story. A PAL is a warning on a prepackaged food product that informs consumers that the product may have been cross-contaminated with a known food allergen during the manufacturing process.¹⁸² The food industry created PALs to balance risk management with increasing allergic consumers.¹⁸³ Consequently, an overwhelming amount of food products contain PALs, with one study finding over 50 percent of certain foods have PALs.¹⁸⁴

The majority of countries discussed in this comment neither mandate, ban, nor regulate precautionary allergen labeling. Rather, most countries with a food allergen labeling framework merely offer suggestions about how to handle PALs. This section identifies countries with PAL laws and offers recommendations or guidelines for food producers to follow.

179. *Id.*

180. *See id.*

181. *Id.*

182. Giovanni A. Zurzolo et al., *Is Advising Food Allergic Consumers to Avoid Foods with Precautionary Allergen Labeling out of Date?*, 16 *ALLERGY & CLINICAL IMMUNOLOGY* 272, 272 (2016).

183. Galvin A. Dunn et al., *Precautionary Allergen Labeling: Perspectives from Key Stakeholder Groups*, 70 *EUR. J. OF ALLERGY & CLINICAL IMMUNOLOGY* 1039, 1042 (2015).

184. B.C. Remington et al., *Unintended Allergens in Precautionary Labelled and Unlabelled Products Pose Significant Risks to UK Allergic Consumers*, 70 *EUR. J. OF ALLERGY & CLINICAL IMMUNOLOGY* 813, 813 (2015).

A. Countries that Suggest Precautionary Allergen Labeling

In the United States, FALCPA regulates foods containing one of the eight major allergens. PALs, however, are unregulated; they are entirely optional, even when products have identifiable cross-contamination risks.¹⁸⁵ The extent of FALCPA's efforts lie in its requirements that the Secretary of Health and Human Services check food producing facilities to make sure they are following good manufacturing procedures designed to reduce or eliminate potential cross-contact with unintended allergens.¹⁸⁶

The EU also does not regulate PALs.¹⁸⁷ The EU's most recent legislation over allergen labeling states PALs are optional. Furthermore, the EU provides zero guidance as to when or how to apply a PAL.¹⁸⁸

Australia has implemented an industry standard to determine if a PAL should be applied.¹⁸⁹ Australia is the first country to introduce a program of its type, called the Voluntary Incidental Trace Allergen Labeling program ("VITAL"), that allows food manufacturers to conduct tests to help determine the risk of cross-contamination.¹⁹⁰ These tests allow manufacturers to make informed decisions regarding the application of a PAL.¹⁹¹

Canada is currently considering policy revisions to include PALs if the food manufacturer believes there is a possibility the product was cross-contaminated.¹⁹² In 2016, Canada acknowledged PALs in amendments to its Food and Drug Regulations.¹⁹³ Though Canada does not require PALs, *if* they are included, current regulations explain

185. See generally 21 U.S.C. § 343 (2012).

186. Food Allergen Labeling and Consumer Protection Act, Pub. L. No. 108-282, § 205, 118 Stat. 905, 909–10 (2004) (codified as amended at 21 U.S.C. § 374a (2012)).

187. EAACI PUBLIC DECLARATION, *supra* note 17, at 21.

188. *Id.*; see generally Council Directive 1169/2011, *supra* note 117.

189. Zurzolo et al., *supra* note 182, at 273.

190. Allen et al., *supra* note 143, at 10.

191. *Id.*

192. See generally GOV'T OF CAN., *supra* note 145.

193. See generally Regulations Amending the Food and Drug Regulations (Nutrition Labelling, Other Labelling Provisions and Food Colours), SOR/2016-305 (Can.), <http://gazette.gc.ca/rp-pr/p2/2016/2016-12-14/html/sor-dors305-eng.html>.

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where and how they must be declared.¹⁹⁴ The PAL must be displayed immediately following a “Contains” statement, listing food allergens, gluten, and/or added sulphite ingredients.¹⁹⁵ If no “Contains” statement exists, the PAL must immediately follow the ingredient list.¹⁹⁶ The PAL must also be “against the same background colour” and, if applicable, “within the same solid-line border as the ingredient list and statement.”¹⁹⁷

Canada guidelines further recommend food manufacturers use only the following PAL on food labels for purposes of consistency and clarity: “May contain: [allergen].”¹⁹⁸ Regulations require, however, that a title such as “May contain:” must be bolded if it is placed on the same line as the ingredient list or statement, but that bold font is not required if the phrase begins on a separate line.¹⁹⁹ If not introduced by a title, such as “May contain: [allergen],” the font must be bolded regardless of whether it is on the same or a separate line.²⁰⁰

B. Countries Regulating Precautionary Allergen Labeling

Eight countries currently regulate the use of PALs: Argentina, Canada, Brazil, Japan, South Korea, South Africa, and Switzerland. Brazil and South Korea are the only countries that require the use of PALs. In Brazil, if a product poses cross-contamination risks, or if a product cannot guarantee the absence of allergens, it must include the statement, “ALLERGIC: MAY CONTAIN [allergen].”²⁰¹ In South Korea, manufacturers must include PALs on allergen-free foods if the food is manufactured using the same process as foods containing allergens.²⁰²

194. Food and Drug Regulations, C.R.C., c 870 (Can.) [hereinafter Canada Food and Drug], http://laws-lois.justice.gc.ca/PDF/C.R.C.,_c._870.pdf.

195. *Id.* § B.01.010.4.

196. *Id.* § B.01.010.4(a).

197. *Id.*

198. *Food Allergen Precautionary Statements*, CAN. FOOD INSPECTION AGENCY, <http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/allergens-and-gluten/eng/1388152325341/1388152326591?chap=4> (last updated May 11, 2018).

199. Canada Food and Drug, *supra* note 194, § B.01.010.4(d).

200. *Id.* § B.01.010.4(c).

201. TRAVELING TO BRAZIL, *supra* note 160.

202. S. KOR. MINISTRY OF FOOD & DRUG SAFETY, *supra* note 177.

Argentina and Japan are the only countries that ban the use of PALs.²⁰³ In Argentina, a 2010 law prohibited the use of PALs.²⁰⁴ The Argentinian government's rationale was simple; either a food contains an allergen or it does not.²⁰⁵ In Japan, prepackaged food manufacturers are banned from including the wording "May Contain [allergen]" on products.²⁰⁶ However, Japan does allow manufacturers to include statements such as, "This food is manufactured in a facility that uses [allergen]."²⁰⁷ This exception is not some clever way around Japan's PAL ban.²⁰⁸ Rather, this language permits manufacturers to promote the high quality ingredients of their food.²⁰⁹ For example, including the statement, "This food was 'produced in the same factory' that uses fish," is allowed because Japanese culture views fish as one of the healthiest foods.²¹⁰ Therefore, a manufacturer can place that label on a product to entice consumers.²¹¹

Switzerland and South Africa are the only countries to implement conditional bans on the use of PALs.²¹² Generally, PALs are not allowed in either country,²¹³ however, in South Africa, a manufacturer may apply a PAL by providing evidence of cross-contamination risk despite complying with South Africa's Food Standards Code.²¹⁴ In Switzerland, a manufacturer is only permitted to apply a PAL by scientifically proving allergens are present in the food as a result of cross-contamination.²¹⁵

203. Allen et al., *supra* note 143, at 8–9.

204. *Id.* at 9.

205. *Id.*

206. *Id.* at 8–9.

207. *See id.* at 9.

208. *See id.*

209. *Id.*

210. *See id.*

211. *Id.*

212. *Id.* at 8–10.

213. *Id.*

214. *Id.* at 10.

215. *Id.* at 8.

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V. ISSUES ARISING FROM ALLERGEN LABELING LAWS AND THE LACK OF GLOBAL FRAMEWORK

Part III identified fifty-three legislative bodies that have enacted their own allergen labeling laws. While a common theme runs amongst the different laws—the foods considered allergens and the emphasis of the allergen on the food label—these laws have many differing components. Some countries recognize only eight major allergens, while others recognize as many as twenty-seven. The differences in the laws and the expanding global supply chain of food, medical professionals, scientists, and researches alike call for a global framework as it relates to both mandatory allergen labeling and PALs.²¹⁶

“There is a clear need for harmonization in PAL statements to decrease the burden felt by food allergic consumers.”²¹⁷ Studies address the widespread ambiguities surrounding the way allergen warnings are worded on labels.²¹⁸ This confuses consumers when reading a label that contains a PAL.²¹⁹ The words, “May Contain,” “Manufactured in a facility that processes [allergen],” and many others fall under the guise of a PAL.²²⁰ However, all of these statements contain different language. Consumers face difficulty differentiating between products that pose a risk, and products with no risk, especially where corporations apply a warning in an attempt to absolve themselves of liability. When food labels use ambiguous phrases, allergic consumers must either believe they have such a strong allergy to make them stay away from the food or ignore the warning altogether because the market is saturated with PALs.

Additionally, food allergic individuals tend to believe that PALs are required by law.²²¹ As a result, consumers believe a hierarchical difference exists amongst the differing statements they see on

216. *See id.* at 11–12.; *see also* Zurzolo et al., *supra* note 182, at 275.

217. Remington et al., *supra* note 184, at 813.

218. Zurzolo et al., *supra* note 182, at 275.

219. *Id.*

220. 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, 172 (2017).

221. Dunn et al., *supra* note 183, at 1040.

products.²²² However, these statements have no differing levels of importance; a “May contain peanuts” PAL deserves identical attention as a “Made in a facility that processes peanuts” PAL. Currently, PALs wording is nothing more than what the manufacturers decide to write.

The lack of regulations surrounding PALs not only confuses consumers,²²³ but could also confuse food manufacturers because they do not abide by clear regulations. As a result, food manufacturers are likely left with making an educated guess about when to include a PAL. Lastly, PALs further confuse doctors and healthcare professionals.²²⁴ A study in the UK found only one-third of doctors would suggest their food allergic patient avoid foods with PALs.²²⁵ That statistic hardly consoles consumer confidence.

VI. SUGGESTIONS FOR IMPROVING ALLERGEN LABELING LAWS

Given the exponential rise in allergic consumers, coupled with a global chain of commerce, it is more important than ever to protect consumers with food allergies. For true consumer protection, the United States and other countries must follow the EU’s lead and require non-prepackaged foods to adhere to the same regulations as prepackaged foods. Considering studies have shown up to 70 percent of allergic reactions result from ingesting non-prepackaged foods, this requirement should reduce the amount of annual allergic reactions.²²⁶ As a person with food allergies myself, the majority of allergic reactions I endured, and general anxiety I experienced, came from eating or deciding to eat some sort of non-prepackaged food.

Additionally, PALs should only be allowed if the manufacturer can scientifically demonstrate its necessity. The lack of PAL regulations hurts the consumer and eliminates the incentive for companies to exercise good manufacturing practices that would reduce the risk of cross-contamination and eradicate the need for a PAL in the first place. Furthermore, the litany of products on grocery shelves containing ambiguous PAL statements, warrant a shift in the law in the United States and other countries towards Switzerland and South Africa’s

222. *Id.*

223. *Id.* at 1040–41.

224. *Id.* at 1041.

225. *Id.* at 1042.

226. EAACI PUBLIC DECLARATION, *supra* note 17, at 21.

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policies preventing manufacturers from applying PALs without showing cause.

VII. CONCLUSION

This comment provides a working knowledge of food allergies, their causes, symptoms, and prevalence. It provides the history of allergen labeling laws in various regions, how those laws have evolved under changing circumstances, and what they are today. If other countries follow the EU's expansion of allergen labeling laws to non-prepackaged foods, the world will be safer for the food allergic consumer.

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* J.D., *cum laude*, California Western School of Law, 2018; I would like to thank Professor Robert Bohrer for his guidance and friendship, while writing and beyond. I must also thank the lead editor of this comment and my good friend, Evangeline Dech, for always being available. Last, I would like to thank our Editor-in-Chief Brooke Raunig and the numerous other Law Review members who provided thoughtful contributions to this comment.