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Legal Implications of Digital Health Apps Informing Food Allergy Labeling for Consumers' Health and Privacy Protection

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Legal Implications of Digital Health and Wellness Apps Informing Food Allergy Labeling for Consumers' Health and Privacy Protection

Kathy Keunghee Kim

Submitted to the faculty of Indiana University Maurer School of Law

in partial fulfillment of the requirements for the degree

Doctor of Juridical Science

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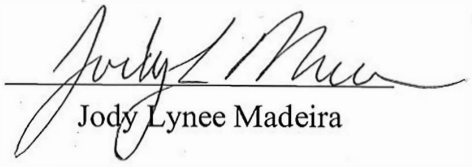
Doctoral Committee



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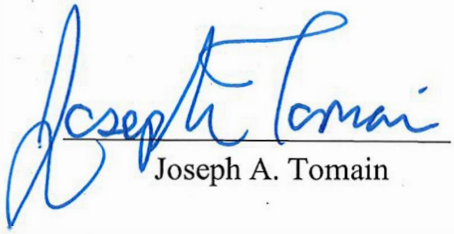

Joseph A. Tomain

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Kathy Keunghee Kim

LEGAL IMPLICATIONS OF DIGITAL HEALTH AND WELLNESS APPS INFORMING FOOD ALLERGY LABELING FOR CONSUMERS' HEALTH AND PRIVACY PROTECTION

This dissertation examines food allergy labeling's use in a digital format. Allergy information is typically found on food packaging and containers to help consumers identify individually concerned allergens. Given the critical role that food allergy labels play in preventing unexpected allergic reactions before selecting or consuming food, it is essential to comprehend the labeling descriptions. However, current regulations and laws regarding allergy labeling often confuse consumers due to the existence of mandatory and voluntary Precautionary Allergy Labeling (PAL) categories and the absence of laws and regulations that require allergy information for restaurant meals. Technology companies have introduced digital health and wellness applications(apps) to detect food allergens in the market in response to ongoing consumer demands. These apps allow users to access information about contained allergens instantly. Digital allergy apps come in various formats.

Considering consumers' popular use of digital health and wellness apps to get allergen information, this research investigates 1) whether these digital applications adhere to existing allergy labeling laws and regulations, 2) whether globally available digital apps follow internationally discussed or U.S. standards; and 3) whether digital apps safeguard consumer privacy when sharing personal health information as a personal setting condition of logging in to the apps and obtaining immediate allergy details through a mobile platform. First, reviewing current laws and regulations analyzed the standards, laws, and regulations of the U.S. Food and Drug Administration (FDA), EU legislation, and other countries for mandatory and voluntary

allergy labeling and its application to pre-packed food and restaurant food. Second, privacy protections in digital apps review the privacy protection regulations of the U.S. FDA, The Health Insurance Portability and Accountability Act of 1996 (HIPAA), HIPAA-Federal Trade Commission (FTC) Acts, EU privacy laws and regulations, and other U.S. state laws. Third, this study further reviews the presently used mobile apps by analyzing allergy labeling laws, regulations, and privacy protection laws.

Consequently, apps available in the U.S. market were observed to comply with the mandatory allergen labeling requirements set by the U.S. FDA while also including additional allergens at the discretion of the app developers. In terms of privacy protection, most food allergy apps implement general privacy law requirements but need to be considered by lawmakers to set up guidelines to safeguard against sharing health-related information for using digital health and wellness apps.

CHAPTER I: INTRODUCTION

1.1. Overview of Demand for Digital Informative Food Allergy Labeling

With the growing worldwide focus on selecting nutritious foods tailored to individual health needs, consumers increasingly seek user-friendly digital tools or applications(apps) that can swiftly identify food allergens or potential risks. These tools provide immediate cautionary information, allowing users to make safe food choices by excluding specific hazardous ingredients without the need to decipher complex labeling statements. Phone-based software can easily recognize food allergy indicators through simple screen interactions. Mobile apps enable consumers to customize their dietary preferences by selecting specific allergens of concern for food menus. Although consumers may lack specialized medical knowledge about allergic reactions to various ingredients, it is essential that food-related digital applications incorporate health information aligned with U.S. federal government guidelines on food allergy labeling requirements and regulations. This approach should also consider how other countries regulate food allergy labeling descriptions to ensure comprehensive coverage.

According to the U.S. Center for Disease Control (CDC) Statistics (2021), nearly 6.2% of the U.S. adult population and 5.8% of children have reported experiencing food allergies.[1] 10% of the global population has reported having concerns about food allergies and experienced unexpected food allergy reactions.[2] Moreover, more than 8% of children suffer from food allergies, and 35% experience bullying or threats with verbal teasing about food.[3]

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[1] Center for Disease Control and Prevention (2023)https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/20220126.htm.

[2] Scott H. Sicherer, and Hugh A. Sampson, *Food allergy: A review and update on epidemiology, pathogenesis, diagnosis, prevention, and management,* J. ALLERGY CLIN IMMUNOL at 42 (2018).

[5] Eyal Shemesh, Rachel A. Annunziato, Michael A. Ambrose, Noga L. Ravid, Chloe Mullarkey, Melissa Rubes, Kelley Chuang, Mati Sicherer & Scott H. Sicherer, *Child and Parental Reports of Bullying in a Consecutive Sample of Children With Food Allergy*, Pediatrics, 131 (1): e10–e17 (2013).

According to the CDC, between 2007 and 2016, food allergic reactions in children increased by 377%, and around 855 million Americans suffered unexpected food allergic accidents.[4] Globally, the prevalence of food allergies in children has doubled over the last 10 years, showing 1.7% in Greece; 3.6% in Denmark; 4% in Italy and Spain, and more than 5% in France.[5] Considering that allergic reactions in children are highly risky and prevalent, the safe choice of food without fear should not be a one-time event. However, precautions and healthy choices for allergic foods remain uncertain everywhere, including in restaurants and cafés.

Food allergy is not a mystery, but its cause and symptoms, including "skin reaction, hives along with itching, or flushed or pale skin, constriction of the airways and a swollen tongue or throat" or "nausea, vomiting or pale skin," are well known to the public and scientifically researched to find the solution to prevent it.[6] If a life-threatening reaction begins, epinephrine injection is the post-solution after people have suffered unwanted allergic reactions.[7] Legislators pursued preventive measures to mandate listing food allergens in the restaurant food, not just limiting prepacked food or meals. Legislative reforms have been raised to implement more effective and clear labeling systems, expand to protect against immediate reactions to unexpected incidents by informing more medical actions, and educate parents and children to educate two different ways of description of labeling and understand the different allergy labeling

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[4] Food Allergy Research Education Survey(2021), https://www.foodallergy.org/?gclid=Cj0KCQiAkNiMBhCxARIsAIDDKNWt_VLfOqLLRl2Lo6btmPdjSPgLxRBYnSjSZqtj4med1EhMDkNnCaoaArJiEALw_wcB.

[6] Food Allergy Rates in Young Children.,www.londonallergy.com (last visited Oct. 23, 2024

[7]MAYO clinic, Diseases and Conditions: Anaphylaxis(2013),, http://www.mayoclinic.org/diseases-conditions/anaphylaxis/basics/symptoms/con-20014324.

[8] In 2013, a 13-year-old girl with a peanut allergy and her father, a doctor, made national news when the girl experienced an anaphylactic reaction to a peanut at a Sacramento, California summer camp. The girl subsequently died in her father's arms, despite the father dutifully following medical protocol to stop the reaction. *See 13-Year-Old Dies at Sacramento Camp from Peanut Allergy Despite Receiving Medicine*, CBS NEWS (July 31, 2013, 11:00 AM), http://www.cbsnews.com/news/13-year-old-dies-at-sacramento-camp-from-peanut-allergy-despite-receiving-medicine/.

requirements between major food allergen as main ingredients of food and voluntary food allergen in the label, aka precautionary allergy labeling that is voluntarily informed by food providers or manufacturers. In an effort to identify unexpected risky allergic reactions, the U.S. Congress designates general systems to decide the factors on which major allergens to be required to list in the labeling. As the allergic reaction is not curable but required to be prevented from individually harmful allergens, Congress's regulation reflects that food allergy is easily not curable and that "a food-allergic consumer must avoid the risky food to which the consumer is allergic."[8]

During the COVID-19 pandemic, the Food and Drug Administration("FDA") temporarily relaxed food labeling requirements because the operation of food supply chains valued priority over delaying providers' food supply due to the strict regulation to investigate all ingredients and list them on the label. By contrast, consumers are more at risk of experiencing food allergen reactions if they have to choose food without knowing which ingredients are contained therein.[9] Considering that food choice is related to individual health concerns, many app developers have started to seek convenient ways of reading allergens without having difficulty understanding label descriptions. At the same time, consumers' daily use of mobile devices seeks a feasible way of reading allergen descriptions during grocery shopping or preparing a meal plan. While consumers order food and check other similar food items or menus using digital apps during the grocery shopping ordering or grocery shopping, their patterns of changing behavior in grocery shopping demand to find, read, and understand label information of selected food items immediately. However, consumers' use of digital apps to detect allergen information in the

[9] Food Allergen Labeling and Consumer Protection Act of 2004, supra note 5.
Kate E C Grimshaw , Joe Maskell, Erin M Oliver, Ruth C G Morris, Keith D Foote, E N Clare Mills, Graham Roberts & Barrie M Margetts, *Introduction of complementary foods and the relationship to food allergy*, Pediatrics 132(6):e1529-38 (2013).

restaurant is limited because labeling information listed or offered for consumer's reviews on the digital apps pulled out the information from commercial grocery retailers' (e.g., supermarkets) websites directly from the manufacturer's websites, and third-party online grocery providers (e.g., digital shopping apps linked to the various grocery retailers). As consumers check allergen information from food menus or labeling descriptions, consumers may receive the allergen information only by reading the food menu or asking the restaurant servants when the food is ordered for ready-to-eat meals (e.g., salad or hot food bars). Therefore, consumers' demands have turned to using digital devices to detect or inform allergens contained in food directly, instantly, and conveniently without having trouble reading food label information.

Individual consumers experiencing food allergies must live with the burden of physical symptoms, psychological stress, and financial costs without guaranteeing they will be able to avoid unexpected allergen taking. An individual's effective protection from unexpected risky food choices must be safely assured during the food selection stage without waiting until the stage of tasting a fully cooked meal to detect risky food allergens. It is too late to cure unexpected risks if consumers experience a serious food allergic reaction by consuming unwanted allergens without noticing it. Consumers may not ask their liability to provide allergens against the manufacturers or food restaurants even if they have experienced allergen risks from their food served by restaurants or sold by food manufactures.

Currently, mandatory labeling in the U.S. requires listing only nine allergenic ingredients. However, these allergens designated in the U.S. are not similarly applied to other countries' food labeling laws and regulations. As each country designates different types of allergens to be regulated, non-categorized allergens as the main allergens, are not regulated according to the description of the food label, even though a specific allergen may cause a severe reaction to a

specific person. For example, because the U.S. does not require mustard to be listed on allergen labels, U.S. residents cannot claim against manufacturers for not informing allergen even if mustard is contained in prepacked or ready-to-eat food but not listed in the allergen section. Many consumers are worried about suffering from food allergies without a solution or proper cure.[10] Although consumers depend on food allergy labeling descriptions to avoid allergic risks, reading the ingredient information on the food labeling is still challenging for consumers. The major allergies that each country regulates may confuse consumers in reading allergen descriptions from one country and assuming the same regulation applies to other countries as consumers understand food providers or manufacturers intended to express contained allergens. Consumers assume that the regulations for listing the number and name of allergens are the same, regardless of the country of origin. In an effort for consumers to ensure that all ingredients are described on the food label, food manufacturers or suppliers voluntarily inform the possibility of containing mandated allergens that are predicted to cause unexpected risks and other food allergy elements when food providers or manufacturers want to voluntarily warn any possibility to add concerned allergens in the type of PAL. However, food manufacturers or food suppliers' voluntary PAL in the U.S. uses various definitions and terminologies, causing more confusion for consumers in interpreting the text meanings of various versions of the labeling.[11]

Moreover, food allergy labeling in each country does not have a universal international list of allergens and requires consumers to have a pre-requisite knowledge of differentiating of not regulated by a unified system of mandated regulations and controlled by each country's laws

[10]Scott H. Sicherer & Huge A. Sampson, *Food allergy: A review and update on epidemiology, pathogenesis, diagnosis, prevention, and management*. J. Allergy Clin. Immunol. 141, 41–58 (2018), https://doi.org/10.1016/j.jaci.2017.11.003.

[11] Mary Jane Marchisotto , Laurie Harada, Opal Kamdar, Bridget M Smith, Susan Waserman, Scott Sicherer, Katie Allen , Antonella Muraro 8, Steve Taylor 9, Ruchi S Gupta 10, Food Allergen Labeling and Purchasing Habits in the United States and Canada, J Allergy Clin Immunol Pract, Mar-Apr;5(2):345-351.e2 (2017).

and regulations in which allergens should be listed the same regardless of the labeling located worldwide. For example, the United States requires nine allergens[12] to be listed as major food allergens,[13] and the European Union (EU) requires listing 14 allergens as major allergens.[14]

Under the current food allergy labeling system and regulations, the allergy section in food labeling still confuses consumers to choose food by reading the allergy label if the voluntary allergen is listed in the labeling. Still, it's not the main ingredient of food. The text description on the food label is the only one for consumers to refer to allergen information.

Current regulations stipulate two distinct labeling requirements for food products: a) mandatory allergen disclosure in the main ingredient list and b) optional allergen warnings or PAL. The latter involves listing potential allergens as a cautionary message, using phrases like "may contain" when food producers or manufacturers suspect the possibility of allergen introduction during any stage of food preparation, production, packaging, or distribution. Given the ongoing need to safeguard against unforeseen risks in food selection, consumers are seeking alternative methods to enhance existing allergy labeling practices. They desire clearer and more explicit indications of food allergens to ensure their ingredient choices do not pose potential health hazards.[15]

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[12] Major Food Allergens in the U.S. (FDA): Milk, Egg, Fish, Crustacean Shellfish, Tree Nuts, Wheats, Peanuts, Soybeans, and Sesame)

[13]Food, Drug, and Cosmetics Act, §21 U.S.C. 343(w)(1).

[14] EU Food Information Regulation 1169/2001 (FIR), regulates the 14 allergens including celery**;** cereals containing gluten (such as wheat;barley, and oats**);** crustaceans (such as prawns, crabs, and lobsters); eggs**;** fish**;** lupin**;** milk**;** molluscs (such as mussels and oysters); mustard**;** peanuts**;** sesame**;** soybeans**;** sulphur dioxide and sulphites (if the sulphur dioxide and sulphites are at a concentration of more than ten parts per million)**,** and tree nuts (such as almonds, hazelnuts, walnuts, Brazil nuts, cashews, pecans, pistachios, and macadamia nuts).

[15] Elizabeth Dunford , Helen Trevena, Chester Goodsell, Ka Hung Ng, Jacqui Webster, Audra Millis, Stan Goldstein, Orla Hugueniot & Bruce Neal, *FoodSwitch: A Mobile Phone App to Enable Consumers to Make Healthier Food Choices and Crowdsourcing of National Food Composition Data*, JMIR Mhealth Uhealth, 2(3):e37 (2014).

Since most consumers carry mobile devices, medical device manufacturers and tech companies develop digital devices that indicate all allergens or customize risky reactions to an individual's health conditions.[16] While mobile app developers offer digital health and wellness apps indicating allergens in food selection or meal suggestion, the regulation of controlling the digital health and wellness apps set the allergen information must be discussed, including which allergens need to be listed and how digital allergen labeling indicates predicted risks by analyzing consumers' real-time collected health information and interacting with other members of mobile apps or recommended experts to discuss personal food choice based on their allergen concerns or information entered when they created the account for using mobile apps to sort out food items contained unwanted allergens.

Easily reading Food allergy labeling descriptions through mobile phone apps has been introduced by tech companies and app developers as the alternative way of reading and recognizing food allergens from presently used food labels by indicating allergens contained in food and warning consumers of expected allergic responses to food, which are predicted to boost consumers' ability to make food choices safely. Although consumers seek to read food label descriptions and steer clear of products containing allergens they're sensitive to, specialized features in mobile applications that highlight allergens motivate users to utilize these apps more frequently. This increased usage allows consumers to review allergen lists prior to making menu selections or choosing food items.

However, various stakeholders, including food manufacturers, food suppliers, and healthcare tech companies, are still unclear on which laws and regulations control food allergy

[16] S.P. Goldstein, B.C. Evans, D. Flack, A. Juarascio, S. Manasse, F. Zhang, E.M. Forman, *Return of the JITAI: Applying a Just-in-Time Adaptive Intervention Framework to the Development of m-Health Solutions for Addictive Behaviors* (2017), https://doi.org/10.1007/s12529-016-9627-y.

labeling devices to monitor the description of allergens or which scope of mobile user's personal information is collected and shared if mobile apps indicating allergens ask users to provide personal information and health information including allergen concerns.

To address this problem, this study analyzed the current food allergy labeling system, laws, regulations, proactive actions, and any concerns about implementing new digital devices to determine whether the currently used digital health and wellness devices indicating allergy labeling can supplement the current system. First, I reviewed several countries' labeling requirements, regulations, and standards, including the U.S., EU, and WHO countries. Actions in law-making at the state level in the U.S. are also introduced to find the current state requirements that may need to be implemented in educating consumers and training restaurant employees to supplement the current federal allergy labeling regulation. Second, this study assessed whether digital mobile health and wellness apps indicating food allergens as the alternative method of allergy labeling descriptions follow current regulations of allergy labeling systems under the U.S., EU, and WHO codex standards. As many U.S. states and industry sections try to establish guidelines to list all the possibly contained allergens to protect people from hazards in food choices, mobile health and wellness apps indicating allergen information have been developed to demonstrate an easy way to read labeling descriptions. Third, this study analyzed current mobile health and wellness apps as the alternative type of allergy labeling indicator and compared them to current food allergy labeling laws and regulations. Finally, this study reviewed privacy laws and regulations for apps that collect and share consumer health information that could apply to mobile health and wellness apps.

1.2. Statement of the Problem

1.2.1. Introduction – Current Issues of Designating Labeling Description

Food allergy labeling descriptions are part of the pre-packaged food label. While consumers use more digital devices handy everywhere, tech developers offer digital health and wellness apps to indicate the allergens as the alternative labeling or provide the same allergen labeling as the digital type by linking to the food label on the mobile. Thus, this section discusses what is the current food allergy labeling issues, regulation and regulation standards, and further what types of digital health and wellness apps are offered to help consumers read food allergen descriptions from food labeling and any disputed concerns in using digital apps as the alternative method of being informed of allergen descriptions.

Food allergy labeling description is composed of two sections that require 1) listing major mandatory food allergens as the component of food and 2) voluntary food allergens, a.k.a PAL that are listed by food manufacturers or food providers, when they found food allergens are likely to be added in the type of artificial flavor or during any stage of the manufacturing process of preparation, processing, and packaging of the food. In addition, WHO defines Reference Dosage, which designates the proper dosage of each allergen that can be tolerated to avoid unexpected food allergen risks. Therefore, this section reviews food labeling standards, the history of defining food items, and flavor as food ingredients.

In regulating allergen description, the EU and U.S. have common regulations in identifying major allergens, also known as “priority allergens,” as mandatory allergens to identify in the plain language on the food label, even though their number of regulated allergens is different. Currently, other countries agreed upon by the Food and Agriculture Organization (FAO) and the World Health Organization follow the regulations of either the European Union

(EU) standard or the Codex General standard.[17] Thus, in section 1.2.3, the allergy labeling standard has been set to review the United States, the EU, and the adoption of the Codex general standard in three categories: mandatory, voluntary, and Codex Reference Doses.

As consumers do not read food labeling descriptions clearly, app developers offer digital health and wellness apps to list food allergens to help consumers select food or plan a meal plan. In Section 1.2.4, this paper review raises issues in using digital health and wellness apps as an accommodated tool to read food label descriptions.

1.2.2 Food Labeling Standards

Food allergy labels are applied to all food products worldwide. Considering food labeling is required to be contained in the pre-packaged food products regardless of production, manufacturing, and consumption location, the issue is whether food labeling standards need to be unified to apply the same standard to all country's food products regardless of which location the prepackaged food items are sold and consume. Food labeling's clear and simple descriptions are the prerequisite for consumers' health and wellness protection because food labeling descriptions can guide consumers to choose the right food without risking their unexpected health concerns.[18] In food labeling, food manufacturers have historically treated allergen descriptions of natural food ingredients differently than artificial/favored ingredients.

The allegation of the "misbranded" definition was first raised in the 1924 "Ninety-Five Barrels (More or Less) Alleged Apple Cider Vinegar" case. The Court first declared it "misbranded" for a supply of "apple cider vinegar made from evaporated apples." At that time, the term 'misbranded' was interpreted to be with a consumer's common understanding and usual assumptions. For example, the Court found that the manufacturer had "misbranded" the apple

[17] SEPEHR, AREF. "Development of Nutrient Profiles in the European Union." 2023, https://core.ac.uk/download/579954008.pdf.
[18] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10169132/table/Tab2/

cider vinegar made from selected apples because the product advertising “evaporated apples” used unevaporated apples but manufactured chemically processed apples. The Court's efforts to review and analyze the exact meaning of the description were directed toward consumer protection.

However, the present law requires food providers and manufacturers to list all ingredients if any ingredient has been added to any type of food or stage of preparing, manufacturing, or packing the food. Thus, this section reviews food labeling standards for 1) natural food and artificial flavor and 2) mandatory, voluntary, and WHO Codex requirements that apply to both natural food and artificial flavor.

A. Designation of Main Ingredient Allergens

The U.S. FDA’s food allergy regulation of ingredients does not specify a "natural" food description when manufacturing food. U.S. FDA allergen labeling does not strictly force farmers or retailers to specify natural food when their food information omits an "all-natural” description in unpackaged farming food products.[19] The 2004 Food Allergen Labeling and Consumer Protection Act (FALCPA) dramatically changed food allergy labeling standards. The FALCPA mandated the enumeration of eight major food allergens on the label: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans.[20] This FALCPA applies to all food descriptions even if consumers clearly understand packaged food produced or manufactured as natural farming products.[21]

[19] Press Release, Inst. Of Food Technologists, Is There a Definition for Natural Foods? (June 30, 2008), available at http://www.am-fe.ift.org/cms/? pid=1000744.
[20] Pub. L. 108-282, Title II.
[21] *Id*

Like the U.S., the EU food labeling law and regulation do not specify the natural food allergen or artificial flavor in the allergen description section. The European Union had the major administrative acts of European legislation in Europe in 1979.[22] The Council Directive on Food Labeling in Europe considers food allergens or intolerance as the main reason for labeling requirements to prevent consumer deception in labeling methods under Article 2.[23] The EU also requires listing intolerance of the mandated food allergens.[24] This requirement may not benefit consumers, even though the label provides each allergen's intolerance level. The main concerns about this intolerance dosage should consider the individual's suffering capacity from allergen consumption. Some people who experience allergen reactions from smell or flavor do not need an intolerance level of allergen, or the suggested intolerance level measured from the average person's reaction to each allergen may not be applied to various groups of people who react to the different amounts of allergens based on their health condition, weight, height or other conditions.

Prior studies analyzed global food allergy labeling requirements in each country to regulate mandatory food allergy labeling and PAL. Gendal states that the classification of allergens in each country is governed by its own set of rules and regulations in accordance with the allergy laws, regulations, and standards of 19 countries.[25] Individual countries have established their own food-allergen labeling laws and regulations, resulting in a lack of

[22] Directive 1979/112 - Approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer.
[23] Article 2 prohibits consumer deception (commonly known as food fraud) by listing in section 1: The Labelling And Methods Used Must Not : (A) Be Such As Could Mislead The Purchaser To A Material Degree)
[24] Regulation (Eu) No 1169/2011 of The European Parliament and of the Council of 25 October 201 11 section 24: When used in the production of foods and still present therein, certain ingredients or other substances or products (such as processing aids) can cause allergies or intolerances in some people, and some of those allergies or intolerances constitute a danger to the health of those concerned.
[25] Steven M. Gendel, *Comparison of international food allergen labeling regulations,* Regulatory Toxicology and Pharmacology 63, 279-285 (2012).

uniformity when applying their allergen regulatory frameworks to other countries.[26] The classification of primary allergens varies among nations. This research examines the allergen designations in several countries and regions, including the United States, European Union, Codex Standards, Australia/New Zealand, Canada, China, Hong Kong, Japan, Korea, and Mexico.[27] Through an analysis of these allergen classifications, the study aims to determine whether a standardized allergy labeling system should be implemented across all countries.

Table 1: Labeling Standard of Food Allergens Regulating Ingredients in Every Country

	Wheat /Cereals	Eggs	Milk	Peanut	Fish	Crustaceans	Soy	Tree Nuts	Sesame	Shellfish/ Molluscs	Mustard	Celery	Lupine	Other
United States	o	o	o	o	o	o	o	o	o* (2023)					
EU	o	o	o	o	o	o	o	o	o	o	o	o	o	
Codex	o	o	o	o	o	o	o	o						
Australia/ New Zealand	o	o	o	o	o	o	o	o	o	o				
Canada	o	o	o	o	o	o	o	o	o	o	o			
China	o	o	o	o	o	o	o	o						
HongKong	o	o	o	o	o	o	o	o						
Japan	o(*)	o	o	o		o								
Korea	o(*)	o	o	o	o (*)	o	o							
Mexico	o	o	o	o	o	o	o	o						

- **Wheat/Cereals**

This allergen is categorized as one of the five internally decided allergens commonly regulated in all countries. However, all kinds of wheat are not categorized under wheat/cereals. In Japan and Korea, wheat/cereal means only wheat and buckwheat. In the cereal section, all

[26] *Id.*
[27] *Id.*

countries classify cereals as primary allergens. However, the Food group definition by each country has designated different allergens under the same cereal group. In the United States, wheat is the only allergen under the cereal section. In the European Union, Cereals are defined as the ingredients containing gluten, i.e., wheat, rye, barley, oats, spelled Kamut, or their hybridized strains. In Codex System, Australia/New Zealand, and Hongkong, the classification of serial includes gluten, i.e. Wheat, rye, barley, oats, spelled, or their hybridized strains. In Canada, cereals mean wheat or Triticale Plus "Gluten" and protein extracted from barley, oats, rye, triticale, wheat or a hybridized strain.[28] In China, the group of Cereals includes grain and products containing gluten protein. In Mexico, cereals are ingredients containing gluten.

- **Egg**

The classification of eggs is designed as a major allergen in all countries.

- **Milk**

The classification of eggs is designed as a major allergen in all countries.

- **Peanuts**

The classification of eggs is designed as a major allergen in all countries.

- **Crustacean Shellfish**

Crustacean Shellfish are the primary allergen in most countries. However, especially, Japan's allergen under crustacean shellfish limits shrimp and crabs. In Korea, the primary

[28]Timmerman, Lise. "Adding Nuts to Your Diet Has Numerous Health Benefits." Winnipeg Free Press, vol. , no. , 2019, p. 15.

allergen list does not specify crustacean shellfish but lists in general terms as fish, which means mackerel only.[29]

- **Fish**

The United States lists Bass, Flounder, and Cod under the Fish section. However, the United States did not specify fish and shellfish as designating allergens. In China, the allergen section of fish means shellfish, shrimp, lobster, and crab.

- **Soy**

Soy is designated as a major allergen in most countries.

- **Tree nuts**

Tree nuts are designated as the primary allergen in most countries. All countries did not specify which nuts should be listed under the tree nuts. Especially, Canada lists which types of nuts should be classified under the Treenuts section, which encompasses almonds, Brazilian nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachio nuts, and walnuts. The United States designates almonds, pecans, and walnuts that can be categorized under Tree nuts. In the European Union, tree nuts cover more nuts, including almonds, Brazil nuts, Cashews, Hazelnuts, Macadamia, Nuts, Pecans, Pine Nuts, and Pistachios.

- **Sesame**

United States, European Union, Australia, and Canada designate Sesame as a primary allergen. Particularly, the United States designated sesame as a primary allergen in 2023.

[29] *Id*.

- **Mustard**

Only the European Union designates Mustard as the primary allergen.

- **Celery**

Only the European Union designates Celery as the primary allergen.

- **Lupine**

Only the European Union designates Lupine as the primary allergen.

Table 2: Food Group Definition by Each Country[30]

	Cereal	Fish	Crustaceans	Tree nuts
United States	Wheat	Examples: Bass, Flounder, Cod Examples: Shrimp, Crab, Lobster		Examples: Almonds, Pecans, Walnuts
European Union	Cereals containing Gluten: i.e., Wheat, Rye, Barley, Oats, Spelt, Kamut, or their Hybridized Strains			Almonds, Brazil Nuts, Cashews, Hazelnuts, Macadamia Nuts, Pecans, Pine Nuts, Pistachios
Codex	Cereals containing Gluten: i.e., Wheat, Rye, Barley, Oats, Spelt, or their Hybridized Strains			
Australia/ New Zealand	Same as Codex			

[30] Food groups, SM. Gendel/Regulatory Toxicology and Pharmacology 63, 279-285. (2012)

Canada	Wheat Or Triticale Plus "Gluten" As Protein From Barley, Oats, Rye, Triticale, Wheat or a hybridized strain			
China	Grain and Products containing Gluten Protein (For Example, Wheat, Rye, Barley, Spelt, Or Cross-Breeding Products)	Examples: Shrimp, Lobster, Crab		
Hong Kong	Same as Codex			
Japan	Wheat, Buckwheat		Shrimp, Crab	
Korea	Wheat, Buckwheat	Mackerel	Shrimp, Crab	
Mexico	Cereals containing Gluten			

B. Designation of Flavor on the Label

While consumers read the allergen list on the food label, they still are unclear whether the food flavor contains any allergen or just artificial flavor. If a flavor containing any allergen does not clearly warn consumers of any possibility of containing the allergen, consumers have more difficulty understanding the meaning of the label descriptions. The issue of artificial flavor is whether non-categorized flavors can cause consumers to misunderstand that artificial flavor contains no allergens. The FDA in the 1906 Act did not define a "misbranded" product and what examples of text descriptions were categorized as misbranded products. The Court in *1924 "Ninety-Five Barrels* did not discern the natural, non-chemical component of evaporation from

the manufacturing process using an unevaporated apple. As shown in the 1924 case, allergen requirements are consistently applied to natural food or artificial flavors.[31]

However, this standard of regulating artificial flavor was not clear. Until the 2004 Act, food manufacturers or supplies did not have any regulation of describing allergens contained in "spices," "flavoring," "additives," or "coloring" as ingredients. The 2004 Act changed to apply the same allergy regulations to "spices," "flavoring," "additives," or "coloring," which requires food manufacturers and suppliers to list any component allergens of "spices," "flavoring," "additives," or "coloring." These regulations standards are made from the analysis of 3900 food additive ingredients listed as the flavor in the label, including "artificial flavor," "natural flavor;" and "artificial coloring."[32]

- **Natural Flavor v. Artificial Flavor**

FDA's decision on allergy regulations on the artificial flavor of spices is monitored under Generally Recognized as Safe(GRAS). However, this system still needs to be improved because this testing does not ensure that consumers will not be affected by unexpected risks. This approval procedure does not require manufacturers to monitor the chemical interactions of the additives to determine whether they have the potential to cause an allergic reaction.[33] Further, in the flavor distinction between "natural" and "artificial," the manufacturing process of adding

[31] *Id.*
[32] See Everything Added to Food in the U.S. (EAFUS), U.S. Food & Drug Admin., http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm? rpt=eafusListing&displayAll=true (last updated July 14, 2011) (listing all known food additives used in the United States); see also Int'l Food Info. Council Found. & U.S. Food & Drug Admin., Food Ingredients and Colors 2-3 (2010), available at http:// www.fda.gov/downloads/Food/FoodIngredientsPackaging/ucm094249.pdf (explaining the use of "artificial flavors," "natural flavors," and "artificial coloring").
[33] Int'l Food Info. Council Found., supra note 55, at 5.

natural or artificial ingredients is not considered to be described on the label. If the artificial manufacturing process consists of the natural flavor, the food label lists the “natural flavor.”[34]

> According to the FDA, "natural flavors" are as follows:
>
> Natural flavoring refers to the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating, or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf, or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional.[35]

Natural flavors are limited to "roasting, heating, and enzymolysis- the decomposition of a chemical compound catalyzed by the presence of an enzyme.”[36] If artificial flavor" is considered "unhealthy" food that does not originate from the naturally listed source in the "natural flavor" category.[37] The FDA's mandatory labeling requirements regulate end-products. So, the FDA cannot restrict the unnatural manufacturing process to create "natural flavor." For example, the FDA defines "naturally flavored" benzaldehyde as a chemical used as an almond flavor that is extracted from the pits of peaches and apricots, even if it contains trace amounts of cyanide[38].

Finding many flavors have similar chemical components either to “natural flavor” or "artificial flavors,“ consumers may need to read allergen descriptions and food ingredients instead of choosing the food based on the promoting definition of “natural flavor” or “artificial flavor.”[39]

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[34] Mass. Gen. Laws Ann. ch. 140, § 6B(b)(1)-(2), (c).
[35] 21 C.F.R. § 101.22(a)(3) (2011).
[36] Horvath, J. C. "How Can Better Food Labels Contribute to True Choice?" (2012), https://core.ac.uk/download/217199785.pdf.
[37] See 21 C.F.R. § 101.22(a)(1) (2011) (“The term artificial flavor or artificial flavoring means any substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof.”
[38] Schlosser, supra note 66, at 127.
[39] Schlosser, supra note 66, at 127. “Natural and artificial flavors are now manufactured at the same chemical plants, places few people would associate with Mother Nature.”

EU also has similar allergen requirement rules to regulate artificial flavors. On May 3, 1989, the EU addressed the composition of artificial flavor must be treated as to list ingredients even though those ingredients are not the main components of the food.[40] EU requires disclosing whether products have qualitative and quantitative ingredients or involve a special manufacturing process that gives the product its particular nutritional characteristics.[41] Furthermore, Article 11 requires member states to monitor what ingredients or processes need to be included in the labeling to avoid endangering human health in Article 11.

In 2002, the EU's general food safety regulation set food safety requirements and asked member states to list the most available and traceable ingredient information on the label to avoid unexpected health consequences.[42] Furthermore, In January 2021, the EU requested to list Reference Doses to decide an individual's intolerance level for each allergen. Thus, the EU applies the same allergen regulation standard to natural food ingredients and artificial flavors, requiring to list of the amount contained in each food and flavor ingredient.

1.2.3. Regulation and Regulation Standard

A. Mandatory Food Allergen Description

- **United States**

[40] Id.
[41] Council Directive 89/298/EEC Article 7
[42] REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002.
laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Article 14: to the information provided to the consumer, including information on the label or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods

At the federal level, the 1906 Act had the first attention to set up allergy labeling standards.[43] The 1906 Act focuses mainly on monitoring misbranded adult foods and drugs in interstate commerce. The 1906 Act regulates the listed labeling description without considering which ingredients should be listed on the label.[44] Moreover, the 1906 Act guidance standards are non-binding recommendations, so manufacturers and retailers do not have to follow them.[45] In 1938, the Food, Drug, and Commerce Act ("FD&C Act") strengthened the FD&C Act's guidance and control over food and drugs.[46] Following the FD&C Act's guidelines, the FDA reviewed food product labels and issued warning letters on a case-by-case basis for mislabeled items that failed to disclose contained allergens. However, this reactive approach to regulation does not ensure that consumers can rely on food labels, particularly regarding allergen information.

In the judicial system, if consumers suffered unexpected risks by consuming food allergens that were not described on the list, consumers took time to prove the causes of the allergen risks. The omission of allergens in the food does not automatically put the liability to the food manufacturers or suppliers.

- **European Union**

EU legislation designates 13 allergenic foods (or food groups) as mandatorily regulated allergens.[47] Out of 13 allergen-containing foods or food categories, the labeling regulations only mandate the identification of items that contain the specific allergen designated for each food

[43] How Did the Federal Food, Drug, and Cosmetic Act Come About? U.S. Food & Drug Admin., http://www.fda.gov/AboutFDA/Transparency/Basics/ucm214416 (last updated Aug. 19, 2010).
[44] *Id.*
[45] What is the Difference Between the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA Regulations, and FDA Guidance?.U.S. Food & Drug Admin., http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194909 (last updated Aug. 19, 2010).
[46] Horvath, J. C. "How Can Better Food Labels Contribute to True Choice?" 2012, https://core.ac.uk/download/217199785.pdf.
[47] Commission Directive 2007/68/EC of 27 November 2007 amending Aneex IIIA to Directive 2000/13/EC of the European Parliament and of the Council as regards certain food ingredients. OJEU 2007; L310: 11-14

group. For example, fish proteins used as finishing agents for vitamins or carotenoids, fully refined soybean oil, and alcoholic distills derived from nuts are exempted from these requirements. This regulation is based on ongoing evidence findings.[48] Therefore, if new evidence demonstrates that particular components triggered the allergic response, the food industry should modify its approach accordingly.[49] EU's food allergy labeling specifies the term using the designated allergen terms instead of listing inflammatory components elicited by allergen ingredients. For example, allergen labeling needs to list "the nature of the allergy; contains milk" instead of "protein found in milk; contains casein."

Under EU No. 110/201, the European Union's allergen labeling regulations mandate the provision of comprehensive information to maximize benefits for those receiving it.[50] In the Cassi de Dijon Case[51], the EU's requirement to provide information must not be eliminated by food suppliers or manufacturers for their purpose.[52]

B. Voluntary Food Allergen Description

- **United States**

In the United States, food suppliers and manufacturers are permitted to use PAL as an optional labeling system. The purpose of PAL is to offer supplementary details about ingredients, even when the allergens present are not primary components of the final food item.

[48] Annex II of the new Consumer Information Regulation (EC) 1169/2011
[49] Supra note 41, Article 21, Section (b),
[50] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 Text with EEA relevance, OJ L 304, 22.11.2011, p. 18–63.
[51] See Case 120/78 REWE v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon) ECLI:EU:C:1979:42
[52] Ward R, Crevel R, Bell I, Khandke N, Ramsay C, & Paine S. A vision for allergen manameent best practicr in the food industry, Treands Food Sct Technol ; 21:619-625 (2010).

PAL advises that food manufacturers and suppliers identify allergens potentially introduced at any point in the food preparation, manufacturing, or packaging processes.

Nevertheless, it is important for consumers to recognize that PAL does not offer support for customer lawsuits regarding the omission of precautionary allergens in labeled products. The FDA permits certain types of statements to be used as PAL. Acceptable PAL statements have indicated that allergens could potentially contaminate products during preparation, production, or through the use of shared equipment."[53] Its voluntary regulation allows the use of the wording: "may contain," "may present," "made on the same equipment," and "made in the same factory."[54]

However, manufacturers or food suppliers should not use PAL's discretionary and non-mandatory declaration, which comes with warnings, as a means to evade responsibility when consumers make food choices based on supplementary cautionary allergen information. Moreover, Food manufacturers voluntarily include PAL to provide additional caution to consumers about potential risks. This practice may be viewed as a marketing strategy to demonstrate the company's concern for allergen-sensitive individuals, even when there is no detectable evidence of the listed allergens in the product. By using PAL, manufacturers can use PAL in their attentiveness to consumers with allergen concerns, regardless of whether the allergens are actually present in traceable amounts.

The requirement of PAL description may not be clearly set up on using digital health and wellness apps. The allergy section of digital apps does not have any different category of voluntary allergy section from the mandatory allergen description section. Nevertheless, FDA

[53] ADunn Galvin, C-H Chan & R. Crevel, Precautionary allergen labeling: perspectives from Key stakeholder groups, European Journal of Allergy and Clinical Immunology, 1039–051 (2015)
[54] *Id.*

rules and regulations do not regulate the content of listed allergens collected and used through digital allergy labeling devices.

- **European Union**

EU's voluntary and precautionary labeling applies to two categories: pre-packaged food and non-packed food. For the pre-packaged regulation in voluntary allergy labeling, a different rule of EU's allergy regulation compared to the US, the EU designates 14 allergens, and the EU does not impose strict regulation on allergens that have possibly trace from any manufacturing process stage, but not the primary component ingredients of the final product.[55] When manufacturers or food providers are uncertain about the potential presence of allergens, they can utilize cautionary phrases such as "may contain" or "trace amount of" to indicate possible allergen content. The EU''s food allergen labeling regulations are notably stringent, requiring the disclosure of more ingredients than many other countries worldwide. As a result, some nations look to the EU's guidelines as a primary reference for their own allergen labeling standards.[56]

Among EU countries, the UK has set strict rules and regulations on ingredients of non-packaged food or ready-to-eat restaurant meals, which is called "Natasha Law."[57] In October 2021, the UK food amendment called **"**Natasha's Law"[58] This Nathasha's is not adopted as the EU countries' regulation but some EU countries are ready to adopt it. Although the US does not explicitly mandate that restaurant proprietors or street food chefs disclose all allergens in ready-to-eat dishes, there is a requirement to evaluate whether this regulation is feasible to incorporate into the U.S. guidelines.

[55] EU Directive 1169/2011
[56] *Id.*
[57] Introduction to allergen labeling for PPDS food, UK (2021) https://www.food.gov.uk/print/pdf/node/5876
[58] Introduction to allergen labeling for PPDS food, UK (2021) https://www.food.gov.uk/print/pdf/node/5876

C. WHO Codex Standard

In addition to mandatory and voluntary allergy labeling regulations, the joint Food and Agricultural Organization (FAO) and World Health Organization (WHO) Food Standard Program suggest the Codex system, which lists more true ingredients in the final product composition.[59]

The CODEX general guidelines require a list of the food's name, ingredients, name, and address of the manufacturer, exporter, importer, packer, distributor or vendor, country of origin, lot identification, and instructions for use.[60]Barbados, Chile, Papua New Guinea, Philippines, Saint Vincent, and Grenadines used CODEX regulations. Argentina, Switzerland, Ukraine, and EU member states follow the EU Food Labeling Guidelines.[61]

The Codex system selects its global priority allergen list based on allergens that affect 5% of the population. While the Codex system does not strictly mandate the wording of PAL statements, it has been considering whether PAL statements should be incorporated as a form of food allergy labeling.[62] CODEX designates the 'big eight' allergens and defines gluten as one of the allergens.[63] This priority allergen list was set up since the 1999 General Codext Standard recommended prirrity allergens.[64] In 2022, WHO offered to use Reference Doses (RfDs) by evaluating risk and allergen-related incidences.[65] Nevertheless, RfDs may not be constant, given

[59] Gazzolo, Diego, et al. "Early Pediatric Benefit of Lutein for Maturing Eyes and Brain—An Overview." Nutrients, vol. 13, no. 9, 2021, p. 3239.
[60] GeneSM.Gendel, Comparison of International Food Allergen Labeling Regulations, Regul Toxicol Pharmacol vol.63: 279-289 (2012)
ral standard for the labelling of prepackaged foods (1985) In: Organization FaAOotUNWH, ed. 9
[61]
[62] Codex General Standard for the Labelling of Pre-packaged Foods (GSLPF) in 1999 (section 4.2.1.4)
[63] Codex section 4.2.1.4 : General Standards
[64] Codex General Standard for the Labeling of Pre-packaged Food (GSLPF) 1999 (Section 4.2.1.4)
[65] Remington BC, Westerhout J, Meima MY, Blom WM, Kruizinga AG, Wheeler MW, Taylor SL, Houben GF, Baumert JL Updated population minimal eliciting dose distributions for use in risk assessment of 14 priority food allergens (2020) Food and Chemical Toxicology, 139, art. no. 111259. 10.1016/j.fct.2020.111259.

that the majority of food consumed varies across countries, individual health conditions can trigger allergic responses, and the specific regulations governing food allergens differ from one nation to another.

1.2.4 Current Digital Device Use as Informative Food Allergy Labeling

A. Industry Development

As allergic reactions are not curable and food allergy labeling systems worldwide remain confusing, digital technologies are being offered to effectively manage food allergies. Digital apps for identifying food allergens are available on both iPhone, iOS, and Android platforms.[66] These apps not only provide lists of allergens on food menus but also allow users to monitor their allergic reactions by uploading personal concerns and potential risks. Some apps offer additional features, such as real-time connections to recommended physicians, dietitians, or nutritionists for users struggling to identify ingredients that may be harmful to their health. Furthermore, these apps enable users to report their symptoms after consuming items from the suggested menu.

Current digital health and wellness apps now offer users the ability to detect allergens from gluten or various protein types. Apps designed for protein-type testing come with a built-in food scanner.[67] Users can observe allergic reactions by utilizing their phone's scanner and a test strip, which is dipped into the food. This method is also referred to as the polymerase chain reaction (PCR).[68] A specific type of PCR employs a food scanner to examine food at the

[66] Current allergy indicator technology information retrieved from The Top 8 Technologies Combating Food Allergy - The Medical Futurist
[67] Wearable Allergy Testing Strips Can Detect Peanuts in Food - Business Insider. https://www.insider.com/allergy-detection-amulet-2016-8
[68] Marc Burrell, Mario Martinez & Geoffrey Mulberry, Portable Polymerase Chain Reaction (PCR) Diagnostics , Dept. of Electrical Engineering and Computer Science, University of Central Florida, 1-8, 2 (2017).

molecular level (known as "Tellspec"). The results of these analyses, which identify the molecular composition of foods, are stored in a cloud database.

The use of digital technology offers benefits, such as the ability to forecast immediate allergic reactions to food. As a result, these devices have been developed to identify various allergens in food products. Nevertheless, the effectiveness of these digital tools in detecting allergens is determined by their technological capabilities rather than the specific allergen regulations of individual countries. This inconsistency may result in consumer confusion about which allergens can be reliably identified. For instance, individuals in the EU might anticipate that allergen test kits adhere to EU standards, while those in the U.S. may expect detection of allergens prioritized by U.S. regulations.

Furthermore, cloud-stored personal data forecast individual allergic reaction collected data of individual allergic reaction from each food. Current food allergy labeling regulations do not address the storage and utilization of personal information. Consequently, it is crucial to examine the existing laws and guidelines governing the use of personal health data in allergen-detecting digital devices and applications.

B. Protected Health Information in Using Digital Health and Wellness Apps

Consumers voluntarily provide personal information and personal health data to use digital allergy devices or apps. Under current privacy laws, consumers who consent to use digital devices rely on digital devices' privacy policy. The U.S. Consumer Privacy Act, the 1996 Health Insurance Portability and Accountability Act ("HIPAA") deals with Protected Health Information (PHI), including any information that can be used to identify a patient, such as name, address, DOB, bank/credit card details, social security number, photos and insurance

information contained with health information,[69] while the EU's General Data Protection Regulation (GDPR) regulates any information that can be used to directly or indirectly to identify person when they are in the EU.[70]

Consumers may be concerned about whether their voluntarily provided information is protected. Consumers' consent to provide their protected health information about food allergies is based on their belief that their privacy is protected. Consumers are given to check whether their data is deleted or shared with third parties. While digital technology offers enhanced protection for personal health data, users may be uncertain about the level of security applied to their specific allergy information. When agreeing to an app's privacy terms, individuals might not fully understand whether their disclosed allergen details are classified as protected health information or treated as general personal data.

Digital apps that help to read food allergens to prevent food allergies raise two questions are mainly composed of two parts: a) how to comply with current governmental regulations for allergen labeling, including how allergens are labeled in pre-packaged food and non-packaged food, and b) how to protect consumers' PHI under HIPAA [71] or all sensitive personal data under various laws, including the U.S. Federal Consumer Privacy Rights Act (COPRA),[72] California

[69] United States Department of Health and Human Services, Summary of HIPAA Privacy Rule, https://www.hhs.gov/sites/default/files/privacysummary.pdf
[70] Directive 95/46/EC, of the European Parliament and of the Council of 27 April 2016 on the General Data Protection Regulation, OJ C 229, 31.7.2012, p. 90
[71] See Supra Note 63.
[72] Introduced in Senate (11/04/2021) of Senate of Commerce, Science and Transportation, S.3195-117th Congress(2021-2022).

Privacy Rights Act (CPRA),[73] New York Privacy Act,[74] the EU's General Data Protection Regulation (GDPR),[75] and the EU's Digital Markets Act.[76]

1.3. Research Questions

For individuals with allergic histories or ingredient-related concerns, a thorough examination of allergen labels is crucial to avert severe allergic reactions, including potentially fatal anaphylaxis from food allergies.[77] While many nations have established food allergy labeling regulations and require more explicit labeling language, these measures may not suffice. Digital health technologies and applications can enhance allergy labeling by providing convenient reading tools or displaying warnings with color-coded text for each allergen, customized to users' personal allergen lists. However, the legal framework governing digital health and wellness apps remains ambiguous in regulating the allergen list and particularly protecting users' protected health data.

Thus, this paper encompasses four primary objectives: 1) an examination of food allergy labeling policies implemented by the U.S., EU, and WHO; 2) an investigation into the regulatory landscape governing digital health and wellness apps that utilize health-related information; 3) an assessment of these digital tools' compliance with food labeling regulations; and 4) an evaluation of how effectively digital health and wellness apps safeguard PHI or all sensitive personal data in accordance with relevant laws and regulations.

The research questions are as follows.

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[73] Cal. Civ. Code § 1798.100 et seq.(Ca. 2018).
[74] Public Officers Law, Article 6-A, sections 91-99.(NY, 2023).
[75] See Supra Note 64.
[76] Directive (EU) 2019/1937 of the European and of the Council of 14 September 2022 on contestable and fair markets in the digital sector and amending Directives PE/17/2022/REV/1.

[77] See Bollinger, M.E at al. The impact of food allergy on the daily activities of children and their families. *Annals of Allergy, Asthma & Immunology*, 96(3), 415-421. (2006)

1. What are the current laws and regulations that support the implementation of digital health and wellness apps for identifying food allergens or labeling?
2. How can digital health apps inform food allergens and labeling comply with current food allergy laws and regulations?
3. What are the current laws and regulations that protect consumers' personal health information used in digital devices/apps?
4. Do digital devices and apps that help consumers identify allergens adequately protect consumers' data?

1.4. Study Importance

Consumers increasingly turn to digital health and wellness apps as a complementary or alternative means of identifying allergens, often finding traditional food label interpretations challenging. While food allergy regulations vary across nations, the emphasis on making safe and healthy food choices remains universal. Globally, consumers seek user-friendly tools to decipher ingredient lists on various food items, from packaged goods to restaurant meals. This trend has prompted an investigation into whether digital health and wellness apps should conform to standardized allergy requirements across different national regulations. The study compares existing apps, highlighting the benefits and drawbacks of applying current allergy laws to these digital platforms. Additionally, the use of digital software raises privacy concerns, necessitating an examination of laws that can protect users' personal information. Notably, these apps fall outside the FDA's classification of "healthcare apps," considered medical devices to regulate to follow HIPAA and GDPR, despite handling allergen information related to disease prevention. Some applications even collect, store, and manage users' health data, further emphasizing the need for robust privacy safeguards.

Findings comparing global allergy standards and privacy protection provide policymakers with guidelines for monitoring and changing food allergy label requirements to protect consumers from unexpected risky choices of food allergens. While the European Union's General Data Protection Regulation ("GDPR") and the U.S. California Consumer Privacy Act ("CCPA") are currently forming regulations to protect sensitive personal information, HIPAA protects PHI that deals with apps.[78]

1.5. Roadmap

The literature review first defines different terms for the same food allergens under U.S., EU, and WHO Codex standards and other countries' allergy laws and regulations in two categories: mandatory descriptions and voluntary descriptions. It explains the possible options for listing mandatory and voluntary allergens during the manufacturing process for packaged food and cooked food in restaurants. The second part of the literature review explores how health and wellness apps are categorized to protect personal data or PHI under privacy protection laws and regulations. Based on this information, this dissertation argues that digital food allergy apps need to use unified food allergy label guidelines and should be regulated to protect PHI and sensitive personal data as a separate category of health or wellness apps under privacy laws related to dealing with allergen information.

1.6. Study Design and Limitations

This study reviewed whether these digital apps followed various food allergy guidelines or whether they created new food allergy labeling standards. Apps researched in this study were located in the U.S. through the Apple App Store (iOS) and Google Play Store (Android). This

[78] Rachel Zuraw & Tara Sklar, *Digital Health Privacy and Age: Quality and Safety Improvement in Long-Term Care*, Indiana Health Law review, 17 Ind. Health L. Rev. 85 (2020).

study narrowed the apps that are able to be located in the U.S. app stores, which are either created in the U.S. or outside of the U.S. Those apps are downloadable in the U.S. app stores; people outside the U.S. possibly use these apps. The following keywords were searched to locate digital health and wellness apps indicating allergy labelings with the terms of using"food allergy," "food allergy label," "food label," and "allergy label." The 11 apps were chosen because they offered features that allowed customers to use them as an alternative food allergy labeling tool or to support the current food allergy label. This dissertation does not address whether regulations should award special status to individuals with food allergies by extending the categories of "disability" to include food allergies.

The dissertation evaluated digital apps used within the United States, assessing their compliance with allergen guidelines established by the U.S. FDA, EU, and WHO Codex for implementing compulsory and optional food allergen regulations and analyzed in relation to privacy laws set forth by the U.S. FTC, FDA, CCPA, EU GDPR, and HIPAA, which are designed to protect PHI and sensitive personal data concerning food allergens. This study only considers digital food allergy labeling apps located in the U.S. used by U.S. consumers. It does not consider whether similar apps outside the U.S. would offer different features or functions. It also considers only "natural" allergens and does not explore allergens that are genetically modified ("GMO") or mislabeling foods as "GMO" or "non-GMO."

CHAPTER 2. LITERATURE REVIEW

2.1. Introduction

Recent research on food allergy labeling has examined whether individuals fully comprehend the descriptions of allergen ingredients and sort out individually risky allergens. Related articles assessed the effectiveness of current food allergy labeling systems in helping consumers make informed choices without confusion. Studies on these digital health and wellness apps have explored how they align with existing labeling regulations and potentially overcome limitations in current systems. As the demand for digital food allergy labeling devices grows, concerns about information privacy in these apps have emerged, particularly regarding the secure storage and sharing of personal data. Researchers have questioned whether existing privacy laws adequately protect users of digital health devices and apps, especially when it comes to sharing personal data. This literature review first reviewed why countries maintain two systems of current mandatory and voluntary labeling, a.k.a precautionary allergy labeling (PAL) regulations and related laws. It then discusses the current status of how digital health and wellness app technology will identify allergens and manage personal data and PHI while app users get the benefits of detecting risky allergens by setting up a personal account. Finally, it assesses consumer privacy protection in the use of digital food allergy labeling devices.

2.2. Concerns and Backgrounds on Current Law and Regulations on Allergy Labeling

A. Food Labeling for Protection or Regulation

Other studies reviews are structured chronologically by year of publication to examine how each country approaches allergen selection for regulatory purposes for food manufacturers or the protection of consumers' health. This review section also analyzes the rationale behind establishing allergen regulation standards, which serve two main purposes: protecting consumers

from unexpected allergic reactions and implementing stricter controls on the manufacturing process through enhanced allergen labeling requirements.

In a 2006 study, PAL was not implemented in every country. Some countries set the regulation of PAL but some countries did not recognize PAL from mandatory allergen labelings. Few regulatory authorities have cautioned that advisory labeling should not be considered an alternative to good manufacturing processes. In 2011, the UK Food Standards Agency and Health Canada[79] The PAL regulations that require precautionary statements were set but did not designate any term of use as PAL. The statements "free from" or "does not contain" were understood as PAL.[80]

In a 2011 study, the case studies between 1992 and 2000 found only 6 cases of law suits related to food allergies or allergic reactions.[81] The small number of lawsuits for allergen reactions does not imply that allergen risks are a small matter. In contrast, this means that judicial claims are not an effective solution for unexpected allergic reactions. For example, in *lmanavitz*, lmanavitz requested workers' compensation after suffering from an allergen reaction, but her claim did not succeed because the claimant's own usual or exceptional physical condition or peculiarity cannot be considered that the patient's own peculiar physical conditions in and of themselves cannot be used to set a standard for the general population.[82] Manufacturers cannot reasonably foresee unexpected harm related to causes of action, including the implied warranty of fitness and the influence of emotional distress caused by suffering an unwanted allergen reaction caused only to peculiar people.

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[79] Health Canada, 2011

[80] *Id.*

[81] The earliest litigation involving a food allergy in a reported US case is in industrial commission of Ohio v. lmanavitz, (4 N.E.2d 265, 265 (Ohio App. 1936).)is not easy to prove the cause of action from the peach juice and claimant's reaction.

[82] *Id.*

In a 2012 article, Sharvani stated that meal habits formed differently because of geographical differences in cuisine, ingredients, and meal habits, and meal habits are related to food allergies. Sharvani pointed out that the reaction to each food allergen depends on the number of allergens contained in the food and how much people tolerate the amount of allergens. Analyzing the number of allergens that cause allergic reactions in the population, Sharvani alleged that the coded allergy label has a particular standard that requires information on Reference Doses of causing allergic reactions to each person having different tolerate capacity. Sharvani's findings on different tolerance level of each allergen are consistent with FAO and WHO's Codex standard informing the Individual Reference Doses to each allergen.

In a 2013 article, Balazic contended that a unified food allergy labeling system is crucial, stressing that such standardization would decrease allergen exposure risks without adding costs for identical products from various origins. This is due to the current necessity for manufacturers to create multiple packaging designs with different labels to sell the same items across diverse countries. [83] Balazic further advocated that most allergens should be listed as mandatory to prevent immediate risks from unexpected food allergen reactions.

Table 3: Summary of Food Labeling Protection Level and Regulations[84]

Protection of Level	Consumer Value Issues	New Technologies	Preventive Health	Food Safety
Regulation Matters	Reflecting Consumer perceptions and ethical views (non-strongly followed regulation)	Technology that requires pre-approval safety issues in general (not following the regulation of allergens)	Indirect, long-term impacts on health individual health, considering the population's reaction to	Direct regulation for immediate threats to health

[83] Balazic S et al., the Food Labeling Matrix, Food Safety Performance: Labeling and Indications of Allergens, p.236; Balazic S et al. (2013)
[84] Commonwealth, Food labeling- hierarchy (2011).

			specific allergens	
Type of Regulation	Co-regulation or self-regulation	Mandatory with time limits	Mandatory co-regulation	Mandatory
Consumer Protection Laws Comparing Food Standard Code	Consumer protection law stronger than Food Code	Both Laws Governed	Both Laws Governed	Food Standard Code strongly regulates Consumer protection law
Initiated Stakeholder	Tech Industry and Consumers Oriented	The tech industry initiated considering government regulations	The government initiated getting the support of the Tech industry alone	Government Centered

Balazic's (2013) research analyzed 16 Organization for Economic Cooperation and Development(OECD) countries' food allergy labeling regulations to review which food allergy labeling components are mandated; these included Australia, Austria, Belgium, Canada, Denmark, Finland, Germany, Ireland, Italy, Japan, the Netherlands, Norway, Sweden, the U.K., and the U.S. None of the 16 countries mandated that manufacturers warn of allergens via precautionary statements. The OECD countries in this table analyzed food labeling in

Table 4: 16 OECD countries Implementation of Food Labeling and indicating Allergens[85]

Mandatory Metrics	Countries	Comparison
Name of Food	All 16 OECD Countries	
"Use by" or "Made on" Date	15 OECD countries except for the U.S.	U.S. does not use the term used by in the label
Nutritional Information	Australia, Canada, and the U.S. only	
List of Ingredients	All 16 OECD countries	
Country of Origin	Australia, Canada, Japan, and the U.S. only	
Warning of Allergens via Precautionary Statement		Countries use PAL as a voluntary statement, not a warning under mandatory requirements.

[85]Balazic S et al, Food Labeling Matrix, *Food Safety Performance: Labeling and Indications of Allergens*, p.236 (2013).

Indication of Food Additives	All 16 OECD Countries	

In conclusion, a review of the different countries' allergen labeling framework demonstrates that a consistent set of international allergen labeling requirements is necessary to protect people from misunderstanding descriptive labeling statements and risking food allergy reactions. Balazic proposed that allergy labeling should encompass comprehensive information, including nutritional content, a full ingredient list, and the product's origin country, all within the designated allergy information area.[86] Other studies have also shown that unified mandated requirements for regulating food allergens efficiently protect public health and reduce confusion. Furthermore, related studies have suggested that countries should regulate PAL by creating standard guidelines for adding more mandated allergens to the food labeling provision.

B. Background on Global Status of Precautionary Allergy Labeling (PAL) Requirements

Food allergy labeling studies on PAL have concluded that countries should regulate it. Up to 8% of allergic consumers report incidents after consuming food products labeled according to PAL.[87] Nevertheless, using PAL still does not avoid unexpected risks because most consumers do not read food labels carefully because they don't have allergic experiences or do not bother understanding the meaning of the manufacturer's voluntary precautionary statements. In addition, up to 35% of food products do not display PAL.[88]

In a 2018 study/article, Baker pointed out that the present PAL system generates uncertainty among consumers interpreting precautionary statements, even as the United States transitions towards stricter regulatory strategies for allergen requirements. Several countries, such as

[86] Id.
[87] Katrina Allen & Steve L Taylor, The consequences of precautionary allergen labeling: Safe haven or unjustifiable burden? J Allergy Clin Immunol Pract 2018;6(2):400–407 (2017).
[88] Fierro V, Di Girolamo F, Marzano V, Dahdah L, Mennini M. Food labeling issues in patients with severe food allergies: Solving a hamlet-like doubt. Curr Opin Allergy Clin Immunol ,17(3):204–211 (2017).

Switzerland and South Africa, have implemented regulations requiring manufacturers to use PAL, despite the fact that not mentioning the potential presence of allergens has no impact on consumers who do not read the optional allergen information. Many articles have emphasized the importance of PAL's expanded regulatory implementation. They emphasized that people suffering from allergic reactions can be harmed by very few allergens, including those in food products that acquired allergens from cross-contact with allergens.[89]

Legal actions arising from allergic reactions caused by misunderstanding Precautionary Allergen Labeling (PAL) often fail due to several obstacles. Establishing a direct connection between the absence of PAL descriptions and allergic responses is challenging, as PAL is not intended to provide a complete list of primary ingredients in a product. Additionally, food manufacturers and distributors voluntarily include allergen warnings when they believe there is a possibility of contamination at any point in the food production process, including preparation, manufacturing, or handling. These elements make it difficult to establish a clear cause-and-effect relationship between inadequate PAL and allergic incidents.[90] For example, under PAL requirements, the term "contain" must be described as the complete requirement of describing ingredients if food manufacturers or processors found any possibility of containing any

[89] 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. & Health 87, 90 (1999-2000) ("As little as half a peanut can cause a fatal reaction for severely allergic individuals.").

[90] 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 (2011).

largeness. Baker asserted that statements that food products "contain" common allergens need to be printed in a specific font.[91]

In a 2014 article, The significance of describing PAL and regulating the specifications and necessities for identifying allergens throughout food processing has become increasingly emphasized. Besnoff defined PAL as an advisory label warning that alerts consumers to the possibility of contamination or "cross-contact" with an allergen.[92] Besnoff indicated that "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 process.[93] According to Zurzolo, the current voluntary PAL system creates confusion among consumers, leading them to disregard the PAL description. In practice, an effective PAL warning necessitates that manufacturers enumerate ingredients that consumers typically wouldn't expect to be present in a product.[94]

Briet argues that PAL can strengthen the trust choice between consumers and manufacturers by prompting the latter to offer comprehensive information. PAL could function as a vital descriptor when voluntary ingredient descriptions are integrated with the "generally recognized as safe" (GRAS) principle in food production. This framework guides manufacturers in their optional decisions to enumerate potential allergens, drawing from their expertise and continuous monitoring efforts. While not explicitly listed, the GRAS exception rule for commercializing food additives is employed in the market for advertising purposes.

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[91] 21 U.S.C. § 343(w)(1) (2012)

[92] 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.”

[93] 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.

[94] (Restatement (Second) of Torts § 402A cmt. j (1965) (emphasis added). A third type of defect, design defect, is not implicated by issues involving nut allergies.)

Briet highlighted a case study featuring Burger King's "Impossible Burger," where the company aimed to categorize soy leghemoglobin as GRAS. Burger King voluntarily included unapproved flavors in its descriptions despite the FDA's lack of endorsement for these ingredients as safe. At that time, the FDA was unable to confirm the GRAS status of soy leghemoglobin. As a result, Burger King was compelled to market only its primary ingredients, avoiding deceptive food descriptions that included unapproved additives.

The disclosure of ingredients provides no advantages to food manufacturers, resulting in a lack of motivation for transparency. Briet points out the absence of a food safety testing system, and without publicly available research, consumers remain uninformed about the number of manufacturers independently determining ingredient safety."[95]

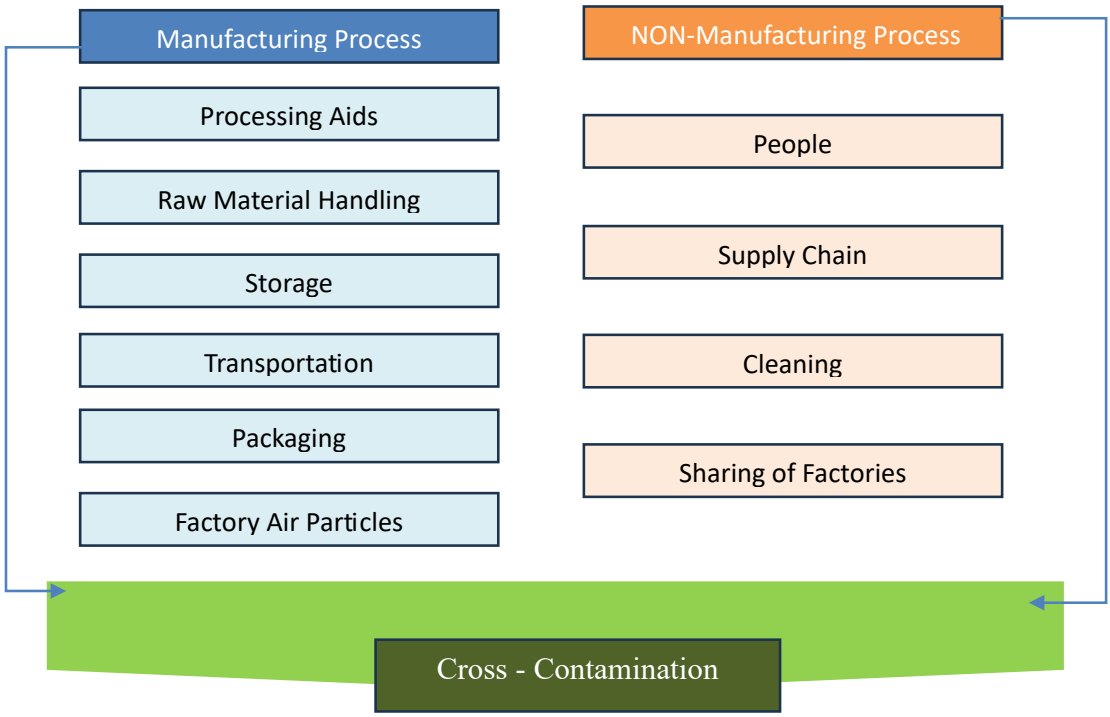
Research conducted by Bugyi in 2023 revealed that most consumers lack a clear understanding of PAL's meaning. Consequently, Bugyi advocated for the regulation of PAL, suggesting that it should include an explicit explanation. Additionally, Bugyi recommended that PAL should provide comprehensive descriptions of allergens and specify which food manufacturing processes lead to the introduction of allergenic substances. Additionally, it is necessary to incorporate a risk evaluation for each allergen, detailing the varying effects based on different quantities of the allergen present.

In a 2014 article, Allen examined the PAL prescription protocols regarding the potential for cross-contamination during food production processes. Allegen reported that the majority of individuals recognized that allergens were only present in food processing facilities where different manufacturers share preparing, packaging, and packaging spaces. Allen's study also explained other potential points of cross-contamination, including processing aids, raw material

[95] Soroudi, R., *Government Repudiation of Americans' Safety: A Call for Reformulation of FDA's GRAS Notification Program*, 75 FOOD DRUG L.J. 39, 50 (2020)

handling, storage, transport, cleaning, shared equipment, air particles in the manufacturing area, supply chains, and packaging[96].

Table 5: Potential Incidence of containing allergens in Cross Contamination (Source: UK FSA)[97]



As reviewed in Table 5, even though manufacturers control and evaluate risk during manufacturing, allergen cross-contamination can occur in non-manufacturing processes; for example, manufacturers may be able to control storage, transportation, and packaging. But when manufacturers use shared factories but do not know other facilities' processes, the other parties who share the facilities are not likely liable for the presence of allergens through cross-contamination.

[96] Allen et al., *World Allergy Organization Journal*, 7:10, http://www.waojournal.org/content/7/1/10 (2014)
[97] Allen et al., World Allergy Organization Journal, 2014 7:10, http://www.waojournal.org/content/7/1/10

Although food manufacturers detect cases of cross-contamination, many countries allow manufacturers to warn consumers about possible cross-contamination through a variety of PAL statements. The study showed that 25 different labeling terms indicate potential contamination of allergens. Examples of such phrases include "may contain…," "produced on shared equipment," and "made in the same factory as…."[98]

Table 6: Currently Used Advisory Warnings Found on Food Labels

MAY	**May** contain, May contain traces of… **May** on the same production line as…, Packed in an environment when .. **may** be present.
PRODUCED	**Produced** in a factory which handles.. **Produced** on shared equipment which also processes..
NO.. BUT CANNOT GUARANTEE	**No** Nuts in the ingredients, but cannot guarantee to be nut-free, **No**t suitable for…
MADE IN	**Made in** a facility that also processes.. **Made in** a production area that also uses

According to Allen,if PAL statements are too vague for consumers to understand, PAL is not practically useful because 1) consumers may think that contamination is so prevalent that it affects all food products and cannot be avoided; 2) consumers may believe that PAL protects manufacturers from any claims arising out of cross-contamination; 3) consumers believe that a PAL statement such as "may contain" indicates low levels or low risk; and 4) When a PAL statement mentions that peanuts are present during the packaging process, consumers typically infer that peanuts were not incorporated into the food through processing methods.[99] The absence

[98] *Id*.
[99] Table is modified from Allen et al., World Allergy Organization Journal, 2014 7:10, http://www.waojournal.org/content/7/1/10

of regulations governing PAL in most countries results in a lack of incentives for manufacturers to provide comprehensive allergen information. Consequently, product labels often omit crucial details such as the amount of allergens present, the varying levels of risk associated with different allergen quantities, and how these amounts—determined through risk assessments—may impact the average consumer. Without regulatory pressure, companies are not compelled to disclose this vital information, potentially leaving consumers uninformed about the true allergen content of their products.

Table 7: Regulation of Additional Precautionary Allergen Labeling on Prepacked Food[100]

Country(Year of Implementing Allergen Disclosure Legislation)	Precautionary Allergen Labeling			"Contains.." statement labeling permitted
	In-Use	PAL regulated	A risk-Based Approach is used for PAL	
United States[101] (2006).	Yes	No	No	Yes
European Union[102] (2003).	Yes	No	No	No longer permitted from Dec. 2014
Australia/New Zealand[103] (2002)	Yes	No	Voluntary-using risk-based approach	Yes
Canada[104] (1994)	Specific phrasing recommended	No	No	Yes

[100] Allen et al. (2014). Precautionary Labeling of foods for allergen content: Are we ready for a global framework, World Allergy Organization Journal, 7:15, http://www.waojournal.org/content/7/a/10.
[101] FDA (Food and Drug Administration): Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108–282, Title II. In 2004. http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm106890.htm#gener.
[102] European Commission: Food labelling – EU rules. http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/index_en.htm
[103] FOOD STANDARDS AUSTRALIA NEW ZEALAND: Review of the regulatory management of food allergens. 2010. http://www.foodstandards.gov.au/consumer/foodallergies/review/documents/Review%20of%20the%20Regulatory%20Management%20of%20Food%20Allergens-FSANZ%20Dec%202010.pdf.
[104] Health Canada. Food Allergen Labelling. http://www.hc-sc.gc.ca/fn-an/labeletiquet/allergen/index-eng.

China[105] (2012)	Yes	No	No	Yes
HongKong[106] (2004)	Yes	No	No	Yes
Japan[107] (2002)	No	Use is prohibited	>10 ppm requires mandatory disclosure for all allergens	Yes, only for allergen present in >10 ppm
Korea[108] (2004)	Yes	No	No	Yes
Mexico[109] (2010)	Yes	No	No	Yes

As shown in Table 7, not all countries use PAL. Countries using PAL do not mandate or regulate which allergens are listed in PAL statements. Manufacturers and food providers in the U.S., EU, Australia, Canada, China, Hong Kong, Korea, and Mexico do not follow any risk assessment process in listing voluntary allergens using the term "contained."

In a 2020 article, De Kock reviewed strengths, weaknesses, and improvements in using PAL. De Kock stated that unified global standards enable consumers to trust PAL. Instead of providing a specific statement, De Kock concluded PAL should include more symbols and safety statements.[110]

Table 8: Suggestions and obstacles for PAL implementation

Suggestions for Future Implementation	Obstacles to Future Implementation
• Unified Standard globally • Encourage science-based evidence system	• Expected additional costs to implement a personalized system using mobile phones and apps.

[105] Wenting Z: Allergens to be listed on food labels. http://www.chinadaily.com.cn/china/2011-12/21/content_14298531.htm

[106] Centre for Food Safety, The Government of the Hong Kong Special Administrative Region. Labelling Guidelines On Food Allergens, FoodAdditives And Date Format. http://www.cfs.gov.hk/english/food_leg/food_leg_lgfa.html.

[107] Akiyama H, Imai T, Ebisawa M: Japan food allergen labeling regulation–history and evaluation. Adv Food Nutr Res 2011, 62:139–171

[108] Korea Food & Drug Administration: Foods Labeling Standards 2003. http://www.mfds.go.kr/files/upload/eng/Foods_labeling_standars_03.pdf.

[109] Allergen Food Labelling. http://foodlawstrategies.wordpress.com/tag/mexico-food-labeling/.

[110] De Kock et al. (2020). 1,2, 6-9,10-12,16,17)

• Needs to indicate safe products by describing PAL • Using the Symbol instead of descriptive statements • Needs to be used in mobile phones or apps • Needs to educate stakeholders for a clear understanding	• Not easy to consent to develop a science-based evidence process globally. • More legal actions are predicted if apps or phone indications react to "safe" food on the device.

In conclusion, PAL has become more important, raising the potential for regulating notices of allergen contamination during manufacturing, packaging, and delivery processes. Nonetheless, many countries do not regulate PAL, which can result in confusing or misleading statements. Considering that the amount of each allergen is crucial for predicting individual allergen risks, it is important to establish universal PAL standards. Many studies have concluded that uniform guidelines be created for PAL that require clear and explicit statements or universal color symbols for risk assessment.

2.3. Digital Health and Wellness Apps Informing Food Allergy Labeling

The recent articles introduced icon-based digital allergen labels using barcode scanning. This device supports the implementation of Mobile Health (mHealth) to change health behaviors. Since most consumers carry smartphones, mobile phone users can receive personalized allergen information if they purchase mHealth applications.[111] mHealth applications can be personalized with consumers' health information and can indicate the presence of food allergens, including those that are not mandatory under government regulations. Fuchs' study followed 74 participants' use of digital health and wellness apps, including non-travelers, frequent travelers,

[111] Dunford E, Trevena H, Goodsell C, Ng KH, Webster J, Millis A, Goldstein S, Hugueniot O, Neal B. FoodSwitch: A Mobile Phone App to Enable Consumers to Make Healthier Food Choices and Crowdsourcing of National Food Composition Data. JMIR Mhealth Uhealth. 2014 Aug 21;2(3):e37. doi: 10.2196/mhealth.3230. PMID: 25147135; PMCID: PMC4147708.

incompetent text readers, and competent text readers; the study found that many users were satisfied with the results of the applications and intended to use them in the future for convenience and reliability.

Research has found that Digital health applications (DiHAs) or wellness apps can encourage consumers to select healthy foods. According to Miskiel, the FDA's review of all ingredients took time to determine which ingredients should be listed as allergens; even though potential allergen contamination incidents occurred manufacturers did not refrain from selling non-labeled products. Current technology has enabled digital food allergy devices, which are strongly recommended for several reasons because they can be used in many locations and can be customized to detect specific allergens. Furthermore, digital allergy apps help users who do not or cannot carefully read food allergy labeling descriptions and minimize risk in food decisions. Shaker discussed the importance of raising public awareness and exercising healthy dietary habits.[112]

Numerous technology firms have launched digital health and wellness apps, after conducting research on several key aspects of food allergens. These investigations focused on determining acceptable risk levels for various allergens across different demographic groups, assessing how well consumers comprehend allergen level information, and analyzing the impact of allergen labeling on individuals' food selections.[113] Several methods are employed by apps to provide allergen information to consumers: 1) implementing unique symbols and individualized barcodes

[112] Dana Shaker, An Analysis of "Natural" food litigation to build a sesame allergy consumer class action, Food, and Drug Law Journal, 103 (2017).
[113] Zurzolo, G.A., Peters, R. A., Koplin, J. J., De C.M., Mathai, M.L., Allen K. J. (2017) Are food allergic consumers ready for informative precautionary allergen labeling?, Allergy Asthma Clin Immunol, 13:42.

for different food allergens; 2) offering toll-free physician consultations; and 3) utilizing specialized mobile applications that aid users in accurately decoding food allergen barcodes.

Considering labeling's convenience in checking individuals' precautions to specific allergen reactions, consumers' data security issues challenge the significant issue of freedom of information. Adler explains that this complete ingredient information has to be protected as the consumer's "right to know." Moreover, Adler argues that consumers have more extensive rights to demand full ingredient disclosure from manufacturers than those granted by the First Amendment. This allegation supports a reassessment of the prevailing legal doctrine, which does not place equivalent disclosure obligations on government agencies overseeing related regulatory programs.[114]

In a 2020 study, Research conducted by Mandracchia highlighted deficiencies in allergen-indicating health and wellness applications. These digital tools often lacked comprehensive and precise descriptions of privacy guidelines, particularly in differentiating between Protected Health Information (PHI) and sensitive personal data. Additionally, the apps failed to elucidate the criteria used for establishing their allergen lists. The issue is exacerbated by the diverse regulatory landscapes across nations regarding the classification of health and wellness applications. Some jurisdictions regulate these apps as health tools, while others consider them general information platforms. This regulatory inconsistency exists despite oversight from global bodies such as the WHO and the US FDA, which may or may not classify these applications as health devices.[115]

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[114] The First Amendment does not impose equivalent requirements on disclosures to government agencies charged with administering related regulatory programs. *See infra* Section VII.C. ,

[115] WHO Global Observatory for eHealth. mHealth: New horizons for health through mobile technologies: second global survey on eHealth. World Health Organization. 2011. URL: https://apps.who.int/iris/handle/10665/44607 [accessed 2020-08-29]

2.4 Protection from Consumer Privacy Concerns in Using Digital Informative and Advisory Food Allergy Labeling

Consumer concerns are becoming more serious as many digital devices and apps are used for food allergy detection and prevention. In detecting allergen presence, digital apps raise broader issues encompassing electronically captured data and technical and user communication. As consumers and regulators are concerned the privacy infringement issues, prior research studies have analyzed ways digital apps can infringe on privacy. Privacy vulnerabilities remain a concern for personal digital devices, even when health information is consistently encrypted. Through the process of sending and receiving data, malicious entities can track personal information, and an individual's identity can be ascertained from their IP address.[116]

Other studies have claimed that personal privacy needs to be protected for users of digital allergy devices, that we should analyze how devices collect personal data, how personal information can be illegitimately gathered, and what types of personal data should be protected.[117]

In a 2021 study, Wood analyzed whether the HIPAA term "covered entity" needs to extend to cover personal digital data device manufacturers or app developers, whether HIPAA regulations provide appropriate administrative, technical, and physical safeguards to protect electronic personal information, and which type of information is handled under HIPAA.[118] Other studies have suggested that The FTC's Health Breach Notification Rule should be reviewed because it relates to consumers' personal data collected and saved through digital apps

[116] *Id.*
[117] Off. of Public Affairs, U.S. Department of Justice (2023).
[118] Daniel Wood, Noah Apthorpe, and Nick Feamster, Cleartext Data Transmissions in Consumer IoT Medical Devices, IoT S&P 17, at 7. (2017)

because “health care provider” comes from 42 U.S.C. § 1320d, which is referenced in Section 318.2(e) of the FTC’s Rule.[119]

A Landi’s study on the use of digital allergy devices was conducted to review whether digital devices handled health data under U.S. HIPAA and EU regulations.[120] Thus, further research is required to determine whether digital health devices or apps informing food allergens and labeling are required to protect consumers' data, how digital allergy devices use and collect personal data, and whether HIPAA and FTC laws and regulations and EU law need to be updated to protect consumers' privacy when using digital allergy labeling devices.

2.5. Implication of Related Articles/Studies Review

The review of related articles and studies summarizes 1) current global mandatory and voluntary food allergy labeling systems and WHO codex standards; 2) digital food allergy labeling in terms of technology and features; and 3) consumer privacy concerns and related regulations in using digital food allergy labeling devices. Prior research has highlighted the importance of digital tools in mitigating unforeseen risks. Consumers who incorporate devices that provide information on food allergens or ingredients into their routine activities benefit from increased safeguards against potential allergic incidents.

Previous studies have alleged that health and wellness apps do not follow any standard laws and regulations of privacy protection, even though apps deal with food allergy allergens that might be related to an individual’s health data. This literature review discussed research studies that concluded that digital apps do not follow current labeling systems and summarized the importance of creating a unified standard. Lastly, as research studies highlighted consumers’

[119] 16 CFR Part 318, FTC’s Health Breach Notification Rule
[120] Heather Landi, FTC steps us scrutiny of digital health apps with proposed changes to data privacy rule, FierceHEalthcare, FTC Steps Up Scrutiny Of Digital Health Apps With Proposed Changes To Data Privacy Rule | EMHIC (emhicglobal.com) (last visited October 6, 2023)

privacy concerns regarding the use of digital devices, this dissertation will evaluate how best to use privacy laws to protect the health information of consumers who use digital allergy labeling devices.

2.6. Methods of Study

This study focused on the laws and regulations that could regulate DiHA or wellness apps. This study analyzes each app's features in comparison to current food allergy labeling regulations and current privacy laws.

For allergy labeling regulations, Chapter 1 analyzed each country of food allergy labeling standards of the U.S., EU, Australia, Canada, China, Hong Kong, Japan, Korea, Mexico FAO, and WHO Codex standards. Many countries follow the EU system because EU regulations require a food risk assessment, and its 13 mandatory allergens cover most of the listed mandated allergens used in other countries' regulations. U.S. regulation guideline set PAL considering U.S.'s food manufacturing condition and risk assessment of analyzing whether the suggested amount of allergens is needed to inform on the allergy labeling section as considering the different amounts of allergens causes the different risks to a different person. Chapter 2 examines relevant studies and research to identify which regulations and laws need to be evaluated regarding food allergy labeling requirements on digital wellness and health applications. It also examined issues surrounding handling allergen information through apps, particularly concerning the use of PHI and sensitive personal data. Chapter 3 analyzes the U.S., EU, and WHO food allergy labeling regulations to suggest which standards should be applied to digital health devices or apps. Chapter 4 analyzes current digital health devices or apps to detect food allergens and PAL allergen labeling. Chapter 4 also examines whether the digital apps adhere to current government regulations for mandated allergens or align with PAL. Chapter 5 analyzes U.S. and EU privacy laws and regulations regarding the use of health data to suggest which

regulations should be used to protect consumers' personal information when using personal digital allergy labeling devices. Finally, Chapter 6 summarizes the outcomes of these research questions.

2.7. Data Collection Process

To review current digital food apps, I used key search terms to identify digital allergy apps, including "food allergy," "food allergy scanner," "allergy label," "food label," "meal plan," "allergy," "food check," and "food label scanner." This search generated around 400 apps. I then narrowed my selection to apps with more than four stars and more than ten million users. For purposes of this study, I selected 11 digital food allergy label applications. I used the standard guidelines of laws and regulations to review these digital apps. First, I analyzed three categories of issues: digital app use for pre-packaged food labels, digital app use for ready-to-eat food, and digital app collected data and related privacy policies. Second, as a researcher, I experimented with each application, using it according to its instructions. Third, based on my experiences using each app, I analyzed whether and how each app implements current laws and regulations regarding mandated food allergens and health information privacy.

CHAPTER 3

CURRENT LAWS, REGULATIONS AND GLOBAL STANDARDS FOR FOOD ALLERGY LABELING

3.1 Introduction

Digital health and wellness devices or apps display symbols, charts, and other graphics in the food allergy labeling. Its tools enable consumers to read precautionary warnings of different allergens clearly and easily recognize different allergens marked with different colors or visual images. This type of mechanism provides more detailed information and encourages consumers to communicate with consumers through digital devices about the list of allergens. Digital apps can bring about significant positive changes in people's healthy lives and support their selection based on individual diet concerns. Nevertheless, digital health and wellness apps' indications for allergens do not follow any mandated allergy labeling requirements, even though the same users with the same apps might be placed on the difficulty of understanding list of allergens designated by each country's own rules and regulations because the app's designation of mandatory allergens is inconsistent in every country.

It is crucial to review which laws and regulations currently regulate and control digital health devices or apps for advising food allergens, precautions, and labeling. This chapter provides an overview of the laws and regulations related to food allergy labeling requirements. Further, it guides how to determine best practices for digital allergy labeling devices to protect consumer health and privacy.

3.2 Food Allergy Laws and Regulations for Pre-Packaged Food

A. United States

The FDA regulates all packed food under the Federal Food, Drug, and Cosmetic Act (FD&C Act) that is labeled on or after January 1, 2006, must comply with the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 ("FALCPA") in terms of food allergen labeling requirements.[121] The FALCPA requires that labels for all packaged food products must list eight major food allergens, and the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act ("FASTER Act") of 2021 requires sesame to be added. According to 27 CFR 5.82, the major food allergens are milk, eggs, fish (e.g., bass, flounder, or cod), crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.[122] Sesame was not a major food allergen under the FALCPA of 2004. A food ingredient protein must be listed on the ingredient label if it is derived from a food specified from major food allergens under 27 CFR 5.82.[123] However, highly refined oils derived from food ingredients containing specific major allergens have been excluded from the allergen regulations.[124]

The requirements of the FALCPA definition are based on the current scientific clinical findings. The FDA's requirement on regulating to list mandated allergens on the labeling description is based on manufacturers' end-product food ingredients, not based on the predicted risks of a manufacturing process that have any possibility to occur in preparing, manufacturing,

[121] Guidance for Industry: Questions and Answers Regarding Food Allergens (Edition 4) | FDA. https://public4.pagefreezer.com/content/1675837241895/FDA/23-11-2021T07:28/https:/www.fda.gov/food/guidance-documents-regulatory-information-topic/guidance-industry-questions-and-answers-regarding-food-allergens-including-food-allergen-labeling
[122] Code of Federal Regulations 27 CFR 5.82. Voluntary Disclosure of Major Food Allergens https://www.ecfr.gov/current/title-27/chapter-I/subchapter-A/part-5/subpart-F/section-5.82
[123] 27. CFR 5.82, Voluntary Disclosure of Major Food Allergens https://www.ecfr.gov/current/title-27/chapter-I/subchapter-A/part-5/subpart-F/section-5.82
[124] Id. At paragraph (a)(ii)(A).

or packing food production.[125] In a 2016 FDA report, the threshold criteria for listing mandated allergens based on state-of-the-art science and clinical findings could come from four approaches: 1) analytical method-based thresholds, 2) safety assessment-based, 3) risk assessment-based, and 4) statutorily derived uses. Analytical method-based thresholds are determined by the sensitivity of the analytical methods used to verify compliance. The safety-assessment-based level is the calculated uncertainty level at which humans react with appropriate uncertainty factors in response to humans. A risk-assessment-based examination is a test to determine the reaction associated with the quantity level of exposure. Statutorily derived uses review other potentially raised risks of the exempted ingredients.[126]

According to the FDA's findings, the FDA's currently available scientific knowledge and clinical findings are used to decide which allergens should be designated as mandatory or listed in the voluntary allergy section. A safety assessment-based approach can monitor all predictable risks by considering the Lowest Observed Effect Level (LOAEL) or No Observed Effect Level (NOAEL); unpredictable levels must be reviewed periodically. As many scientific data and digital devices can use the risk-assessment-based allergen to decide which allergens should be listed on the label for consumers to opt out in selecting food or menu through the apps, the FDA has also reviewed the risk-assessment approach to enable consumers to prevent any unexpected reactions. However, clinical and epidemiological data are needed to analyze the risk reactions in all populations and periodically monitor whether allergens accurately indicate risky reactions.[127]

Thus, under the FALCPA Act, manufacturers must list the major food allergens detected by current technology and clinical evidence but do not have to monitor any risk or safety

[125] The Center for Food Safety and Applied Nutrition Food and Drug Administration, Approached to Establish Thresholds for Major Food Allergens and for Gluten in Food (2006)
[126] Id.
[127] Id.

assessment at the quantity level. To avoid confusion, FALCPA is required to list well-known names and names of sources not created or composed by manufacturers' conventional names. Manufacturers must list the name of the specific type of food source from which each major food allergen is derived.

i. In the case of a tree nut, it means the name of the specific type of nut (for example, almonds, pecans, or walnuts);
ii. In the case of crustacean shellfish, it means the name of the species of crustacean shellfish (for example, crab, lobster, or shrimp) and
iii. The names "egg" and "peanuts," as well as the names of the different types of tree nuts, may be expressed in either the singular or plural form, and the names "soy," "soybean," or "soya" may be used instead of "soybeans."

27 CFR. 7.82 provides specific directions for the ingredients from three food groups. Labels must include the common names of optional ingredients, including spices, flavoring, and coloring.[128] It is necessary to describe the total percentage of each ingredient unless it is sold as spices, flavorings, or such colors.[129]

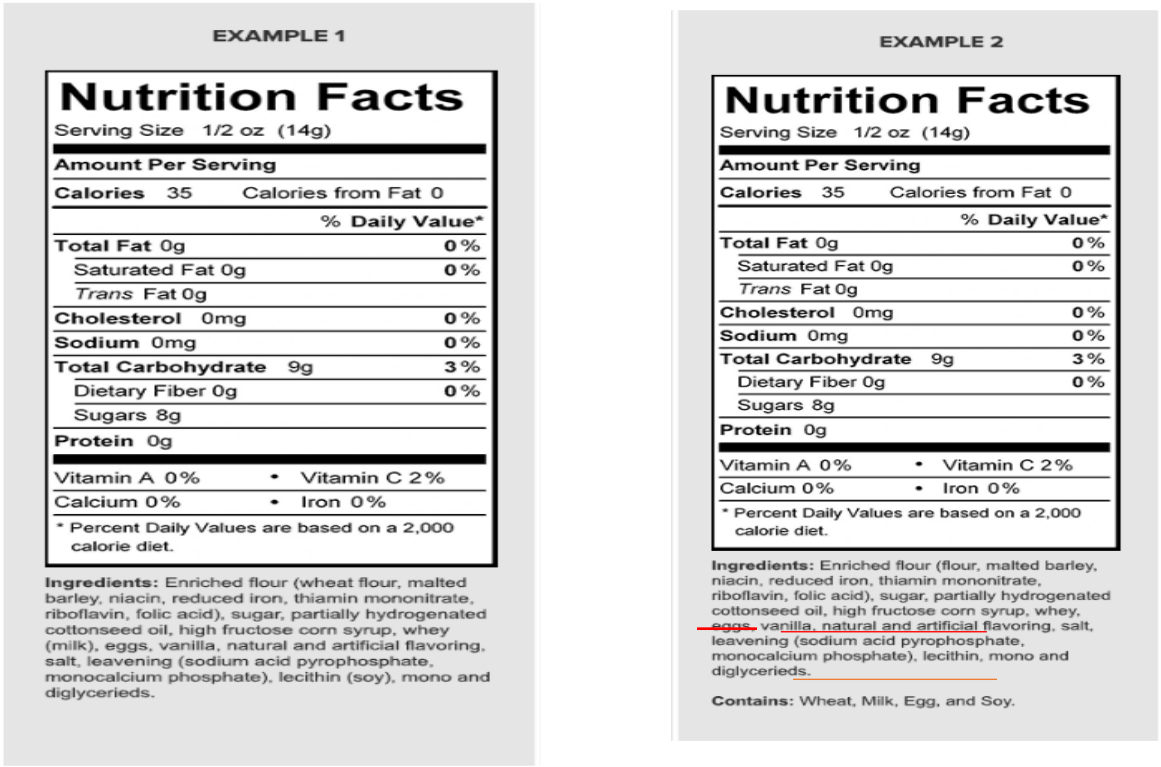
The FDA designated in Section 403(w)(1) that the "contain" statement listing the allergens must be limited to just the word "contains" followed by the food sources of all major food allergens. "Contain" does not have the same meaning as "May Contain" because the term "contain" is used to list mandatory allergens that are contained in food products, and the "may contain" statement was used by manufacturers to voluntarily list any allergens to warn consumers about any possibility of containing allergens during any stage of processing food preparation, manufacturing, and packing. The food source of any major allergens declared on the label must be named using its FALCPA-designated common name; the only discretionary

[128] 21 U.S.C. 343
[129] 21 U.S.C. 343(a)(i)

adjustments are a) using singular terms versus plural terms (e.g., walnut versus walnuts) and b) using the synonyms "soy" and "soya" instead of the food source name "soybeans."[130]

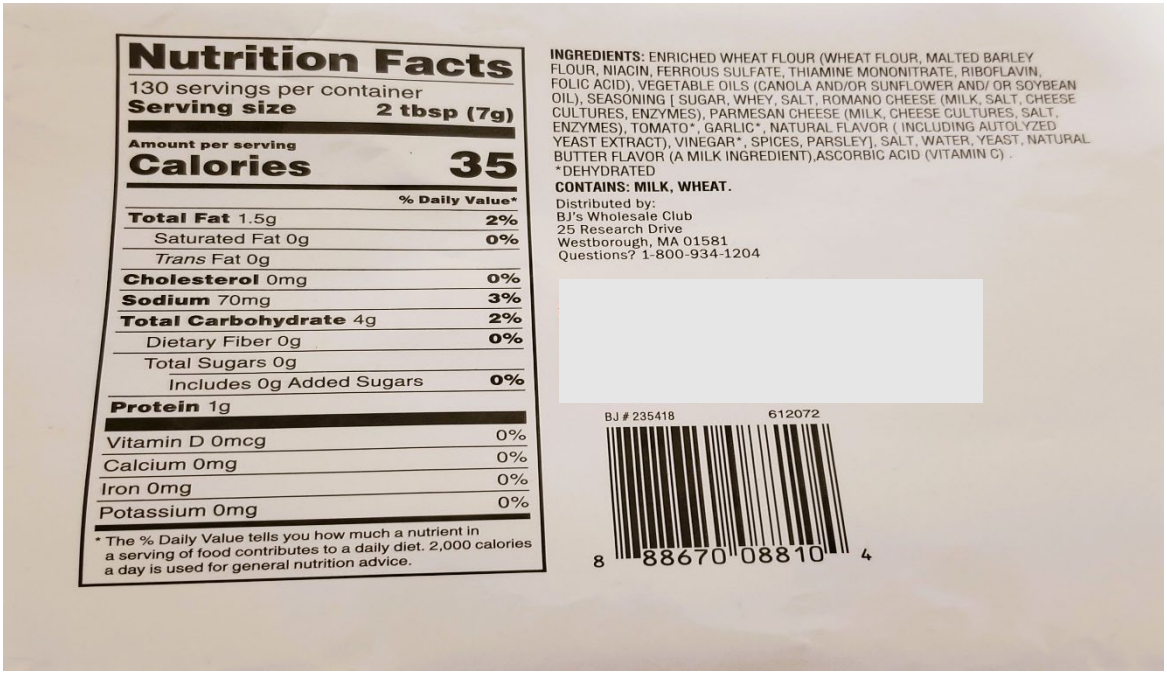
Labeling regulations permit two ways of describing allergens.[131] First, the major allergens are described in parentheses, following the names of the ingredients. For example, the example product label below shows "Lecithin (soy), Flour (wheat), and whey (Milk)." Second, the label uses the term "contains" right after the list of ingredients, as shown in example 2: "**Contains**: **Wheat, Milk, Egg, and Soy**."

Figure 1: Food labeling examples followed US FDA requirements



[130] U.S. Department of Health and Human Services, A food Labeling Guide. (2013)
[131] Webstaurant store, https://www.webstaurantstore.com/article/22/food-allergy-overview.html (last visited Oct. 13. 2023)

Figure 2: Food labeling in Use in the US



Nutrition Facts

130 servings per container

Serving size 2 tbsp (7g)

Amount per serving

Calories 35

	% Daily Value*
Total Fat 1.5g	2%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 70mg	3%
Total Carbohydrate 4g	2%
Dietary Fiber 0g	0%
Total Sugars 0g	
Includes 0g Added Sugars	0%
Protein 1g	
Vitamin D 0mcg	0%
Calcium 0mg	0%
Iron 0mg	0%
Potassium 0mg	0%

* The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

INGREDIENTS: ENRICHED WHEAT FLOUR (WHEAT FLOUR, MALTED BARLEY FLOUR, NIACIN, FERROUS SULFATE, THIAMINE MONONITRATE, RIBOFLAVIN, FOLIC ACID), VEGETABLE OILS (CANOLA AND/OR SUNFLOWER AND/ OR SOYBEAN OIL), SEASONING [SUGAR, WHEY, SALT, ROMANO CHEESE (MILK, SALT, CHEESE CULTURES, ENZYMES), PARMESAN CHEESE (MILK, CHEESE CULTURES, SALT, ENZYMES), TOMATO*, GARLIC*, NATURAL FLAVOR (INCLUDING AUTOLYZED YEAST EXTRACT), VINEGAR*, SPICES, PARSLEY], SALT, WATER, YEAST, NATURAL BUTTER FLAVOR (A MILK INGREDIENT),ASCORBIC ACID (VITAMIN C) .
*DEHYDRATED
CONTAINS: MILK, WHEAT.
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B. European Union

EU No. 1169/2011 includes the list of 14 major allergens to indicate their presence on a label. Annex II lists the major allergens to be regulated in pre-packaged and non-packaged food.[132]

1. **Cereals** containing gluten, namely wheat (such as spelt and Khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof, except:
(a) wheat-based glucose syrups including dextrose (15);(b) wheat-based maltodextrins (15) ; (c) glucose syrups based on barley;(d) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin;
2. **Crustaceans** and products thereof;
3. **Eggs** and products thereof
4. **Fish** and products thereof, except (a)fish gelatine used as a carrier for vitamin or carotenoid preparations; (b) fish gelatine or Isinglass used as a fining agent in beer and wine;
5. **Peanuts** and products thereof;

[132]European Union, EU No. 1169/2011, https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02011R1169-20180101#E0017

6. **Soybeans** and products thereof, except:
(a) Fully refined soybean oil and fat (15) ; (b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources; (c)vegetable oils derived from phytosterols and phytosterol esters from soybean sources; (d)plant stanol esters produced from vegetable oil sterols from soybean sources.
7. **Milk** and products thereof (including lactose), except:
(a) whey used for making alcoholic distillates, including ethyl alcohol of agricultural origin; (b) lactitol;
8. **Nuts,** namely: almonds (Amygdalus communis L.), hazelnuts (Corylus avellana), walnuts (Juglans regia), cashews (Anacardium occidentale), pecan nuts (Carya illinoinensis (Wangenh.) K. Koch), Brazil nuts (Bertholletia excelsa), pistachio nuts (Pistacia vera), macadamia or Queensland nuts (Macadamia ternifolia), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin;
9. **Celery** and products thereof;
10. **Mustard** and products thereof;
11. **Sesame** seeds and products thereof;
12. **Sulphur dioxide and sulphites** at concentrations of more than 10 mg/kg or 10 mg/liter in terms of the total SO2, which are to be calculated for products as proposed, ready for consumption, or as reconstituted according to the instructions of the manufacturers;
13. **Lupin** and products thereof;
14. **Molluscs** and products thereof.

In reviewing the EU's mandatory allergen list, the EU specified the type of cereal as wheat, rye, barley, and oats; nuts also specified in point 8 of Annex II required to list the name of allergens, including almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia, and Queensland nuts. According to Article 21(1), the EU requires that the list of allergens be in a font or typeset that clearly distinguishes them from the rest of the ingredients; they can be in different fonts, styles, or background colors but not in a separate text block.[133]

EU regulations apply to food business operators at all stages of the food manufacturing stage of preparation, making or packing.[134] Regulation (EU) No. 1169/2011 sets out a list of

[133] EU Commission Notice Doc. 520 17 XC 1213 (01), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52017XC1213(01)
[134] EU, Mandatory Food Information (2003), https://food.ec.europa.eu/safety/labelling-and-nutrition/food-information-consumers-legislation/mandatory-food-information_en

mandatory information items to be provided to the ultimate consumer of food products (Article 9, par. 1).[135]

A. **Name of the food**;
B. **List of ingredients**;
C. Any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II **causing allergies or intolerances** used in the manufacture or preparation of food and still present in the finished product, even if in an altered form;
D. **Quantity of certain ingredients or categories of ingredients**;
E. **Net quantity** of the food;
F. **Date of minimum durability ('best before' date)** or the **'use by' date**;
G. Any special **storage conditions** and/or **conditions of use**;
H. **Name or business name and address** of the food business operator referred to in Article 8, par.1;
I. **Country of origin** or **place of provenance** where provided for in Article 26;
J. **Instructions for use** where it would be difficult to make appropriate use of the food in the absence of such instructions;
K. With respect to beverages containing more than 1,2% by volume of alcohol, **the actual alcoholic strength by volume**;
L. **Nutrition declaration**.

As the example, Figure 3 shows that labeling example listing the allergen on the food label. Each ingredient lists the name of allergens with bold font required under EU regulations.[136]

[135] Regulation (EU) No 1169/2100 of the European Parliament and of the Council 25 October 2011, https://eur-lex.europa.eu/eli/reg/2011/1169/2018-01-01
[136] Rachel Arthur, Bold, underlined, italics, or colored? Food Navigator , https://www.foodnavigator.com/Article/2014/09/25/Allergen-Manager-RS-Solutions-labelling-EU-1169-2011# (2014)

Figure 3:EU labeling example derived from food navigator

C. FAO/ WHO International Standards

The Codex Committee on Food Hygiene (CCFH) developed a code of practice (CoP) to guide food business operators and competent authorities in managing allergens in food production, including controls to prevent cross-contacted allergens that may have been contained during any stage of a manufacturing process or sharing the facilities of other factories handling different food products.[137] The main discussion in the Codex Standard in the Codex Committee on Food Labeling (CCFL) in May 2019 required that certain foods be exempted from the mandatory declaration if mandated allergens are not enough amount to cause hypersensitivity

[137] Baumert, Joseph, et al. "Risk Assessment of Food Allergens. Part 1: Review and Validation of Codex Alimetarius Priority Allergen List Through Risk Assessment." 2022, https://core.ac.uk/download/539621667.pdf.

risk to average people even though mandated allergens are likely to be contained during the manufacturing process.[138]

The Codex standards categorize the allergic nature of some foods into three categories by identifying safety hazards: 1) immunoglobulin E (IgE)-mediated (immediate hypersensitivity), 2) non-IgE mediated (cell-mediated or delayed hypersensitivity), and 3) mixed IgE- and non-IgE-mediated. IgE-mediated symptoms typically develop within minutes–1-2 hours of ingesting food. Non-IgE-mediated and mixed IgE- and non-IgE-mediated food allergies present symptoms several hours later after ingesting food. Symptoms of IgE-mediated food allergies include itching around the mouth, hives, swelling of the lips and eyes, breathing difficulties, drop in blood pressure, diarrhea, and anaphylaxis in most cases, which may result in death.[139]

The World Health Organization (WHO) Food Standards Program established general label requirements. Designated items declared on packaged food include the food's name; list of ingredients; name and address of the manufacturer, exporter, importer, packer, distributor, or vendor; country of origin; lot identification, and instructions of use.[140]

In paragraph 4.2.1.3, an ingredient that contains two or more ingredients is a compound ingredient and may be declared in the list of ingredients if it is immediately accompanied by a list (in brackets) of its ingredients in descending order of proportion (m/m). Where less than 5% of a compound ingredient has a name in the Codex standard or national legislation, its

[138] In the second meeting, reference doses (RfDs) were recommended for the global priority allergens (FAO and WHO, 2022a), which consisted: walnut (and pecan), cashew (and pistachio), almond, peanut, egg, hazelnut, wheat, fish, shrimp, milk, and sesame. However, RfDs were not recommended for a number of regional or national priority allergens as they did not meet the criteria to be global priority allergens. An additional fifth meeting was held after the Codex Committee on Food Labelling (CCFL) indicated interest in potential RfD derivation for the following specific food allergens: specific tree nuts (Brazil nut, macadamia nut or Queensland nut, pine nut), soy, celery, lupin, mustard, buckwheat, and oats (FAO and WHO, 2023b).
[139] Food and Agriculture Organization of the United Nations ; Code of Practice on Food Allergen Management For Food Business Operations, CXC 80-2020 (Adopted in 2020).
[140] General standard for the labelling of prepackaged foods (1985) In: Organization FaAOotUNWH, ed. 9

component ingredients (other than food additives that serve a technological function in the finished product) need not be declared.

Paragraph 4.2.1.4 requires that manufacturers need to declare the major allergens causing hypersensitivity on the label.[141]

> • Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt, or their hybridized strains and products of these;
> • Crustacea and products of these;
> • Eggs and egg products
> • Fish and fish products
> • Peanuts, soybeans, and products of these;
> • Milk and milk products (lactose included);
> • Tree nuts and nut products; and
> • Sulphite in concentrations of 10 mg/kg or more

If it is not possible to provide adequate information on the presence of an allergen through labeling, the product containing the allergen should not be marketed.[142] As of March 2022, the Codex Alimentarius Commission consists of 199 Member Countries and one member organization.[143]

3.3. Voluntary Precautionary Food Allergy Labeling

A. United States

Voluntary allergy labeling is different from mandatory food allergen labeling requirements.[144] Manufacturers may voluntarily place other information or statements on the

[141] https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B1-1985%252FCXS_001e.pdf
[142] Supar note 105.
[143] Codex Alimentarius, Food Import and Export Inspection and Certification Systems, https://www.fao.org/3/a1391e/a1391e00.pdf.
[144] U.S. Dept. of Health and Human Services, Food and Drug Administration Center for Food Safety and Applied Nutrition Office of Regulatory Affairs, Section 555. 250 Major Food Allergen Labeling and Cross-Contact Draft Compliance Policy Guide (May 2023), https://www.fda.gov/media/168000/download

labels of food products to disclose information about allergens to consumers. Allergen advisory statements are not mandated, and companies can freely choose what to include in their advisory statements.[145] Some examples of allergen advisory statements describe the voluntary labeling phrase "**may contain [allergen]"** or "**produced in a facility that also uses [allergen]**."[146]

Allergen advisory statements are not a substitute for manufacturer adherence to best standards in manufacturing processes and food-allergen preventive controls to prevent cross-contamination in facilities. However, the advisory statement must be truthful and not misleading consumers because consumers rely on labeling descriptions to detect any risky allergen during the manufacturing process, and consumers do not recognize any difference between a mandatory statement and a voluntary statement If that statement is truthful and not misleading. [147] Companies can state there are no allergens or gluten in the food by stating that it is "allergen-free" and "gluten-free" as defined in 21 CFR 101.91.[148] The FDA considers the statement "free" as the product has "no allergen" or "no gluten."

Consistent with other allergy labeling, manufacturing advisory statements are required to be separated from the "contains" statement: 1) a manufacturer may give a warning message to alert about allergens that are likely to be contained instead of having a separate section informing other countries' listed allergens contain in the food, or 2) a manufacturer may need to give a clear message of warning the gluten instead of having the separate statement mentioning of "other information: includes gluten" or listing gluten in the food ingredient sections without recognizing the gluten in specific ingredients.

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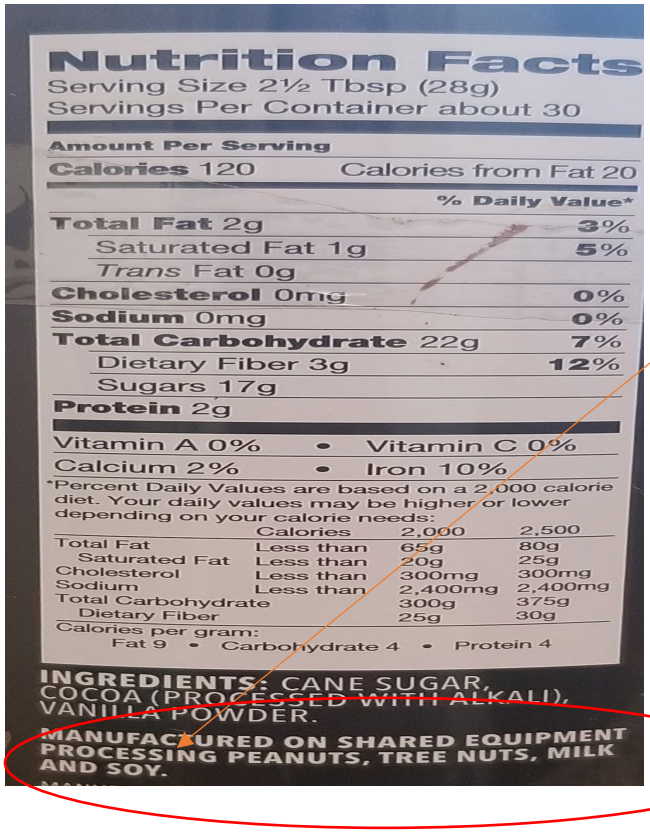
[145] Allergen advisory statements are also known as precautionary allergen labeling (PAL).
[146] Food processors that use sesame as an ingredient need to update allergen statements by January 1, 2023 - Product Center. https://www.canr.msu.edu/news/food-processors-that-use-sesame-as-an-ingredient-need-to-update-allergen-statements-by-january-1-2023
[147] section 403 (a)(1) of the FD&C Act (21 U.S.C. 343 (a)(1)).
[148] Enforcement policy related to the gluten-free labeling requirements (21 CFR 101.91) is outside the scope of this CPG.

The U.S. FDA's voluntary statement aims to protect consumers from inadequate manufacturing process controls or to prevent allergen cross-contamination or cross-contact.[149] "Cross-contact occurs when a residue or other trace amount of a food allergen is present on a food contact surface or production machinery or is airborne and unintentionally becomes incorporated into a product.[150] Since the FDA considers that cross-contamination cannot be removed, it considers it important to provide consumers with more information. Precautionary voluntary labeling is a way for manufacturers or food suppliers to provide supplemental information to warn consumers about any allergens to be concerned be included in any stage of the process of food making without having any predicted result of the amount of allergen to cause serious allergen reactions depending on consumer's sensitivity of allergen. As the FDA gives discretion to manufacturers to list voluntary allergens on the labeling description, FALCPA does not voluntarily regulate supplemental statements such as "may contain," "manufactured in a shared facility," and "processed on the same equipment"[151]

[149] FDA's Request for Comments on Use of Allergen Advisory Labeling, 73 Fed. Reg. 46,302 (Aug. 8, 2008) [hereinafter Allergen Comments].
[150] Horvath, J. C. "How Can Better Food Labels Contribute to True Choice?" 2012, https://core.ac.uk/download/217199785.pdf.

[151] Food Allergy & Anaphylaxis Connection Team, Food Allergy & Analphylaxis Food Allergy & Anaphylaxis | Food Labeling | Food Labeling (foodallergyawareness.org) (last visited October 24, 2023)

Figure 4: A Picture of Labeling taken by the author



The label describes the sentence " **Manufactured on shared equipment** processing peanuts, tree nuts, milk, and soy."

A manufacturer voluntarily provided this statement, which was not regulated by the FALCPA.

B. European Union

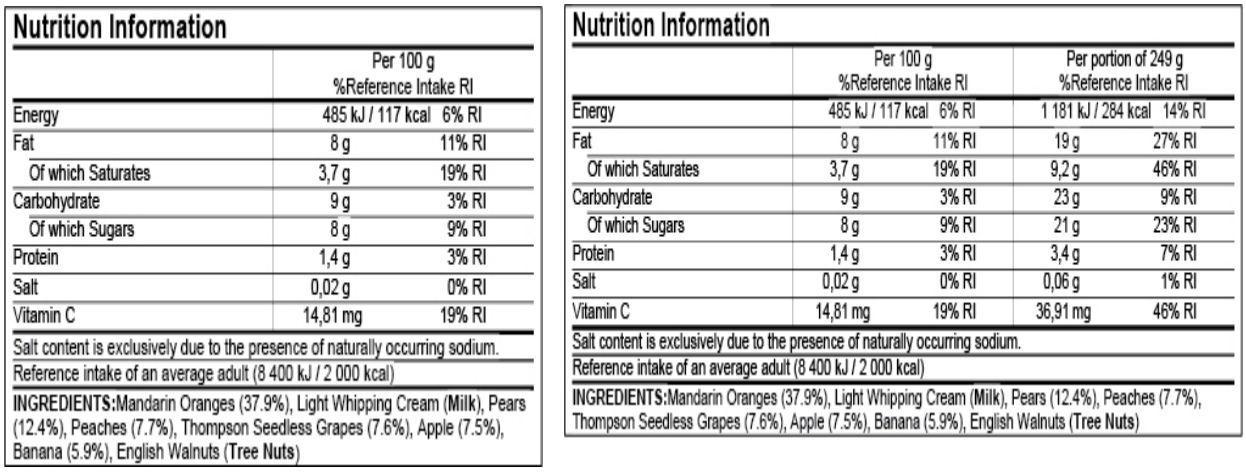
As many stakeholders request that PAL be implemented with a comprehensive, consistent, and science-based approach, Article 36 of Regulation (EU)1169/2011 ("FIC Regulation") sets up a PAL framework. Article 7 on fair information practices states that voluntary food information shall not mislead the consumer, shall not be ambiguous or confusing for the consumer, and shall be appropriate based on relevant scientific data.[152] The Commission's implementation of voluntary food labeling needs to meet suggested guidelines on when voluntary labeling is needed or some amount of allergens only cause risk to highly

[152] Food information to consumers - legislation - European Commission. https://food.ec.europa.eu/safety/labelling-and-nutrition/food-information-consumers-legislation_it

sensitive people.[153] Further, gluten information has been regulated under voluntary labeling guidelines.[154]

According to FIC regulation Article 36, the Commission has the option to introduce new rules on voluntary information concerning the possible and unintentional presence of substances or products causing allergies or intolerance in food.[155] Similar to U.S. PAL regulations, the EU allows precautionary allergen warnings ("may contain"). In contrast, unlike the U.S., the EU permits the introduction of agreed phrases or allergen recommended intake or reference intake for the accidental presence of allergens in pre-packaged reference intake. The reference intake is defined as the quantity of that ingredient that is served per 100g or for the portion of the entire packed food in each food product.

Figure 5: EU labeling Screen Captured by the Author



Nutrition Information

	Per 100 g	%Reference Intake RI
Energy	485 kJ / 117 kcal	6% RI
Fat	8 g	11% RI
Of which Saturates	3,7 g	19% RI
Carbohydrate	9 g	3% RI
Of which Sugars	8 g	9% RI
Protein	1,4 g	3% RI
Salt	0,02 g	0% RI
Vitamin C	14,81 mg	19% RI

Salt content is exclusively due to the presence of naturally occurring sodium.
Reference intake of an average adult (8 400 kJ / 2 000 kcal)
INGREDIENTS: Mandarin Oranges (37.9%), Light Whipping Cream (**Milk**), Pears (12.4%), Peaches (7.7%), Thompson Seedless Grapes (7.6%), Apple (7.5%), Banana (5.9%), English Walnuts (**Tree Nuts**)

Nutrition Information

	Per 100 g	%Reference Intake RI	Per portion of 249 g	%Reference Intake RI
Energy	485 kJ / 117 kcal	6% RI	1 181 kJ / 284 kcal	14% RI
Fat	8 g	11% RI	19 g	27% RI
Of which Saturates	3,7 g	19% RI	9,2 g	46% RI
Carbohydrate	9 g	3% RI	23 g	9% RI
Of which Sugars	8 g	9% RI	21 g	23% RI
Protein	1,4 g	3% RI	3,4 g	7% RI
Salt	0,02 g	0% RI	0,06 g	1% RI
Vitamin C	14,81 mg	19% RI	36,91 mg	46% RI

Salt content is exclusively due to the presence of naturally occurring sodium.
Reference intake of an average adult (8 400 kJ / 2 000 kcal)
INGREDIENTS: Mandarin Oranges (37.9%), Light Whipping Cream (**Milk**), Pears (12.4%), Peaches (7.7%), Thompson Seedless Grapes (7.6%), Apple (7.5%), Banana (5.9%), English Walnuts (**Tree Nuts**)

Reference intake information is listed for each ingredient. The EU allows several options for listing reference intake because the EU system does not require manufacturers to list calorie counts on serving size or the number of "servings per container" for food labels.

[153] EU website, Voluntary Food Information, https://food.ec.europa.eu/safety/labelling-and-nutrition/food-information-consumers-legislation/voluntary-food-information_en (last visited Oct. 22, 2023)
[154] Annex XIII of Regulation (EU) No 1169/2011
[155] Gaceu, Liviu, et al. "Methodology for Analyzing EU-conform Label Information Content of Meat Products in Romania." 2014, https://doi.org/10.17700/jai.2014.5.1.132.

On the EU label description, an ingredient must follow the EU guidelines for defining each food item. For example, olive and palm oil must be additionally declared "vegetable oils" if the olive or palm oil is produced from vegetables as the source of ingredients because many consumers do not clearly understand whether olive and palm oil came from vegetables or mixes of other non-vegetable ingredients. Thus, compared to the U.S.'s voluntary food allergen labeling, consumers have additional the EU have focused more on food labels, which can generally list food products that can be categorized as vegetarians or vegans, reference intake, or gluten information.

C. FAO/ WHO – International Standards

The WHO's RfD is expressed as mg of total protein from propriety allergenic sources. Codex standards require a list of cross-contacted allergens during food manufacturing processing and suggest predicted results on differently impacting highly sensitive people, including food preparation, manufacturing, or so for different products. The list of allergen ingredients must include the latest "allergen mapping," a facility diagram that identifies where allergens are stored, handled, and prepared on-site, overlaid with the main allergen on the food label. This requirement can be useful in identifying areas where controls should be applied to prevent or minimize allergens contained through cross-contact.[156]

The Joint FAO/WHO's recent 2023 report showed the percentage of risk that can be prevented through PAL and recommends using PAL by describing reference intake for each ingredient per average person's weight.[157] The 2023 report suggested that PAL should be based on Risk Assessment, including but not limited to quantitative risk assessment.[158] In addition to

[156] Id.
[157] Food and Agriculture and World Health Organization, Food Safety and Quality Series, Risk assessment of Food Allergens – Part 3: Review and establish precautionary labelling in foods of the priority allergens (fao.org) (2023)
[158] Id at 22

listing the mandated allergens, PAL is designed to prevent the probability of non-severe anaphylaxis from < 5 percent of exposures in the allergen population. The risk of severe outcomes (which the WHO defines as anaphylaxis not readily responsive to first-line treatment) would be less than 1 per 60,000 exposures in the allergic population,[159] or risk of severe anaphylaxis (according to the World Allergy Organization definition) of <1:100,000 person-years in the population of individuals with a relevant IgE-mediated food allergy.[160]

The WHO suggests that Reference Doses (RfD) conform to the definition of health-based guidance values (HBGVs). A Health-Based Guidance Value (HBGV) is a science-based recommendation that decides that less intake or exposure than recommended doses or referenced intake does not cause any risks and helps consumers avoid unsafety concerns when they are exposed to allergen ingredients. HBGVs recommendation has resulted in minimum level causing allergy risks by collecting the current safety data.[161]

The WHO constitutes a critical first step in assessing the risk from allergens, as they are characteristic of allergens, to inform that the recommended intake of allergens is differentiated in each ingredient. Mere exposure or a small intake of allergens is not enough to cause high risk to the average population. WHO suggested the consensus reference intake for each allergen. For example, the recommended protein amount that affects allergen risk in each allergen is suggested: 1.0 mg for Walnut(and pecan); Casher (and Pistachio); and Almond, 2.0 mg for Milk; Peanut Egg; and Sesame, 3.0 mg for Hazelnut, 5.0 mg for Wheat and Fish; and 200mg for Crustacea. WHO's main purpose in developing its RfDs is to avoid consumer confusion and

[159] Paul J Turner, Peanut Can Be Used as a Reference Allergen for Hazard Characterization in Food Allergen Risk Management: A Rapid Evidence Assessment and Meta-Analysis, J Allergy Clin Immunol Pract, 10(1):59-70 (2022).
[160] See supra note 127.
[161] EFSA Scientific Committee, Simon More, Statement on the derivation of Health-Based Guidance Values (HBGVs) for regulated products that are also nutrients, Vol.19, issue 3, (2021).

consistently make the information simple, clear, unambiguous, and not false or misleading.[162] Related to the statement "contain." WHO alleged that consumers have to receive more detailed information on reference doses of each allergen that causes the potential risk on the food label, and its' listed name of allergen in the food label is not enough for consumers to realize that the specific amount of allergen intake causes the actual risks.

3.4. Regulations in Non-Packaged Food in Restaurants and Cafes

A. United States

The current mandatory allergen labeling requirements under the 2004 FALCPA interpret that the regulation of the menu to list allergens in restaurants operating in fewer than 20 locations is not applied because the food offered for sale was interpreted with the exception of the food for immediate human consumption.[163] The lack of regulations to list allergens on the labeling description for packaged food does not apply to restaurant owner's liability.[164] The survey demonstrated that restaurant staff showed that 34% thought baking or frying could destroy an allergen, and only 42% had received food allergy training.[165] If restaurant food contains the same mandatory allergens ingredients under the FDA's guidelines, the law regulates that restaurants and grocery stores must list those allergens, but there is no duty to list ingredients containing other allergens under FALCPA.

The Patient Protection and Affordable Care Act ("ACA") 4205 is the first federal law to apply to menus. Under Section 4205, a "restaurant or similar retail food establishments that are

[162] FAO/WHO Recommend Uniform Precautionary Allergen Labeling as Codex Develops Guidance | Food Safety. https://www.food-safety.com/articles/8609-fao-who-recommend-uniform-precautionary-allergen-labeling-as-codex-develops-guidance

[163] The FALCPA contains an exception in 21 U.S.C. § 343(q)(5)(a)(2), for food "which is processed and prepared primarily in a retail establishment, which is ready for human consumption . . . and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment."

[164] Leavitt, 2011

[165] Ryan Ahuja & Scott H. Sicherer, Food-allergy Management from the Perspective of Restaurant and Food Establishment Personnel, 98 Annals Allergy, Asthma & Immunology 344, 344 (2007).

part of a chain with 20 or more locations doing business under the same name and offering for sale substantially the same menu items" must disclose calorie information and identified nutritional information.[166] Restaurants that do not meet these requirements can "opt-in to menu labeling requirements."[167]

The FDA proposed regulations in 2011 that were consistent with those of §4205.[168] The FDA defined a "restaurant or similar retail establishment" as "a retail establishment that offers for sale restaurant-type food, except if it is a school.[169] This definition incorporates "bakeries, cafeterias, coffee shops, convenience stores, delicatessens, food service facilities located within entertainment venues or vendors, food take-outs, delivery establishments in grocery stores, retail confectionary stores, superstores, quick-service restaurants, and table-service restaurants."[170] However, the FDA regulation excludes "restaurant-type food," or "food that is usually eaten on the premises while walking away, or soon after at another location," if the restaurant or similar food establishment chains operates fewer than 20 locations.[171]

As labeling used in the menu that applies in restaurants of more than 20 locations, the FDA defined "menu or menu board broadly in light of the importance for all consumers to have nutrition information when making order selections."[172] It is interpreted as "primary writing."

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[166] Boyd, Marie. "Serving Up Allergy Labeling: Mitigating Food Allergen Risks in Restaurants." 2019, https://core.ac.uk/download/187155130.pdf.
[167] HEALTH CODE (2008), and FDCA §§ 403(q)(5)(H), 403A(a)(4), 21 U.S.C. §§ 343(q)(5)(H), 343-1(a)(4), with H.R. 3444.
[168] .FDCA § 403A(a)(4), 21 U.S.C. § 343-l(a)(4). "Federal Register." (2011) https://core.ac.uk/download/71030620.pdf.
[169] See Supra note 171.
[170] Id.
[171] *See* FDCA §§ 403(q)(5)(H), 403A(a)(4), 21 U.S.C. §§ 343(q)(5)(H), 343-1(a)(4); Food Labeling , 79 Fed. Reg. at 71,165, 71,164, 71,168, 71,254 (defining "restaurant or similar retail food establishment").
[172] Food Labeling, 79 Fed. Reg. at 71,177; *see also id* at 71,209-10 (responding to comments expressing concerns about space constraints on menus and menu boards).

from a consumer's vantage point" and concluded that" this term can be more than one form of written materials."[173]

B. Recent Cases in the United States Involving Negligence for Allergens: Cline v. Publix Super Markets, Inc

Cline v. Publix discussed whether a Publix bakery had a duty to list allergens in bakery food. An 11-year-old child with food allergies, including tree nuts, ate a cookie sold by the Publix bakery and then died from a severe allergic reaction. Publix's packaged bakery products bore labels identifying their ingredients, including food allergens. However, other bakery products that were identical to those in packaging were displayed for sale and, when purchased, were placed in bags without allergen labels.[174]

This case examined whether FALCPA labeling requirements apply to ready-to-serve bakery items. The ruling aligns with the exemption granted to menu listings, which the FDA does not mandate to include allergen information.under section 343(q)(5):

> (i) food "which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments;" and
> (ii) food "which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in subclause (i), and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment."[175]

While the Chocolate Chew Cookie could be consumed in Publix, the court distinguished the grocery store bakery from a lunch, wagon, food truck, or vending machine. The court reasoned that Publix sold its chocolate cookies for consumption at home, similar to the packaged bakery

[173] *Id*. at 71,176-77 (citing Food Labeling Nutrition Labeling of Standard Menu Items in Restaurants and Similar Food Establishments, 76 Fed. Reg. 19,192, 19,202 (proposed Apr. 6, 2011) (codified at 21 C.F.R. pts. 11, 101)).
[174] Cline v. Publix Super Markets, Inc. Case No. 3:!5-0275 (M.D. Tenn, Jun, 11, 2015)
[175] *Id.*

products sold in the same area of the store.[176] Thus, according to FALCPA regulation, there is no liability for Publix not to list allergens on their food label of Chocolate Chew Cookie.

C. European Union

Under Article 44, EU members' non-prepacked foods are exempt from mandatory labeling requirements. Member states may adopt specific laws on mandatory particulars for non-prepacked foods, producing considerable variation. Member states may specify which allergens should be listed on the menu for ready-to-eat meals or restaurant food. Under Article 44, providing information about allergic ingredients is mandatory when foods are offered for sale to the final consumer or mass caterers without prepackaging or where foods are packed on the premises of the sale at the consumer's request or prepacked for direct sale.

In addition, the UK allows for an oral statement of informing allergen information by food suppliers, such as restaurant owners, managers, or food servers. The duty of informing allergen information encourages consumers to talk with food suppliers of non-packaged food and ask about allergens. An oral statement must be clear and accurate.[177]

[176]

[177] EU Food Allergen Labeling Solution (2023), https://amlabels.co.uk/eu-food-allergen-labelling-solution

Figure 6: Warning Messages for Non-Packaged Food in Restaurants

It is a legal requirement for food providers and servers to clearly provide allergen information to consumers when consumer have any questions about ingredients or uncertainty about choosing their meal by reading labeling descriptions.

Figure 7: Food Allergy Labeling containing Allergen information for pre-wrapped food in a bakery

3.5. State Allergen Labeling Laws

Some states, including California, Illinois, Massachusetts, Maryland, Michigan, Rhode Island, and Virginia, have advocated Food Allergy Research and Education (FARE) to prevent

allergies in restaurants. Massachusetts and California require that restaurant managers or food suppliers be certified.[178] Rhode Island and Virginia require restaurant personnel to receive allergy awareness and safety training and display food awareness posters in the staff area.

A. Massachusetts

Massachusetts General Law Section 6 B requires food providers to display the poster that the Department of Public Health approved on notices and menu boards stating, " Before placing your order, please inform your server if a person in your party has a food allergy."[179] regarding food allergy awareness. Food providers have the duty to provide any food allergy information and possible risks.[180] At the same time, customers also must inform the server about any food allergies that should be listed on the menu. Massachusetts encourages restaurants to voluntarily participate in "Food Allergy Friendly" as a voluntary program and issues guidelines and requirements for restaurants to receive the designation.[181] This duty of informing food allergens to patrons includes maintaining the premises to make it available to the public and following a master list of all the ingredients used in the preparation of food items available for consumption[182].

B. New York

New York Public Health Law 1356 requires to display 1) food allergy awareness, 2) a notice to consumers about all the menu items, and 3) certification of a food protection manager

[178] Food Allergy Research & Education, Food Allergies and Restaurant, https://www.foodallergy.org/resources/food-allergies-and-restaurants#:~:text=California,allergens%20and%20preventing%20cross%2Dcontamination. (last visit Oct. 31, 2023)
[179] Massachusetts General Laws, Section 6B, https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXX/Chapter140/Section6B
[180] Id.
[181] General Law - Part I, Title XX, Chapter 140, Section 6B. https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXX/Chapter140/Section6b
[182] Id at Section 6B,(g).

who has received training concerning food allergies.[183] According to the NY Public Health Law, the menu needs to notify " If you have a food allergy, please notify us," or a food allergy message needs to inform the customer about the allergy information for each prepared food item or item on the menu.[184]

This allergy regulation applies to online menu orders. When the customer orders food for delivery or takeout, including under a third-party food agreement under general business law, an online menu may need to indicate any food allergy or provide a food allergy message that informs the customer about the allergy information for each prepared food.[185]

3.6. Summary

For the mandatory labeling requirement, In the United States, food labels must disclose allergens for each ingredient and enumerate component allergens in a separate section following the word "contain." The EU mandates the identification of 14 primary allergens using distinct fonts but does not require a dedicated text block. The WHO establishes a general standard for packaged food labeling, which includes the food name, ingredient list, total protein content of each ingredient, and a catalog of allergens that may trigger hypersensitivity reactions.

For the voluntary precautional labeling requirement, the United States does not regulate food manufactueres' voluntary warning statements or menu listings for restaurants and ready-to-eat meal facilities with fewer than 20 locations. In contrast, the European Union, while not regulating voluntary statements, mandates that they should not be misleading, ambiguous, or confusing. The EU also requires listing recommended intake for allergens, identifying vegetarian or vegan sources, and providing gluten information. Although the EU does not regulate allergen

[183] N.Y. Pub. Health Law § 1356
[184] Id.
[185] Id.

descriptions for non-packaged food, the United Kingdom requires food suppliers, including managers, servers, and owners, to inform customers about allergens in food consumed on the premises. The WHO's standards in the voluntary section suggest that allergens require a minimum amount to pose a high risk to the average person if potentially present through air or surface contamination during food production.

Furthermore, an examination of California and New York state laws and regulations was conducted, as these states impose greater responsibilities on restaurant owners to provide allergen information during food ordering. Notably, in New York, the requirement to disclose allergen information applies equally to online orders, whether for dine-in or takeout meals.

CHAPTER 4
PRIVACY REGULATORY STRUCTURE FOR DIGITAL HEALTH APPS INFORMING FOOD ALLERGY LABELING

4.1 Introduction

As many people use Digital health applications (DiHAs), wellness applications ("apps"), or wearable devices (e.g., smart watches or smart trackers), users are getting concerned about whether their privacy information is protected safely. Individuals who rely on DiHAs or the Wellens app for allergen identification or allergy-related information exhibit increased concern regarding the security of their personal data. This heightened vigilance becomes particularly evident when these users are obligated to provide their private health details during the account setup process, which is necessary to access the full range of app functionalities. Personal health information is more vulnerable than other data types; it cannot be replaced like credit cards.[186]

Users' concerns are reasonable because they don't notice if third parties would use their personal health information and the security of apps is breached. Despite offering user data protection agreements, software developers may not be able to anticipate all potential security breaches in their applications.[187] Most digital food allergy apps are categorized as general fitness, health, or wellness apps, which provide food allergy information through digital software. DiHAs or Wellness devices dealing with personal health information in receiving allergen information or detecting allergen from the food label are categorized into two sections depending on who provides the information.: 1) clinical digital devices available through prescription from healthcare providers; and 2) mass-market devices and apps available directly to consumers. Clinicians can already prescribe several FDA-approved wearable devices for patient

[186] Sarah Kellogg, Every Breath You Take: Data Privacy and Your Wearable Fitness Device, 72 J. MO. B. 76, 76 (2016)
[187] Id.

use, including insulin monitors, cardiac event monitors, smart thermometers, electronic diaries for clinical trials, and smart inhalers for people with asthma.[188]

Despite collecting some user health information, DiHAs and wellness apps that identify allergens and offer dietary recommendations are not classified as medical devices requiring FDA approval for market entry. These products are exempt from such regulations as they primarily serve to detect the presence of allergens and provide meal planning guidance. The FDA only regulates devices that are classified as "devices" under 321 (h)(2).[189] While DiHAs and wellness apps provide health information, self-care, and health management, those apps are not classed as the devices that the U.S. FDA, Medicines and Healthcare Products Regulatory Agency (MHRA) or equivalent in EU member states. Despite the regulation of CEN/ISO 82304-2 controlling the quality and reliability of guiding standards for health and wellness apps, these regulations are not strictly related to their allergy detection or suggesting guidelines for allergy reading.[190]

An ongoing issue revolves around consumer-oriented health and wellness applications that, despite not being prescribed by medical professionals, have the capability to collect, store, and share health-related information. These apps enable communication between users and recommended experts for utilizing app features, raising concerns about data privacy and security in the consumer health sector. Numerous wellness apps provide features such as allergen identification in food labels, advice on meal planning, weight control, and daily schedules.

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[188] Brian Dolan, 23 Notable FDA Clearances for Digital Health Apps, Devices So Far This Year, MOBIHEALTHNEWS (Sept. 24, 2014), http://www.mobihealthnews.com/36795/23-notable-fda-clearances-for-digital-health-apps-devices-so-far-this-year.

[189] 21 U.S.C. § 321 - U.S. Code - Unannotated Title 21. Food and Drugs § 321, Under the FDA, devices are categorized into three classes based on the level of "consumer risk." Class 1 devices are categorized as representing small risks to consumers, whereas Class 3 devices represent high risks. Although Class 1 and Class 2 devices do not represent a high risk, the FDA requires a pre-market notification to ensure that the devices are safe, effective[189], and equivalent to those already legally marketed.

[190] ISO/TS 82304-2:2021:Health software,Part 2: Health and wellness apps — Quality and reliabilityhttps://www.iso.org/standard/78182.html#lifecycle

However, it's crucial to understand that apps designed for allergen detection are not meant to diagnose health conditions through the exchange of personal health data or information.[191] While the FDA monitors mobile applications beyond FTC guidelines to assess the need for additional or alternative protective measures, the current regulatory landscape for DiHAs and wellness apps remains ambiguous. This lack of clarity extends to apps that provide information on food allergy severity or allergens. Notably, existing regulations fail to adequately address the issue of data protection following a breach, particularly in cases where app content is leaked or shared without the user's explicit consent. This regulatory gap leaves users vulnerable to potential misuse of their sensitive health information.[192] Thus, A separate regulatory framework is necessary for digital health applications and wellness software not classified as medical devices by the FDA. Current privacy laws, including HIPAA and other federal or state legislation in the United States, should govern these applications as health-related devices. The concept of privacy needs to be reevaluated in the context of DiHAs and wellness apps, considering the handling of health-related and sensitive personal information on digital platforms. This discussion should encompass the specifics of data types, providers, and users, as the content managed through these websites originates from personal health information. Despite this, the data utilized is often treated as mundane or insignificant, lacking protection even when shared among users. This leaves it susceptible to potential breaches through user-to-user communication within the app ecosystem.

Privacy definitions vary in each area, and understanding privacy in different contexts has different meanings that may be summarized as seven areas, including information privacy right,

[191] Ryan Faas, Why Your Doctor Doesn't Want You Using iPhone and iPad Health Apps, Cult of Mac (June 20, 2012, 7:43 AM), http:// www.cultofmac.com/174776/why-your-doctor-doesnt-want-you-using-iphone-and-ipad-health-apps/, archived at http://perma.cc/9YMU-MGUU.
[192] *Id.*

autonomy privacy rights, and data privacy in using digital apps; it is also interpreted as U.S. Supreme Court Justice Louis Brandies defined privacy as the "most comprehensive of rights and the right most valued by civilized men."[193] With an increasing emphasis on safeguarding privacy in digital apps, more comprehensive regulations are being developed to address privacy protection measures.

Current regulations need to be revised to protect the privacy of consumers' health information. Whether a legally protected privacy interest exists requires examination of the "basic nature of the privacy interest at a general level."[194] The decision to protect, depending on whether a legally recognized privacy interest exists in a case, is a legal and political question.[195] Legally protected privacy rights have two categories: information privacy and autonomous privacy.

4.1.1 Information Privacy Right

Information privacy is the "principal focus" or "core value" of the constitutional right to privacy.[196] Information privacy rights protect against unauthorized dissemination or misuse of sensitive and confidential information.[197] Information is deemed sensitive and confidential "when well-established social norms recognize the need to maximize individual control over its dissemination and use to prevent unjustified embarrassment or indignity.[198]

In dealing with medical Information and records, informational privacy rights extend to medical records, although the right is not absolute because the information privacy right requires

[193] Nonunionized Workers' Employment Rights and Opportunities – Michigan Labor Law: What Every Citizen Should Know – Mackinac Center. https://www.mackinac.org/2315
[194] Mathews v. Becerra, supra, 8 C5th at 770, 257 CR3d at 13-14
[195] [All of Us or None - Riverside Chapter v. Hamrick (2021) 64 CA5th 751, 798, 279 CR3d 422, 455]

[196] Sheehan v. San Francisco 49ers, Ltd. (2009) 45 C4th 992, 999-1000, 89 CR3d 594, 601; Grafilo v. Wolfsohn (2019) 33 CA5th 1024, 1033-1034, 245 CR3d 564, 571
[197] [Hill v. National Collegiate Athletic Ass'n (1994) 7 C4th 1, 35, 26 CR2d 834, 856
[198] Pioneer Electronics (USA), Inc. v. Sup.Ct. (Olmstead), supra, 40 C4th at 370, 53 CR3d at 520

the doctoral duty of confidentiality to her patients and to observe its file.[199] Privacy interests also protect the physician's files, including symptoms, family history, diagnoses, test results, and other intimate details.[200] However, it is important to note that this privacy interest is considered less substantial compared to the privacy concerns associated with medical records." [201] When evaluating a trial court's ruling on a pharmaceutical company's request to access dispensed medication data and individual patient records for substance abuse treatment, prescription records are protected. Individuals possess legally recognized privacy interests and maintain reasonable expectations of confidentiality in their prescription information.[202]

4.1.2 Autonomy Privacy Right

The individual also has a legally protectable interest in making certain intimate personal decisions or conducting personal activities without undue observation, intrusion, or interference.[203] Whether a reasonable expectation of privacy exists depends on particular circumstances, including the customs, practices, and physical settings surrounding particular activities.[204] The expectation of privacy must be "objectively reasonable."[205] The expectation of privacy may be diminished if they are given advance notice of a potential intrusion and voluntarily give consent.[206] The agreement to abide by company policies diminishes employees' reasonable expectation of privacy in files on work on computers.

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[199] Grafilo v. Wolfsohn, supra, 33 CA5th at 1034, 245 CR3d at 571-572
[200] Love v. State Dept. of Ed. (2018) 29 CA5th 980, 993-994, 240 CR3d 861, 871
[201] County of Los Angeles v. Sup.Ct. (Johnson & Johnson) (2021) 65 CA5th 621, 641-642, 280 CR3d 85, 103-104]
[202] Id.
[203] [Hill v. National Collegiate Athletic Ass'n, supra, 7 C4th at 35, 26 CR2d at 856; see also Pioneer Electronics (USA), Inc. v. Sup.Ct. (Olmstead), supra, 40 C4th at 370, 53 CR3d at 520; California Advocates for Nursing Home Reform v. Smith (2019) 38 CA5th 838, 861-862, 251 CR3d 636, 653-654]
[204] Hill v. National Collegiate Athletic Ass'n (1994) 7 C4th 1, 36-37, 26 CR2d 834, 857; Lewis v. Sup.Ct.
[205] [Hernandez v. Hillsides, Inc. (2009) 47 C4th 272, 287, 97 CR3d 274, 286; Sheehan v. San Francisco 49ers, Ltd. (2009) 45 C4th 992, 1000, 89 CR3d 594, 601; Hill v. National Collegiate Athletic Ass'n, supra, 7 C4th at 37, 26 CR2d at 857
[206] Hernandez v. Hillsides, Inc., supra, 47 C4th at 294, 97 CR3d at 291, fn. 8; Hill v. National Collegiate Athletic Ass'n, supra, 7 C4th at 42, 26 CR2d at 860-861

4.2 Data Privacy in Using Digital Devices

Consumer reliance on digital platforms, such as smart phone apps, is increasing. Apps for health and wellness plans collect data such search history, purchase history, personal health information, favorite food, and habitual meal plans.

Many countries recognize the need for some form of privacy law for data privacy. Data privacy refers to the appropriate use of information through law or regulation. Generally, under most laws, "personally identifiable information" is defined as an individual's information that, when combined with data from other sources, can be used to identify that person. Personally identifiable information can be sensitive and non-sensitive.

Many countries protect certain types of personal information through privacy laws. Personal data is protected and classified based on its type. The type of classification in protection is categorized as international, state, or industrial. The European Union's General Data Protection Regulation (GDPR) imposes an obligation to protect personal data internationally. According to the GDPR, personal data is any information that relates to an individual who can be identified directly or indirectly. Location, ethnicity, gender, biometric data, religious beliefs, web cookies, and political opinions can also be personal data. Pseudonymous data also fall under the definition[207] that they are easily recognizable as ID.[208]

In the US, state laws such as the California Privacy Rights Act (CPRA), Virginia Consumer Data Privacy Act (VCDPA), and Utah Consumer Privacy Act (UCPA) uphold the rights of data subjects, including satisfying data subject access requests by retrieving a set of documents with data about a given individual. The Health Insurance Portability and

[207] Number of Users/Customers Affected | Novata. https://www.novata.com/metric/number-of-users-customers-affected/

[208] GDPR, What is GDPR, the EU's new data protection law? https://gdpr.eu/what-is-gdpr/?cn-reloaded=1 (Last visited November 12, 2023)

Accountability Act of 1996 (HIPAA) establishes protections for protected health information.[209] In particular, stakeholders handling health data vary, including patients, doctors, lab service companies, pharmacies, insurance companies, public insurance, manufacturers, data analytics companies, regulators, legislators, and the public.

4.3 U.S. Federal Laws and Regulations

General health apps in FDA regulations, including allergy indicators and wellness maintenance, are not devices to cure, treat, mitigate, or diagnose a specific disease, disorder, patient state, or any identifiable health condition. For example, apps can track dietary patterns, track food consumption, give users reminders, provide warnings about allergens, recommend exercises, or suggest meal plans; these apps are "generally related to a healthy lifestyle and wellness." Because the FDA does not regulate these apps, the question arises whether any other federal and state laws apply. The Food and Drug Administration (FDA) has a key role in defining medical devices, including some digital health devices. - According to the FDA, the classification of medical devices or wellness devices is determined by risks when devices are used.[210]

According to the FDA definition, the FDA refers to "software functions" such as apps are described as device software functions if that software is operated as treating caring health

[209] Future-proofing sensitive data privacy and compliance, How contextual data classification gives organizations greater compliancy agility, https://explore.spirion.com/data-classification-privacy-google-2023/data-class-privacy-use-case-ebook?utm_source=google&utm_medium=cpc&utm_campaign=Non-Brand_Compliance_Data_Breach_Search&gad=1&gclid=Cj0KCQiAjMKqBhCgARIsAPDgWlzmVEZCw3blDjM1ATsDnNRMjok4MxxYmrutbsojpRECBcNEw47j_SgaAt06EALw_wcB, Spiron, 2023

[210] According to FDA classification of Medical Device, (1) Class I represents no risk, (2) Class II devices represent moderate risk and require 510(K) clearance from the FDA before they may be legally marketed, and (3) Most class III devices represent high risk devices and require Premarket Approval before they may be legally marketed.

[210] FDA, How to Determine if your product is a Medical Device, https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device (last visited November 23, 2023)

issue.[211] Device Software functions may encompass "Software as a Medical Device (SaMD)" and "Software in a Medical Device (SiMD)."[212] SaMD, which functions as a stand-alone medical device, does not need any hardware medical device because it functions as its own. For example, SaMD includes 1) an app that circulates appropriate insulin dosage based on a person's different dosage levels and 2) the software itself functions as medical equipment even though medical equipment is separately sold and used for patients. According to the FDA, SiMD refers to software that is required to be incorporated into a medical device for functioning in specially designed purposes.[213]

If the software meets the definition of a device and is deployed on a mobile platform, it may be referred to as a "DiHAs or wellness app."[214] However, the FDA has not yet regulated such software applications or devices.[215] Section 3060(a) of the 21st Century Cures Act (Cures Act) amended Section 520 of the Federal Food, Drug, and Cosmetic Act (FD &C Act) to remove certain software functions, including those intended to maintain or encourage a healthy lifestyle

[211] FDA, How to Determine if your product is a Medical Device, https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device (last visited November 23, 2023)
[212] Monica R. Montanez, What is the Difference Between SiMD and SaMD?, 2024, https://namsa.com/resources/blog/what-is-the-difference-between-simd-and-samd/#:~:text=There%20are%20two%20different%20types,of%20a%20hardware%20medical%20device.
[213] Id.
[214] FDA, Policy for Medical Software Functions and Mobile Medical Application: Guidance for Industry and Food and Drug Administration Staff, (2022), https://www.fda.gov/media/80958/download#:~:text=device%20may%20be%20deployed%20on,medical%20app.%E2%80%9D
[215] This guidance does not change or rescind any requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or any applicable regulations. This guidance also does not preclude FDA from consulting with the Consumer Product Safety Commission (CPSC) as to whether a general wellness product is a consumer product under CPSC's authority or a device. FDA may coordinate with other agencies and authorities, such as the CPSC, to determine jurisdiction over products. If a product is a device under section 201(h) of the FD&C Act, it is generally excluded from CPSC's authority over "consumer products" under the Consumer Product Safety Act (15 U.S.C. § 2052(a)(5)(ii)(H)). However, CPSC and FDA may both have jurisdiction over certain medical devices under other statutory authorities the CPSC administers.

that is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition, from the definition of "device" in section 201(h) of the FD & C Act. [216]

Users may question whether digital wellness applications that assist in reading allergy labels or identifying allergens adhere to the same regulations as the FDA's food labeling standards, given their provision of allergy-related information. The FDA listed 18 examples of digital software that treats and manages content related to medicine or wellness but that it does not regulate. Among the 18 listed digital software app categories, food allergy labeling software is categorized as a health wellness app.

According to the FDA's guidelines, digital food allergy apps do not enforce the FDA requirements under the Federal Food, Drug, and Cosmetic Act.[217] Software functions that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health, or wellness.[218] Software functions mean that software itself works as its own function. For example, 1) providing tools to promote or encourage healthy eating, exercise, weight loss, or other activities generally related to a healthy lifestyle or wellness; 2) providing meal planners and recipes; 3) tracking general daily activities or making exercise or posture suggestions; 4) tracking a normal baby's sleeping and feeding habits; 5) active monitoring and treading exercise activity, 5) helping healthy people track the quantity and quality of their normal sleep patterns; 6) providing and tracking scores from mini-challenging games or generic "brain age" tests; 7) providing daily motivational tips (e.g., via text or other types of a message) to reduce stress and promoting a positive mental

[216] FDA, Guidance Document, General Wellness: Policy for Low Risk Devices General Wellness: Policy for Low Risk Devices | FDA (2019)
[217] FDA Guideline Document, Policy for Device Software Functions and Mobile Medical Applications FDA-2011-D-0530, (2022)
[218] See Supra Note 196.

outlook; 8) using social gaming to encourage healthy lifestyle habits, and 9) calculating the calories burned during the workout.[219] These guidelines list examples of digital wellness applications. When examining the definitions to determine which regulation applies to wellness apps that identify allergens or serve as tools for users to categorize allergens, particularly when these apps list food allergens in the same manner as food labels, the functionality of such wellness apps is considered to fall under the category of software function.

4.3.2. Health Insurance Portability and Accountability Act (HIPAA)

A. The History and Privacy Protection under HIPAA

Because digital devices show health data, including personal health information, this chapter reviews whether HIPAA-covered emerging technologies protect genealogical databases and new data privacy risks. The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that "requires the creation of national standards to protect sensitive patient health information."[220] It regulates unauthorized disclosure without patient consent or knowledge.[221] HIPAA was passed on August 21, 1996, with the dual goals of enabling health care delivery to be more efficient and regulating information exchanges within health insurance coverage. HIPAA has three main purposes: (1) portability, (2) tax, and (3) administrative simplification. In using electronic health information, Congress recognized that advanced health technology can endanger information privacy. Regarding privacy matters, HIPAA regulations have three parts: (1) the HIPAA Privacy Rule (use and disclosure of PHI), (2) the HIPAA Security Rule

[219] FDA Guideline for Device Software Functions, Supra Note 219.
[220] What is HIPAA - Craw Security. https://www.crawsecurity.com/web-stories/what-is-use-of-cisa-certification/
[221] Center for Disease Control and Prevention, Public Health Professionals Gateway, Health Insurance Portability and Accountability Act of 1996. https://www.cdc.gov/phlp/publications/topic/hipaa.html#:~:text=Health%20Insurance%20Portability%20and%20Accountability%20Act%20of%201996%20(HIPAA),-Print&text=The%20Health%20Insurance%20Portability%20and,the%20patient%27s%20consent%20or%20knowledge.

(safeguarding of PHI), and (3) the HIPAA Breach Notification Rule (Breach Notice).In enacting HIPAA, the U.S. Department of Health and Human Services (HHS) created system-mandated privacy protection under 45 C.F.R. §160.03.[222] Mandated privacy protection under HIPAA is "to define and limit the circumstances in which an individual's protected health information may be used or disclosed by the covered entity."[223]

The primary purpose of the HIPAA privacy rule is to safeguard the release of patients' "protected health information" ("PHI") used in transactions.[224] HIPAA breaks down information uses and disclosures into three areas – required, permitted without authorization, and requires authorization. To protect individuals, "covered health entities" like health plans, healthcare providers, healthcare clearinghouses, and third parties must follow certain rules when electronically exchanging PHI for certain purposes. Covered entities must also provide patients a notice of privacy practices that describes the ways that their PHI can be used or disclosed; patients must sign to acknowledge that they received this privacy notice and can give permission for other parties to receive their PHI.

B. HIPAA Stakeholders and Procedures

Covered entities are defined in the HIPAA rules as (1) health plans, (2) healthcare clearinghouses, and (3) healthcare providers who electronically transmit any health information in connection with transactions for which the HHS has adopted standards. Covered entities can be institutions, organizations, or persons.[225]

[222] 42 U.S.C. 1302, 65 FR 82798. Dec.28, 2000.
[223] Id.
[224] Different types of compliance by industry - MRI Software | HK. https://www.mrisoftware.com/hk/blog/different-types-of-compliance-by-industry/
[225] HIPAA: To Whom Does the Privacy Rule Apply and Whom Will It Affect? - Easy Cloud Solutions. https://easycloudsolutions.com/2018/04/24/hipaa-to-whom-does-the-privacy-rule-apply-and-whom-will-it-affect/

A health plan is an individual or group plan that provides or pays the cost of medical care, health, dental, vision, and insurance employee health plans.[226] A healthcare clearinghouse is a public or private entity that either processes or facilitates the processing of health information received from another entity (from nonstandard data elements into standard elements or vice versa).[227] A healthcare provider is any person or organization who furnishes, bills, or is paid for healthcare in the normal course of business, such as hospitals, pharmacies, and nursing homes.[228]

Healthcare refers to care, a service, or supply related to the health of an individual, including (1) preventive, diagnostic, therapeutic, rehabilitation, maintenance, or palliative care, and counseling services, assessment, or procedures concerning the physical or mental condition or functional status of an individual that affects the structure or function of the body, and (2) sale or dispensing of drugs, devices, equipment, or other items following a prescription.[229] A business associate conducts certain functions on behalf of a covered entity; they may be software or other product vendors or provide administrative services, data analysis, consulting services, or legal and financial services. [230] Under HIPAA, a covered entity-must disclose a written agreement made with business associates and allow the business associate to use, create, or receive PHI on its behalf in the form of general assurance. The contract may not authorize the business associate to use or further disclose the PHI in a manner that would violate the Privacy Rule if done directly by the covered entity.[231]

[226] Section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2),
[227] Id.
[228] section 1861(u) of the Act, 42 U.S.C. 1395x(U), a provider of medical or health services defined under section 1861(s) of the Act, 42 U.S.C. 1395x(s),
[229] Id.
[230] Id.
[231] HIPAA Rule 160.310, Responsibilities of Covered Entities and Business Associates (b) cooperate with complaint investigations and compliance review.

Protected Health Information (PHI) is any information in the medical record or record set that can be used to identify an individual and that was created, used, or disclosed while providing healthcare services such as diagnosis or treatment. HIPAA protects PHI only when the health information is used for treatment, payment, or operations. Regulations protect Individually Identifiable Health Information only.[232]

The HHS Protection of Human Subjects Regulations Title 45 CFR Part 46 protects only health information that is individually identifiable and is held by a covered entity.[233] FDAs protection does not define what is individually identifiable health information.[234] Although HHS has a broader definition of privation information that is not limited to health information, it still requires information to be personally identifiable i. Under the HHS Protection of Human Subject Regulations, private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) to obtain the information to constitute research involving human subjects, unless data are obtained through intervention or interaction with the individual.[235]

Table 9: Privacy Rule of HIPAA, HHS Protection, and FDA

Area of Protection of Health Information	**HIPAA Privacy Rule**	**HHS Protection of Human Subjects Regulations Title 45 CFR Part 46**	**FDA Protection of Human Subjects Regulations Title 21 CFR Parts 50 and 56**
Identifiable Information	Defines PHI as **individually identifiable** health information that is transmitted or maintained in any form or medium (electronic,	Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects. **Individually Identifiable** means the	Title 21 CFR Parts 50 and 56 do not define **individually**

[232] Id.
[233] HIPAA Privacy Rule and Its Impacts on Research. https://privacyruleandresearch.nih.gov/pr_07.asp
[234] FDA Protection of Human Subjects Regulations Title 21 CFR Parts 50 and 56
[235] Id.

	oral, or paper) by a **covered entity or its business associates**, excluding certain educational and employment records	identity of the subjects is or may readily be ascertained by the investigator or associated with information.	**identifiable** health information[236].

(**Source: US. Department of Health and Human Services, National Institute of Health[237], HIPPA Privacy Rule*)

4.3.3. U.S. FTC Act

The US Federal Trade Commission (FTC) Act prohibits companies from engaging in deceptive or unfair acts or practices in or affecting commerce.[238]. The FTC has prohibited more than 60 cases since 2002 against companies that have failed to adequately protect consumers' personal data.[239] However, Applying the FTC Privacy Act's provisions regarding the use, disclosure, and security of personally identifiable information (PII) to determine if DiHAs or wellness apps engaged in deceptive practices concerning private health data proved challenging. This difficulty arose because these apps' primary function is allergen detection, and they request users to voluntarily share health information or personal details when consulting with wellness professionals. Section 5 of the U.S. FTC Act prohibits unfair/deceptive practices in the marketplace. Under unfair practices, 15 USC 45(n)[240] defines unfair practices as when conduct violates public policy (statutes, common law, and practice) and when consumer injury is

[236] However, the FDA protects health devices under the definition of health medical devices under 21 CFR Part 807, Medical Device Listing. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation
[237] U.S. Department of Health and Human Services, National Institutes of Health, HIPAA Privacy Rule https://privacyruleandresearch.nih.gov/pr_07.asp (Last visited November 23, 2023)
[238] Sharing Consumer Health Information? | HHS.gov. https://public3.pagefreezer.com/content/HHS.gov/17-08-2021T06:42/https:/www.hhs.gov/hipaa/for-professionals/special-topics/hipaa-ftc-act/index.html
[239] See Privacy & Data Security Update: 2017, FEDERAL TRADE COMMISSION, at I.
[240] See Federal Trade Commission, A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority, A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority | Federal Trade Commission (ftc.gov) (last visited November 21, 2023)

substantial, not outweighed by benefits to consumers or competition, and unavoidable by the consumer. From a consumer's perspective, "deception" refers to any representation, omission, or practice that is likely to mislead individuals who are acting reasonably, given the circumstances. This concept is evaluated based on how a typical consumer would interpret the situation when examined. The representation, omission, or practice[241] must be “material,” meaning that consumers are likely to have chosen differently but for deception. [242]However, consumer protection under the current FTC Act is limited.

4.4. HIPAA-FTC New Rules -Mobile Health Apps

The FTC released its Privacy and Data Security Update for 2023, which highlights the FTC’s work to protect consumer privacy and consumer data, such as in the development of artificial intelligence models and misuse of health data.[243] In February 2023, the FTC announced its first enforcement action under the HBNR against telehealth and prescription drug provider GoodRX Holdings.The FTC’s action was enforced against the violation of GoodRx and Premon by failing to notify users about the companies’ unauthorized disclosure of users’ personally identifiable health information.[244] .Further, on July 29, 2024, the FTC expanded consumer privacy protections to the users of online health platforms and health and wellness apps. Privacy concerns in using health apps increase, the FTC’s updated privacy and security laws will play a

[241] Roth, Lauren. "Deception Perception: The Marketing of Student Loans." 2022, https://core.ac.uk/download/541696488.pdf.
[242] James, Tisha. "The Real Sponsors of Social Media: How Internet Influencers Are Escaping FTC Disclosure Laws." 2017, https://core.ac.uk/download/231868747.pdf.
[243] FTC Releases 2023 Privacy and Data Security Update, The update details agency actions relate to AI, health privacy, and other key areas, (2023), https://www.ftc.gov/news-events/news/press-releases/2024/03/ftc-releases-2023-privacy-data-security-update
[244] FTC, FTC Proposes Amendments to Strengthen and Modernize the Health Breach Notification Rule, Proposed Changes would underscore the rule’s applicability to health apps and other evolving technologies (2023), https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-proposes-amendments-strengthen-modernize-health-breach-notification-rule.

more important role in privacy protection in conjunction with the Office of Civil Rights (OCR), the HHS Office of the National Coordinator for Health Information Technology (ONC), and the Food and Drug Administration (FDA), which have worked together to update regulations governing health information in apps. [245] The revised regulations include the FTC Act, the FTC's Health Breach Notification Rule, HIPAA, the FD &C Act, the Children's Online Privacy Protection Rule (COPPA), and the 21st Century Cures Act and ONC Information Blocking Regulations.[246] The cooperative guidance of FTC and HIPAA provides guidance for the manufacturer's health apps interactive tool, which treats app manufacturers as business associates under the HIPAA rules. According to section 318.2 (e) of the FTC's Rule, the FTC's Health Breach Notification Rule applies to most health apps that aren't covered by HIPAA because of most developers of health apps are acting as "health care providers" by furnishing health care services or supplies.[247] Historically,

The FTC's guidance list of mobile health apps also integrates with apps that help consumers track or monitor other health behaviors such as fitness or activity, diet, mood, sleep, menstruation and fertility, smoking and alcohol consumption[248], medications, devicesdefined as "medical devices" under the FDA.[249] This ensures that these apps protect our personal health information and personal information under HIPAA. The FTC's recent changes in considering all mobile health apps by expanding the interpretation of healthcare providers by clarifying the

[245] U.S. Department of Health and Human Services, Resources for Mobile Health Apps Developers, https://www.hhs.gov/hipaa/for-professionals/special-topics/health-apps/index.html (last visited November 23, 2023)
[246] *id*
[247] 42 U.S.C. §1320d
[248] Mobile Health Apps - which U.S. federal laws may apply? - MedSysCon Medizintechnik GmbH. https://www.medsyscon.com/en/blog-ftc/
[249] FTC lists digital health medical devices in four categories: (1) Apps that help consumers track or monitor fitness or activity or diet,)2) Apps that help consumers view, use, or share their medical records of health insurance claims data.(3) Apps that sync with health platforms or internet-connected deices, and (4) Apps that diagnose or treat a disease or health condition. Mobile Health Interactive Tool, https://www.ftc.gov/business-guidance/resources/mobile-health-apps-interactive-tool (Last visited November 23, 2023)

rule's applicability to direct-to-consumer health technologies, such as fitness trackers.[250] The Health Breach Notification Rule(HBNR) applies to vendors of PHRs and related entities that are not covered by HIPAA.[251] The FTC's 2024 breach notification rule demonstrated enhanced safeguards against unauthorized disclosure of health information and data breaches. This regulation provided increased protection for sensitive medical data.

The health apps providing allergen identification are regulated under the FTC Act. Section 5 of the FTC Act prohibits mobile apps from developing an app and sharing consumers' health information with third parties after telling or implying to consumers that their information will remain private.[252] Developers of these health apps are encouraged to certify them through voluntary ONC Health IT certification programs and to make certain transparency attestations regarding the app's privacy or security features. If they breach these promises, the FTC can bring enforcement actions against app developers.[253]

The FTC's Health Breach Notification Rule Section[254] § 318.1 applies to mobile health apps that are not categorized as HIPAA-covered entities or business associates[255]. Suppose a mobile health or wellness apps are breached and the party responsible discloses or transfers health information without authorization. In that case, the FTC mandates that app developers must 1) notify everyone whose information was breached, 2) notify the FTC, and 3), in some

[250] 16 CFR Part 318, Health Notification Rule
[251] FTC, Updated FTC Health Breach Notification Rule puts new provisions in place to protect users of health apps and devices, 2024, https://www.ftc.gov/business-guidance/blog/2024/04/updated-ftc-health-breach-notification-rule-puts-new-provisions-place-protect-users-health-apps#:~:text=HIPAA%20%E2%80%93%20HHS%27%20Health%20Insurance%20Portability,unsecured%20personally%20identifiable%20health%20data.
[252] Mobile Health Apps - which U.S. federal laws may apply? - MedSysCon Medizintechnik GmbH. https://www.medsyscon.com/en/blog-ftc/
[253] *Id.*
[254] Health Breach Notification Rule, CFR Title 16, Part 318. https://www.ecfr.gov/current/title-16/chapter-I/subchapter-C/part-318
[255] The definition of "health care provider" comes from 42 U.S.C §1320d, which is referenced in Section 318.2(e) of the FTC Rule.

cases, notify the media.[256] If mobile health app developers do not provide that notice, the FTC can seek to impose civil penalties against them.[257] The FTC's regulation of general mobile health applications is notable as it governs health information breaches, even for apps not subject to HIPAA. This regulatory approach extends protection without constraining the safeguarding of Protected Health Information (PHI), which falls under the purview of the HIPAA privacy protection rule.

In May 2023, the FTC-HIPAA considered the challenges of protecting health information.[258] Digital Apps were not regulated under HIPAA because HIPAA can't regulate health -related data if it is not treated by covered entity. The 2023 FTC-HIPAA Law calls for personal health records (PHRs) that third-party vendors directly manage and that are not controlled by the covered entity under HIPAA.[259] The FTC Health Breach Notification Rule (HBNR) requires vendors of PHRs to notify individuals.[260]

The American Recovery and Reinvestment Act of 2009[261] ("Recovery Act" or "The Act") defines and enforces the protection of the privacy and security of health information. As HIPAA does not protect health information used by non-covered entities,[262] HIPAA requirements do not prevent digital companies from collecting personal health information through their websites or apps because company vendors and software vendors are not

[256] See supra note 274
[257] FTC. Health Breach Notification Rule: The Basics for Business: "Companies that fail to comply with the Rule could be subject to penalties of up to $51,744 per violation." https://www.ftc.gov/business-guidance/resources/health-breach-notification-rule-basics-business (last visited December 9, 2024)
[258] NIH, Personal Health Record (2022), https://www.ncbi.nlm.nih.gov/books/NBK557757/
[259] FTC Press Relesae, FTC Finalizes Changes to the Health Breach Notification Rule
Final rule underscores its application to health apps and similar technologies not covered by HIPAA (2024), https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-finalizes-changes-health-breach-notification-rule (last visited May 23, 2024)
[260] Id.
[261] Am. Recovery and Reinvestment Act of 2009, Pub. L. 111-5, 123 Stat. 115 (2009).
[262] See Supra note 200.

categorized as covered entities.[263] Section 13407 of the Recovery Act created certain protections for "personal health records" or "PHRs."[264] Electronic records of identifiable health information from one individual that can be primarily managed, shared, and controlled by or primarily for that individual[265]. Personal health record (PHR) is the collection of an individual's medication documentation that they maintain; it may contain the patient's medical history, applicable diagnoses, historical and ongoing medications (including over-the-counter and alternative treatments), past medical and surgical interventions, immunization status, allergies and other relevant medical conditions that can impact the delivery of emergency care, blood type, contact in the event of an emergency, insurance information, and contact information for the patient's regular health providers.[266]

A PHR can be either physical or electronic. It forms all self-reported and self-recorded health data, including health issues and treatments; records of vital signs and activity recorded with personal devices, including smartphones and smartwatches;[267] and nutritional data, such as diet composition and calorie intake[268].

To protect PHR under the New rule[269], the FTC first revised the definition of personal health records (PHR) and then added two new definitions for "covered health care provider" and "health care services or supplies."[270] Second, it defined PHR-related entities, which are entities that offer products and services through online services, including mobile applications, involved PHR. The Rule the Commission issued in 2009 ("2009 rule") is significant in requiring

[263] See supra note 200.
[264] 42 U.S.C. 17937.
[265] 42 U.S.C. 17921(11).
[266] Id.
[267] Personal Health Record Article. https://www.statpearls.com/ArticleLibrary/viewarticle/27048
[268] NIH Personal Health Record (2022), https://www.ncbi.nlm.nih.gov/books/NBK557757/
[269] FTC Health Breach Notification Rule, 16 CFR Part 318 (2024)
[270] FTC Proposes Changes to the Health Breach Notification Rule | AAMC. https://www.aamc.org/advocacy-policy/washington-highlights/ftc-proposes-changes-health-breach-notification-rule

notifications when breaches of information occur. The 2009 rule requires vendors of personal health records and PHR-related entities to provide notice to consumers whose unsecured PHR has been breached, notice to the FTC, and (when 500 or more have been confirmed to be affected) notice to prominent media outlets.[271]However, the 2009 rule has not been evaluated as a complete breach notification because it applies only to "unsecured" health information, which defines health information that is not secured through technologies or methodologies specified by HHS.).[272]

As other direct-to-consumer health technologies, including wellness trackers and wearable fitness apps, become more common, the rule changed in May 2020 to reflect technological changes, such as the proliferation of apps and similar technologies.[273]

On September 15, 2021, the commission issued.[274] A policy statement clarifies that the rule covers most health apps and similar technologies that are not covered by HIPAA.[275] Personal health information is defined as the PHR, which requires an electronic record that can

[271] The Recovery Act does not limit this notice to particular types of media. Thus, an entity can satisfy the requirement to notify ''prominent media outlets'' by, for example, disseminating press releases to a number of media outlets, including internet media in appropriate circumstances, where most of the residents of the relevant State or jurisdiction get their news. This will be a fact-specific inquiry that will depend on what media outlets are "prominent" in the relevant jurisdiction. 74 FR 42974.

[272] Per HHS guidance, electronic health information is "secured" if it has been encrypted according to certain specifications set forth by HHS, or if the media on which electronic health information has been stored or recorded is destroyed according to HHS specifications. See 74 FR 19006; see also U.S. Dep't of Health & Human Servs., Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals (July 26, 2013), https://www.hhs.gov/hipaa/for-professionals/breach-notification/guidance/index.html. PHR identifiable health information would be considered "secured" if such information is disclosed by, for example, a vendor of personal health records, to a PHR related entity or a third party service provider, in an encrypted format meeting HHS specifications, and the PHR related entity or third party service provider stores the data in an encrypted format that meets HHS specifications and also stores the encryption and/or decryption tools on a device or at a location separate from the data.

[273] Comments are available at https://www.regulations.gov/docket/FTC-2020-0045/comments.

[274] Health Breach Notification Rule: The Basics for Business | Federal Trade Commission. https://www.ftc.gov/business-guidance/resources/health-breach-notification-rule-basics-business

[275] Statement of the Commission on Breaches by Health Apps and Other Connected Devices, Fed. Trade Comm'n (Sept. 15, 2021), https://www.ftc.gov/system/files/documents/public_statements/1596364/statement_of_the_commission_on_breaches_by_health_apps_and_other_connected_devices.pdf ("Policy Statement").

be drawn from multiple sources.[276] The major rule changes applied to digital wellness devices are definition and entity changes in the revised definition of PHR-related entity, multiple sources, electronic notification, expanding consumer notice content, and time requirement; 1) revised definition of PHR-related entity revised to "The entity covers products and services offered through online services, including mobile applications, of vendors of personal health records. This Personal health information is cleared, and public health records are not secured."; 2) the section on "Multiple Sources" is revised to "personal health information covered, taken from multiple sources; 3) the section of "expanding consumer notice content" is revised to that " the notice must list the name of identity (or where providing the full name or identity would pose a risk to individuals or the entity providing notice, a description) of any time requirement; and 4) the provision of "time requirements" is added requiring that "for breaches involving 500 or more individuals, a covered entity must notify the FTC while sending notices to affected individuals, and this must occur without unreasonable delay, in no case later than 60 calendar days." [277]

As FTC-HIPAA expands the definition of a non-entity under HIPAA and the scope of protection for unsecured health information, digital health and wellness app developers are expected to follow the rules when they collect, save, and send health data when breached.

4.5. State Regulatory Frameworks

A. New York

Some states have initiated regulation and case law of digital devices that escape regulation under federal law. In March 2017, New York Attorney General Eric Schneiderman announced

[276] The Policy Statement provided this example: "[I]f a blood sugar monitoring app draws health information only from one source (e.g., a consumer's inputted blood sugar levels), but also takes non-health information from another source (e.g., dates from your phone's calendar), it is covered under the Rule." Id. at 2.

[277] FTC Health Breach Notification Rule, Supra note 277

settlements with three health apps sold in Apple's App Store and Google's Play Store.[278] These apps use users' accurately measured heart rates and guide their lifestyle and exercise, representing some risk under FDA Class 2. Moreover, Cardiio Inc. Placed Cardio-Heart Rate in the "Health & Fitness" category in Apple's App Store but claims that "the Cardio app turns your iPhone or iPad into a heart rate monitor" and "Cardiio's technology is based on cutting-edge research and science conducted at the MIT Media Lab. The measurement principles are the same as clinical pulse oximeters." [279]The New York Attorney General found that the app's privacy policy also stated that collected information may be disclosed to affiliates, agents, and business partners.

New York law extends privacy protection laws to digital health apps despite the absence of a comprehensive federal regulation structure. According to New York Executive Law § 63(12), the New York State Executive Law prohibits "illegal or fraudulent acts" in conduct of any business, trade or commerce, and allows the Office of Attorney General (OAG) to institute a special proceeding for restitution, damages, and/or injunctive relief against any party which as committed such acts.[280] This case also applies the New York General Business Law that prohibits "deceptive acts of practices in the conduct of any business, trade or commerce of in the furnishing of any service" in New York State.[281] In New York, failing to disclose privacy protection elements in app marketing is considered deceptive and classified as "illegal or fraudulent acts." Non-medical apps that claim to function as medical devices and share personal data with third parties without proper authorization are in violation of these regulations.

[278] The case of the Attorney General of the State of New York, In the Matter of Cardio, Inc. Assurance No.: 16-173. https://ag.ny.gov/sites/default/files/cardiio_aod_executed.pdf
[279] Id.
[280] Supra note 178. Selection 28 referred N.Y. Exec. Law § 63(12).
[281] N.Y. Ge. Bus. Law §349 and 350.

B. California

California's innovative action to protect privacy rights was enforced by the California Civil Code § 1798.91.04, a cybersecurity bill governing IoT devices in California.[282]

> (b) "Connected Device" means any device or other physical object that is capable of connecting to the Internet, directly or indirectly, and is assigned an Internet Protocol address or Bluetooth address.
> (d) "Security Features" is a feature of a device designed to provide security to that device.

The bill became effective on January 1, 2020.[283] This law mandates that any manufacturer or developer of a "smart" device, including connected health devices, ensure that their products are equipped with reasonable security features to protect against unauthorized access, destruction, use, modification, or disclosure of data that the device may collect to transmit.[284] This law, known as the California Internet of Things Cybersecurity Improvement Act of 2017 (California IoT Law), applies to any object with built-in connectivity, including smart appliances fill the gap the federal government regulations.[285]

Previously, many other states adopted the U.S. Department of Commerce's National Institute of Standards and Technology Cybersecurity Framework, developed in 2014.[286] The NIST Cybersecurity Framework has general cybersecurity principles that are applied to IoT devices. California's state legislation establishes a definition for IoT devices, which may encompass health-related technologies, as a means to bridge the regulatory gap left by the federal government. This law seeks to address potential risks associated with app creators and device

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[282] California Civil Code § 1798.91.04 (2018), Information Privacy: Connected Devices https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201720180SB327 (Date Published September 28, 2018). It's essentially a law that requires manufacturers selling devices in CA to equip their products with reasonable security features to protect against unauthorized access, destruction, use, modification, or disclosure of data the device may collect or transmit.
[283] County of Los Angeles v. Sup.Ct. (Johnson & Johnson) (2021) 65 CA5th 621, 641-642, 280 CR3d 85, 103-104]
[284] Id.
[285] Id.
[286] NIST Framework for Improving Critical Infrastructure Cybersecurity, https://nvlpubs.nist.gov/nistpubs/CSWP/NIST.CSWP.04162018.pdf (2018)

manufacturers who gather sensitive information without being subject to a comprehensive regulatory framework.[287]

4.6. EU

In the U.S., developers of digital allergen apps may be able to use health data without being monitored by healthcare professionals but by regulatory agencies. The EU prioritized policies to support the digital transformation of health care.[288] Under the EU system, the new General Data Protection Regulation (GDPR) regulates companies marketing digital technologies using health data.[289] Even if mobile health apps detect food allergens as well as provide meal plans or wellness guidance, this information can be defined as health data under the GDPR.

Article 3(1) applies GDPR to medical health apps that process personal data through a controller or possessor in the EU.[290] Under Article 3(2), the GDPR applies when goods or services are being offered to data subjects in the EU.[291] Or it applies if behavior monitoring takes place in the EU.[292]

4.6.1. GDPR's Protection of Personal Data in Using Digital Apps

Digital health and wellness apps ask consumers to enter a large amount of personal data and implicate consumer privacy protections.[293] In the EU, GDPR defines controllers and processors who have obligations to protect personal data. The controller determines the purpose

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[287] See supra note 243.
[288] See for example the rapport on enabling the digital transformation of health and care in the Digital Single Market;
empowering citizens and building a healthier society, Brussels COM(2018) 233 final.
[289] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), Article 5 paragraph 1 Sub a. The GDPR goes into effect May 2018.
[290] Mulder, Trix. "The Role of Law in Protecting Personal Data Generated by Health Apps and Wearables." 2022, https://doi.org/10.33612/diss.207391472.
[291] Carr, Indira, et al. "Ethical Design. At the Interface of Ethics for Big Data and the European Union'S General Data Protection Regulation : Deliverable D13.2." 2018, https://core.ac.uk/download/pdf/162144311.pdf.
[292] Article 3 GDPR
[293] Recital 2 GDPR

and means of the personal data.[294] In other words, the data controller who can be " the natural or legal person, public authority, agency or other body, which, alone or jointly with others" decides the how and why of a data processing operation.[295] The processor processes the personal data on behalf of the controller.[296]

According to Article 5 of the GDPR, personal data should be lawfully, fairly, and transparently processed.[297] Personal data should be collected for specified, explicit, and legitimate purposes and should not be processed further in an incompatible manner, which allows for archiving purposes in the public interest, scientific or historical research purposes, or statistical purposes.[298] Thus, digital apps used in consumer markets must list valid reasons for consent, contracts, legal obligations, vital interests, public tasks, and legitimate interests.[299] To determine whether digital health apps had legitimate interests in using health data, a three-part test is used to review their purpose, necessity, and balance. According to Recital 49 of the GDPR, processing personal data for the main network security can constitute a legitimate interest.[300]

According to GDPR, any individual whose personal data is "being collected, processed, or stored by an organization" which called a "data subject." [301] GDPR Articles 6, 7, and 9 (2)(a) are related to any data subject's consent on how data is used through information like their name,

[294] Article 4(7) GDPR
[295] Id.
[296] Article 4(8) GDPR
[297] Terms of Service / Privacy Policy | TEKA. https://teka.gov.gr/en/terms-service-privacy-policy
[298] Ntinapogias, Athanasios, and George Nikolaidis. "The Right of Children to Be Heard in Participatory Research on Violence." Emerald Publishing Limited EBooks, 2023, https://doi.org/10.1108/978-1-80455-526-220231004.
[299] Article 6 GDPR
[300] Ntinapogias, Athanasios, and George Nikolaidis. "The Right of Children to Be Heard in Participatory Research on Violence." Emerald Publishing Limited EBooks, 2023, https://doi.org/10.1108/978-1-80455-526-220231004.
[301] GDPR Article 4

address, email or other identifying details, giving them rights under GDPR. [302] Article 13 provides an overview of the information that the controller must provide to the data subject. Article 12 regulates that this information needs to be provided "in a concise, transparent, intelligible and easily accessible form, using clear and plain language."[303] In the processing of health data within the medical context, the data subject's consent is not needed because the exception of Article 9(2)(h), in conjunction with (3), applies.[304].

Consent must be freely given, specific, informed, and unambiguous.[305] Consent may not be deemed voluntary when the execution of a contract or the delivery of a service is contingent upon agreeing to data processing for purposes unrelated to the contract's fulfillment or service provision. Such practices potentially undermine the concept of freely given consent in these contexts.

4.7. Summary

U.S. regulations such as HIPAA and FDA narrowly protect the limits of individually identifiable health information. The next chapter reviews whether digital health apps collect and save individually identifiable health information that could be covered under HIPAA or FDA regulations. It is necessary to determine whether current digital health apps follow these regulations voluntarily when collecting and using health data.

Digital health apps marketed in the U.S. are also likely to be used in the EU. The GDPR regulates all EU digital health apps. It is also necessary to determine whether these apps follow

[302] Mulder, Trix. "The Role of Law in Protecting Personal Data Generated by Health Apps and Wearables." 2022, https://doi.org/10.33612/diss.207391472.
[303] Id.
[304] Id.
[305] Essential GDPR Information (& How it Affects Content Marketing) – HQ Content writer. https://hqcontentwriter.com/2018/03/14/essential-gdpr-information-you-need-to-know-about/

EU regulations for legitimate purposes and freely give specific, informed, and unambiguous consent to users.

CHAPTER 5

DIGITAL HEALTH APPS INFORMING FOOD ALLERGY LABELING

5.1. Introduction

This study reviewed Android and iOS applications that offer food allergy labeling descriptions. There are many brands of devices, but each operates in a slightly different manner. Android is an open-source software or mobile platform for mobile devices that operates as a Google project. This open-source software ensures that no other party can restrict or control the innovations of any other party.[306]

On both platforms, consumers can download apps that allow them to avoid allergens, track dietary habits, and provide meal plan suggestions. These apps are called diet programs, fitness, or wellness support. Most health and wellness apps are "technically" reliable, and they suggest which allergens are present in certain menus. Nutritional information is made accessible through DiHAs or wellness apps, which display data from pre-packaged food labels or offer lists of potential allergens based on chef recommendations, recipe suggestions, or the app's own guidance to minimize allergy risks during meal planning or grocery shopping. To receive accurate feedback on food reactions or manage dietary habits, many of these applications require users to input personal information.

In response to consumers' desire for healthier eating habits and allergen-free food choices, many developers of DiHAs and wellness apps have incorporated features that address these concerns. These applications now offer functionalities that enable users to identify allergens in pre-packaged foods through comprehensive allergen lists or by scanning food labels. This approach aims to assist consumers in making informed decisions about their diet plans, grocery purchases, and meal preparations while avoiding potential allergenic ingredients. To

[306] Open Source Project, htttp://source.android.com

select the digital apps to be analyzed, I used key terms including “food allergens,” “food allergies,” “food scanners,” “healthy labeling,” “food labeling,” “meal planning,” and “allergy.” With a keyword search, I could narrow the list of relevant apps to 15 apps consistent with my research questions that showed allergy labeling regardless of whether the food was prepacked or obtained food from a restaurant.

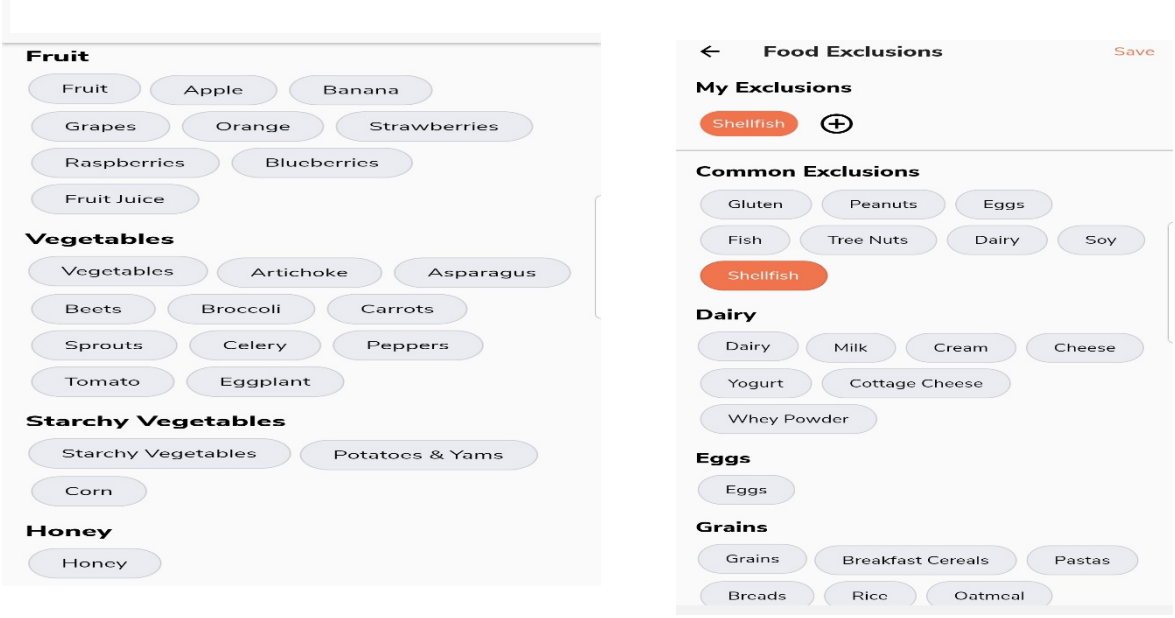
This research summarizes current apps using iOS and Android technology that detect food allergens as a supplement to ingredient labels on pre-packaged food. I reviewed each app with 1) a general description of features and allergen detection, 2) the app’s compliance with mandatory food allergy labeling regulations, 3) the app’s compliance with voluntary allergy labeling regulations, and 4) the app’s personal information protection.

5.2. Digital Health Apps Informing Food Allergy Labeling

5.2.1 Eat This Much

“Eat This Much” is described as a meal planner and operates in Android and iOS. To use this personal meal planner app, users are required to provide personal information such as height, weight, biological sex, age, and body fat to use the program. Then, the user must select either a general goal of losing fat, maintaining weight, or building muscle, or select an exact weight and weight change rate goal. All requested information is mandatory. The user must choose their main diet type. The app then asks about the user’s allergy concerns, including gluten, peanuts, eggs, fish, tree nuts, dairy, soy, and shellfish. Users must choose which food types should be excluded when the app suggests a meal plan. The app then shows the daily nutrition target.

Figure 8: Screenshots of available choices to set up exclusion from meal plans



As shown in the app, users can individually select allergens to remove them from the suggested meal plan. The app suggests meals for breakfast, lunch, and dinner, and the user can review each ingredient in each menu. Nutritional information, encompassing calories, carbohydrates, fats, and proteins, is available for all food products and ingredients. Individuals can receive tailored food suggestions by customizing their preferences, which may include selecting specific meal plans, opting for branded items, or exploring restaurant offerings.

A. Mandatory Food Allergy Labeling Regulations

This app detects eight food allergens to exclude based on personal preferences. The suggested allergens do not list sesame, which has been mandatory under U.S. regulations since 2023. This meal plan containing eight detected allergens is useful when consumers want to choose any branded food because it detects and lists allergens on the prepackaged food label. However, different information is available for restaurant food, which is described mostly in terms of nutrient information such as calories, carbs, fat, protein, fiber, net carbs, sodium,

potassium, cholesterol, or sugar or vitamin information. “The "Eat This Much" system does not identify potential allergens in unwrapped foods that may be present due to packaging or cross-contamination. Additionally, by omitting the cautionary section of allergen labeling, the system does not alert users to the possible presence of allergens in their meal selections.

B. Precautionary Allergy Labeling Regulations

Under US FALCPA, food manufacturers report the possibility that their products contain allergens. FALCPA does not regulate voluntary supplemental statements, such as “may contain,” “manufactured in a shared facility,” and ‘processed on the same equipment. [307] “Eat This Much” is inconsistent with the US FDA mandatory or voluntary labeling list. The app detects allergens if the pre-packaged food lists allergens with a “contain” statement. According to the EU, a voluntary statement is used to warn about possible and unintentional presence.[308] However, the app does not detect any voluntary statements. Instead, “Eat This Much” uses the consumer’s chosen allergens to sort the suggested food list to identify food containing those allergens.

For PAL, the WHO suggests the use of reference doses (RfD) to avoid unusual allergic reactions in very sensitive people. “Eat This Much” is designed for weight control, so each food item on the app provides information on quantity (RfD). However, this app is not intended to protect consumers from avoiding allergic reactions to risky foods when suggesting food items. Since consumers can select which allergens to avoid, the WHO’s RfD does not need to be listed in this digital app. Thus, this app for allergy prevention and voluntary allergy labeling is not used to provide ingredient information in food items. The list of allergens does not prevent consumer risks if the manufacturer does not describe the main allergens in the mandatory food allergy

[307] See supra note 114.
[308] See supra note 115.

labeling section. Moreover, this app does not protect from allergens unexpectedly present through cross-contact.

C Personal Information Sharing

A shared password is protected, and login is needed to access the web.

To receive the meal plan, app users need to provide personal information, such as basic body information, weight, and height, with weight control goals divided into three sections: lose fat, maintain weight, and build muscle, and primary food type, food exclusions, and nutrition targets. Users must provide personal information to access suggested meal plans. This app does not ask for other health information or users' communicating with health providers. This app merely allows consumers to get recommendations for suggested food. As users must provide their choice of food and favorite diet style, sharing this information could raise concerns about sharing this data with third parties.

5.2.2 AllergyEats

AllergyEats "app is free and can be used for restaurants nationwide allows users to use the search function "find near me" to find restaurants with information on allergy-friendly rankings. This app can be used throughout the U.S..

Users can find restaurants with allergen information by either typing the name of the restaurants or entering a zip code. If the user has concerns about specific allergens, the user can choose one or more of the listed allergens: peanuts, eggs, fish, soy, tree nuts, wheat, shellfish, dairy, gluten, and sesame.

When the app finds the restaurants where individual allergic condition meets, the app user can click the interactive allergy menu from each restaurant. The app's recommended menu is connected to the restaurant's website. From the restaurant website, the consumer can find and

order from the allergy-friendly menu. The registered restaurant mostly asks whether the customers have any allergies. In reviews of the app, customers have described their order experiences to share how to order their food without avoiding allergic reactions.

The "AllergyEats" enables consumers to order food in ways similar to other apps. However, as this app shows restaurants that voluntarily participate in an allergy-free program by actively describing all allergen ingredients, consumers may find that their favorite restaurants are not listed.

A. Mandatory Food Allergy Labeling Regulations

Restaurants included in the AllergyEats app list all the allergens contained in their food. AllergyEats screens for 10 allergens: peanuts, eggs, fish, soy, tree nuts, wheat, shellfish, dairy, gluten, and sesame. In addition to screening the selected restaurant, the app users can call a restaurant or review the menu directly to check whether their choice of food contains allergens.

B. PAL Regulations

This app allows users to order food; before the user orders food, they can discuss their food allergy concerns with one of the suggested experts to help them avoid allergens. The restaurant menu shows and alerts users to any allergens that the ordered food may contain. In the reviews, these restaurants also employ managers or serving personnel who first ask users about their food allergy concerns. In addition to screening for the main 10 allergens, customers can ask for specific allergens to be removed or left out when they order food. For example, if the user chooses to order a burger from the menu that discloses where tree nuts, dairy, wheat, shellfish, gluten, cacao, cocoa, chocolate, corn, or pork are present, the restaurant will give customers a choice whether they order calamari fries if they are worried about the same fryer being used for

other food. Restaurant managers and chefs understand the meaning of cross-contact with allergens and can explain all possibilities to customers.

Many customers using this app have very specific concerns about allergic reactions, not just avoiding the main allergen contained in the food. Consumers left comments saying that they have specific allergic reactions that were not described in the allergic reaction risks. For example, some people experience allergic reactions because of cross-contamination with allergens like sesame, shellfish, and peanut (and a few other uncommon allergies). Customers can order their own menu choice by describing individual concerns about cross-contact with any other risk ingredients.

C. Personal Information Sharing

The app "AllergyEats" provides different levels of personal information. If customers do not want to provide personal information, they can choose the login option and still get the same features in allergy-free restaurants. If the app users want to save their personal information, they can log in by creating their own account. AllergyEats does not require any personal information to be reviewed under privacy laws and regulations.

5.2.3. Meal Plans & Recipes

The app, "Mealtime Meal Plans & Recipes," is in Android and iOS and is available in English. Mealtime's developers describe their app as providing healthy recipes, meal plans, and an auto grocery list with all ingredients. As of December 2023, more than 1 million users had downloaded this app. When the user selects their own diet style, Mealtime asks the user to choose any allergens to be avoided in the meal plan; it tracks 12 allergens, including shellfish, fish, gluten, dairy, peanut, tree nut, soy, egg, sesame, mustard, sulfite, and nightshade. If the user

chooses any allergens, the next screen asks users which foods they dislike food. Then, the user needs to choose how many servings per meal. The app also gives a reminder at any set date or day.

App users can see all suggested meals with the food pictures, cookware, ingredients, and instructions. Meal plans can be used in two ways: 1) app users use Mealtime to learn how to cook the meal; and 2) the app has a more interactive system users can use to contact a chef to ask about more detailed ingredients and arrange for the delivery of the ingredients.

A. Mandatory and PAL Food Allergy Labeling Regulations

Mealtime recognized 12 allergies: shellfish, fish, gluten, dairy, peanut, tree nut, soy, egg, sesame, mustard sulfite, and nightshade. Mealtime requires users to set up allergens from the food list to avoid. As this app supports users in following their guided meal plan, PAL regulation is not directly applicable to this app. If app users are concerned about cross-contamination, they can choose all potential risky allergens when setting their personal information.

The app provides information about chefs, including their cooking style and suggested meal ingredients. However, users cannot ask the chef whether specific ingredients can be removed from a suggested meal plan or replaced with other alternative ingredients. “Mealtime” members can use the chefs' recommended meal plan but are not allowed to communicate individual allergens.

B. Personal Information Sharing

Mealtime described data safety, data-sharing, collecting crash logs, and diagnostics in the data policy. The data collected comprises location, message, app information, and performance,

including individual's allergen information and meal plan, app activity, photos and videos, and personal information. The collected personal information in Mealtime includes email addresses, User IDs, and other information. Security practices state that data is encrypted in transit and describe a process for users to request that their data be deleted. Users can provide personal email addresses to set up more personal plans and receive reminders. If the app users want a general meal plan, they do not have to set up their personal information with providing their personal email address. Mealtime users can share their personal meal plans with others in public or the Facebook community. If they share their personal meal plan, they can also receive public comments on the public sharing website.

5.2.4. SideChef

SideChef is described as a meal planning app.[309] The available language is English. Users are required to set up a personal profile with allergies, intolerance, food preferences, and cooking goals. The app itself is not focused on allergy labeling or allergic information. However, in the meal choice and cooking guidelines, users can choose not to include any allergens from the suggested cooking, meal menu, or grocery shopping items. The app suggests meal plans, provides step-by-step cooking instructions, and enables the user to choose online grocery shopping.

A. Mandatory and PAL Food Allergy Labeling Regulations

This app detects 8 food allergens, including gluten, milk, crustaceans, fish, peanuts, nuts, soya, and eggs. However, it does not include allergen or labeling for individual ingredients in the meals it suggests; it only provides that information for the meal itself. For example, when the

[309] The number of viewers and downloading apps is based on the data on December 19, 2023.

user chooses French toast in a Mug, the app guides the user to choose bread with suggested ingredients, cooking time, and price per serving; the app suggests that users purchase pure vanilla extract and Pepperidge Farm raisin cinnamon swirl breakfast bread at Walmart but does not describe the ingredients of those.

The app SideChef allows users to customize their meal plans by selecting preferred ingredients and excluding specific allergens or adding items to their shopping list. By default, users can eliminate allergens from the recommended meal plans during the initial setup process. But app users do not have the opportunity to see any potentially contained allergens if they choose items for shopping. SideChef users can choose to add the meal plan, which guides step-by-step cooking. App users can cook by themselves without adding any ingredients they might be concerned about avoiding in cooking.

B. Personal Information Sharing

In the account creation settings and general privacy information section, SideChef provides details about its overall privacy protection measures. App users have two options for setting up their personal information. First, users can download the app only on their phones to receive recommended meals without providing any personal information or selecting allergens or intolerances. Second, if users choose to design a personal meal plan, they must provide a personal email address, diet preference, and allergen information. The privacy protection for this application aligns with the standard app privacy policy found on Android and iOS platforms. The guidelines for data usage, privacy safeguards, and information sharing with external parties are consistent with the Android or iOS privacy and data policies. This includes regulations on data collection types, encryption methods, and users' rights to request data deletion. Data collected for this app is listed as app information and performance, devices or other IDs, app activities,

photos and videos, and personal information. Considering privacy protection. the risk of sharing personal information is low. As this app is a meal planner, it does not share any personal health information; users do not provide any health information except choosing particular allergens. For the requirement of creating the account to use this app, the required information is email address only.

5.2.5. Tasty

The digital app "Tasty" is introduced as an app providing "food and drink" information and "recipes" for the purpose of meal planning. The app is available on Android and iOS.Users can select types of meals, cooking levels, meal occasions, types of diets, allergen options, types of cuisine, and dish styles. To set up the meal plan so that it removes allergens, Tasty detects 2 food allergens,: gluten and milk. It is only available language in English. The app information lists the privacy policy linked to the external website, www.buzzfeed.com.

A. PAL Regulations

The "Tasty" app does not observe any PAL regulations in describing suggested meals. The nutrition info does not have any section for food allergens. Listed ingredients for suggested meals can be added to the user's personal shopping cart and connected to the online Walmart shopping or the location if someone is shopping in person. However, the individual ingredients do not have any food label information.

B. Personal Information Sharing

Tasty lists the privacy policy in its login section. When the user is required to provide an ID and password to set up a personal profile, the app states that the user consents to the privacy policy by logging in. Except for voluntarily sharing favorite food choices with the public community, the app does not require the user to share extra information. Users have to list

favorite foods that are shared with other users of the “Tasty” app, but it is less likely to show personal information about health since this app does not detect any allergens.

5.2.6. Mercadona

Mercadona mainly provides food products available on Android and iOS. This app is categorized as shopping and food/drink. The available languages are English, Spanish, Catalan, and Basque.

A. Mandatory Food Allergy Labeling Regulations

The app does not mention the names of any allergens. However, users can review mandatory allergens by reviewing the labeling.[310] Mercadona detects 14 allergens, including gluten, milk, crustaceans, fish, mollusks, peanuts, nuts, soya, eggs, sesame, mustard, celery, sulfur dioxide lupin. In addition, each item's food allergy labeling enables consumers to detect allergens. This app shows pictures of products and food allergy labels with the product's name and price, and it advises users to check physical items to ensure there are no allergens.

At the bottom, Mercadona provides a disclaimer:

> The listed statement is “The product or pack shown may not be up-to-date. We recommend that you check the physical product to confirm the details about the product and allergens. For additional information, contact us at our customer service Freephone 800 500 220.”[311]

Thus, this app does not show mandatory allergen information related to the suggested items.

[310] , listed categories are oils, spices, sauces; water & soft drinks; snacks; rice, pulses & paster; sugar, sweets & chocolate; Baby; beer; wine & spirits; chocolate drinks; coffee & tea; meat; cereal & biscuits; deli & cheese; frozen food; cans, soups & creams; hair care; facial & body care; herbal remedies & para-pharmacy; fruits & vegetables; Eggs, milk & butter; cleaning & household; makeup; seafood & fish; pet; bread & bakery;pizza & ready meals, 25) dessert & yogurt, and 26) juice

[311] This statement mentioned as the disclaimer is reflect the information as the date of December 19, 2023.

B. PAL Regulations

The app provides information on each product, including images, the original labeling description, and a picture of the packaged labeling. This helps consumers see any possibility of cross-contact with allergens when introducing food items. Labeling information, which incorporates PAL details, is found on all prepacked and manufactured items available in supermarkets. The application provides visual representations of this labeling information, showcasing the included PAL data.

As a precaution, the app cautions encourages consumers to check the physical packaging for more detailed information about the food products. The app itself does not provide any allergen information or allergy labeling that is different from the packaging. However, reviewing the labeling of each product can avoid allergens from food products.

This application is designed solely for packaged foods with images that display allergen information for meal plans. Consequently, individuals who dine at restaurants and need to inquire about specific ingredients in their meals before ordering will not find this app useful for identifying their allergen concerns.

C. Personal Information Sharing

The app sets a low level of privacy protection and doesn't require users to input any sensitive personal data. When registering for membership, users are only asked to provide their name and email address as personal information. The personal information collected consists of name, email address, address, and phone number in app functionality and account management.

Under data safety protection, personal information to share for any purpose for using this app is name, email address, and address for analytics. Data shared for other purposes is listed on the device description on the app, which is used to analyze users' general information. The

collection of data footage is not intended to analyze app users' food preferences. The information-sharing agreement states that data is utilized to evaluate feature functionality and identify the primary locations where users engage with the applications. This application gathers information on system crashes and performs diagnostic assessments.

5.2.7 Cara Care: ODMAP, IBD, IBS Tr

This app is categorized as medical and health care. Users must agree when they sign up for the app to allow app managers to monitor the user's sharing, use, and posting of information. According to the description, app managers support unlimited charts with the app's recommended experts to find out individual triggers of users' symptoms.

Logging into the app requires the user to report symptoms, including bloat, stomach pain, heartburn/acid reflux, constipation, diarrhea, nausea/vomiting, or others. The user can also choose from several conditions, including irritable bowel syndrome (IBS), gastroesophageal reflux disease (GERD), Crohn's disease, ulcerative colitis, leaky gut, food intolerance and allergy, diverticulitis, celiac disease, and gastritis. As this app detects food allergies, the food allergy section requires users to provide more detailed information. Detected items to avoid allergens of this app are lactose, cow's milk/dairy products, fructose, gluten, grains and cereals, onion/garlic, beans, cabbage, peanut, nut, soy, sesame, celery, fish, seafood (shrimp, calamari), eggs, and lupine. This app lists histamine under the allergen section for users to set up and either take out or detect when they use the app. If the user reports experiencing symptoms from an allergen, they also must select to what extent the symptoms limit daily life, from "not at all" to "extreme."

Further, the app asks whether the user has received any treatment recently and whether the user is currently taking any medication. If the user adds a medication to the app, Cara Care compares the individual symptoms with the user's stored symptoms. After all information is

provided, the user can create an account to ensure that they can back up, restore, and export data. At the same time, the user can choose not to create an account. As the last step in setting up the account, the user is required to agree that the app is not a tool to replace a doctor's visit when experiencing serious health conditions.

A. Mandatory Food Allergy Labeling Regulations

Cara Care tracks personal medication, bowel movements, headache symptoms, and experiences of back, joint, muscle, injury, knee, bones, and soreness pain. If users have additional symptoms, they can send a message to the app manager. The listed allergens that users set in using the apps do not itemize which allergens they have to avoid when choosing a meal plan. Instead, app users review suggested meal plans and find their concerned allergens from the food recipes section.

Once users examine the proposed ingredients for creating their own recipe, they must determine if they can eliminate or substitute potentially hazardous ingredients with other suggested options at their own discretion. This applies if a user wishes to avoid a particular ingredient from each food item. The app records users' meal plan selections and the removal of specific allergens, enabling it to monitor eating patterns and consider adherence to medication regimens and other health-related behaviors.

B. PAL Regulations

Care Care mainly provides a meal plan, and shows alternative ingredients for each meal so that the consumer can choose food without risking allergens. The app does not provide any ingredient-specific warnings as a precautionary measure. Users concerned about allergens or experiencing symptoms can opt to consult with selected experts regarding their health issues.

Notably, the app does not address the PAL regulation, which stipulates that manufacturers should include voluntary warning labels.

C. Personal Information Sharing

When users create accounts by agreeing to the terms, the app shares their health information for analysis. This includes examining individual symptoms, monitoring medication usage, and tracking eating patterns. The data is then used to generate personalized meal recommendations. While the app is not a substitute for medical consultations, it does keep a record of doctor visits. Based on this information, along with user-specific allergen settings and medication details, the app may suggest consulting a physician or offering advice from its own experts regarding medication intake. The software app accumulates and retains individuals' health-related data, offering the option to disseminate this information to recommended health professionals should users seek expert consultation regarding their medical conditions.

The issue is whether the app falls under the jurisdiction of FTC-HIPAA regulations, which govern the management of personal and health-related data. The app collects and shares various types of information through its website, providing users consent to its comparison with other personal data. This information encompasses details about medications, health symptoms, and wellness data related to various aspects such as dietary habits, water intake, gastrointestinal issues, emotional states, menstrual cycles, skin health, physical activity, sleep patterns, and headaches, among other users. However, this app asks users to agree to the Cara Care Privacy Policy, in particular, the EU Data Protection Regulation (GDPR). In terms of dietary preferences and allergic reactions, this app is not expected to disclose comprehensive allergen details, given that its food recommendations are intended for individual reference purposes. However, if the

user chooses to share health data with CaraCare's recommended experts, they share their data through apps. Even if a recipe is suggested, consumers can choose alternatives.

The app has been designed to safeguard personal data by monitoring individual choices related to health status, dietary habits, or emotional states as a form of "self-management." As a prerequisite, the app limits the utilization of information or the extent of application descriptions. Before signing, the app also gives users a privacy policy to read, mentioning that the application's personal data are protected under the EU Data Protection Basic Regulation.

The app's private information has separate sections for general and health data. Users provide health data for 1) information about health (e.g., complaints, diseases, body measurements, medication); 2) information about eating habits; and 3) information about activities. The app analyzes that data and recommends suitable therapies and tips based on the user's voluntarily provided information. The healthcare nutritionist can access personal data when the user agrees. Users are also informed that all collected data are used for research. The app's privacy notice states that it cooperates with research partners and provides anonymized information to medical and pharmaceutical institutions (e.g., researchers, universities, clinics, or drug manufacturers) for research purposes.

Since the app is managed by a German company, personal information is safeguarded in accordance with the EU GDPR's "DiGAV" (privacy protection) standards. These include the principles of "data minimization," "integrity and confidentiality," "purpose limitation," and "accountability.". The app is also available in the U.S., but its data policy does not mention U.S. data privacy protection. The app's privacy policy provides comprehensive information about the collection, storage, and sharing of personal data, given that the app handles and processes such

information.Thus, its policy on processing personal data has a deletion of data that prevents transmission to third-party companies.

5.2.8. Fig: Food Scanner & Discovery

Fig is mostly a food label scanner. If the consumer scans the manufactured food label, the app is able to detect whether the product contains any ingredients that the user has selected as allergens.[312] This app supports consumers struggling to read and understand the ingredients' label descriptions.

A. Mandatory Food Allergy Labeling Regulations

This app follows the U.S. mandatory food allergy regulations. Using the scanner, app users can read listed allergens following U.S.-mandated food allergy regulations. In the allergy section, there are 23 items, including barley, celery, citrus fruit, corn, eggs, fish, latex, lupin, milk, mustard, nickel allergy, oats, peanut, rice, rye, seeds, sesame, shellfish, soy, tree nut, and wheat. If app users are concerned about non-listed allergens, they can add them.

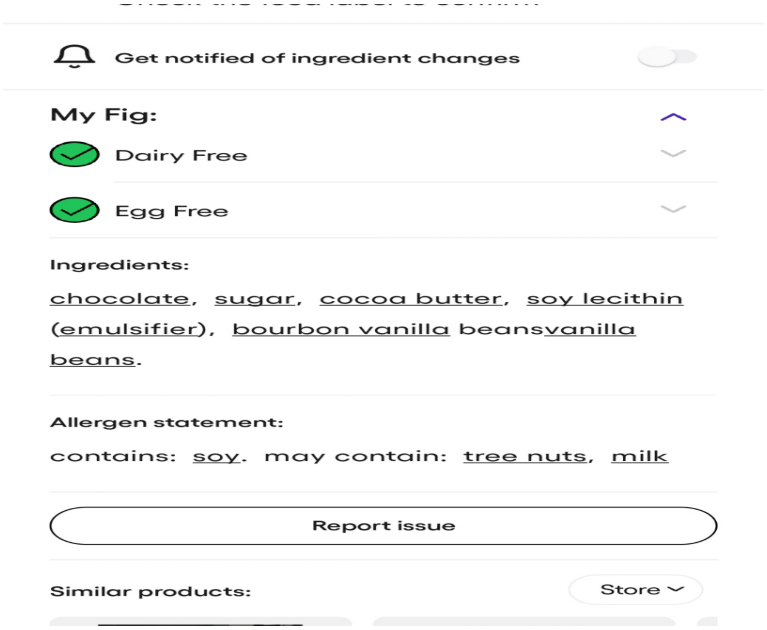
B. PAL Regulations

Fig does not set up cautionary language to differentiate between mandatory food allergens and voluntary food allergens. App users can configure the system to emphasize specific allergens from the ingredient list on food labels, regardless of whether they are voluntarily disclosed or legally required. For instance, if users select particular allergens they are concerned about, the scanning feature can identify and highlight those specific allergens when examining the food label information.. The allergens that a user has selected determine the safety level. When a user identifies an allergen, the system scans for all declared allergens in a product, including those

[312] The app, "Fig: Food Scanner and Discovery" is offered in cell phone apps through iOS and Apple. The production information can be referred in the website, https://foodisgood.com/ (Recent visit on April 23, 2024)

voluntarily listed, and indicates that the food item is not safe for consumption. Thus, if the ingredients are listed on the food label, the app detects all listed allergens that the user selects to avoid.

Figure 9: Screenshot showing the result from a barcode scanning, screenshot by author



(Feature: screenshot showing the result from a barcode scanning, screenshot by author)

A screenshot shows that the scanned information deals with all allergen information following the individual user's settings. The listed allergens did not distinguish PAL from the mandatory allergen descriptions.

C. Personal Information Sharing

The app has a privacy policy section that describes what information is collected and which information can be shared with third parties.[313] The Fig food scanner is not connected to personal health information. Allergen labeling itself is not changed when app users interact with

[313] The website of privacy section listes the app's privacy policy, https://foodisgood.com/privacy-policy/ (Last visit on April 23, 2024)

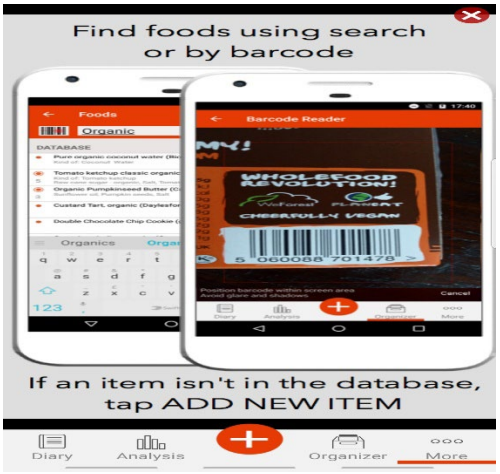
food labeling to detect their concerned allergens. As this food scanner provided food label information, food labeling information from food manufacturers was stored in the app's program.

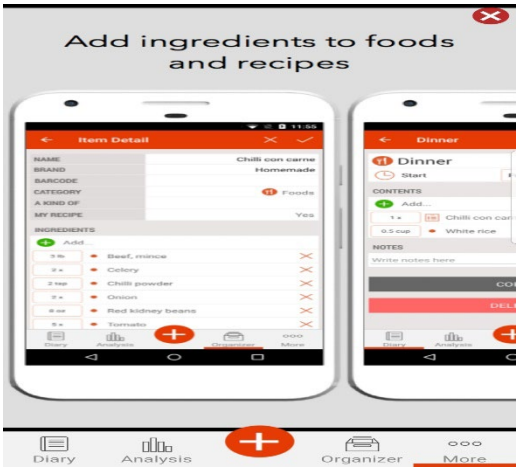
To collect information, the Fig app informs app users if their personal information is shared with a third party. According to Fig's data protection policy, the company utilizes Google Analytics to examine user app usage and location data in compliance with California Privacy Laws and Regulations. The policy's user rights section broadly references California privacy rights. For users outside the United States, the app is described as a U.S.-based service, and international users are considered to be accessing apps located within the United States.

5.2.9. MySymptoms Food Diary

Mysymptoms Food Diary has a diary format for personal information about dietary style, exercise, and tracking individual food habits. It uses a barcode to read food labels or find allergens in a food search.

Figure 10: screenshot of the application barcode (screenshots taken by the author on the phone.)





A. Mandatory Food Allergy Labeling Regulations

This app identifies nine U.S. mandatory allergens: milk, egg, fish (including bass, flounder, or cod); shellfish (including crab, lobster, or shrimp); tree nuts, wheat, soybean, and sesame. The application's scanning functionality enables users to access allergen information for meal planning and grocery shopping purposes. By scanning food labels in proximity to each barcode, individuals can instantly view ingredient details through the app's interface. For food items with difficult-to-read barcodes, a barcode scanner can be utilized to access food labels and provide comprehensive information about the ingredients. Users can interact with the ingredient data obtained through barcode scanning in the application, selecting whether to exclude or include specific ingredients in future meal plan recommendations.

B. PAL Regulations

A food product Picture taken by the author / Detailed label from Barcode when scanned using the phone, Screenshot by the author.)

Figure 11:same product, left- food ingredient labeling, right -scanned label

Barcode scanners identify all ingredients, regardless of whether they are listed in the mandatory food allergen section or the voluntary warning allergen section. These scanners

enumerate all allergens in the product, irrespective of their classification as mandatory allergens (indicated by "Contains") or potential allergens (marked with "MAY CONTAIN"). The app's scanning feature provides users with the ability to examine each ingredient by connecting to the items listed on the product label. However, this functionality does not distinguish between ingredients mentioned in the optional cautionary statement and those in the required allergen information section when displaying allergens through the scanner. The App scanner provides a comprehensive display of all information found on food labels, allowing users to examine every ingredient. This includes both primary components and potential allergens that may be present due to the manufacturing process of pre-packaged foods.

C. Personal Information Sharing

MySymptoms is not a covered entity under HIPAA because a tech company operates the app. However, after each individual writes a diary entry about their meal plan based on selecting from the scanned food and their own meal choices, users can see automatically created meal eating patterns by 6 months, 3 months, or another range. As an option, each individual can choose to share their diary with the clinician. When selecting a clinician, the app requires the user to use a real name (not anonymous) to get advice on selecting an individually appropriate meal plan. To ensure the protection of personal data, the application requires users to activate security features on their devices. These features encompass the implementation of a passcode, the use of fingerprint authentication, or the adoption of unique identifiable characters, effectively safeguarding sensitive information. The app implements a standardized meal planning approach, with users selecting their desired plan in conjunction with medical experts to obtain advice on food choices or lifestyle changes. User-specific meal plan information is not disclosed by the app without explicit authorization from the individual.

5.2.10. Open Food Facts

Available for both iOS and Android platforms, the "Open Food Facts" application features functionality to obtain food product information. Users can either scan a product's barcode or access details through a website interface. This app helps the user look at the ingredients, labels, nutritional quality, environment, food processing, allergens, traceability, where to buy ingredients, and alcohol content of beverages. The Open Food Facts database comprises information and data voluntarily submitted by its contributors, encompassing food producers and distributors. Each product's page on Open Food Facts features an image, label, ingredient roster, and nutritional information table, all of which are voluntarily added by app users. However, when the app scans a prepackaged food item, it cannot display ingredient details if the product's manufacturers or suppliers have not shared this information. The "Open Food Products" application proposes potential ingredients that might be present in comparable pre-packaged food items when its users are unable to scan product labels due to food manufacturers or producers not supplying detailed ingredient information.

A. Mandatory Food Allergy Labeling Regulations

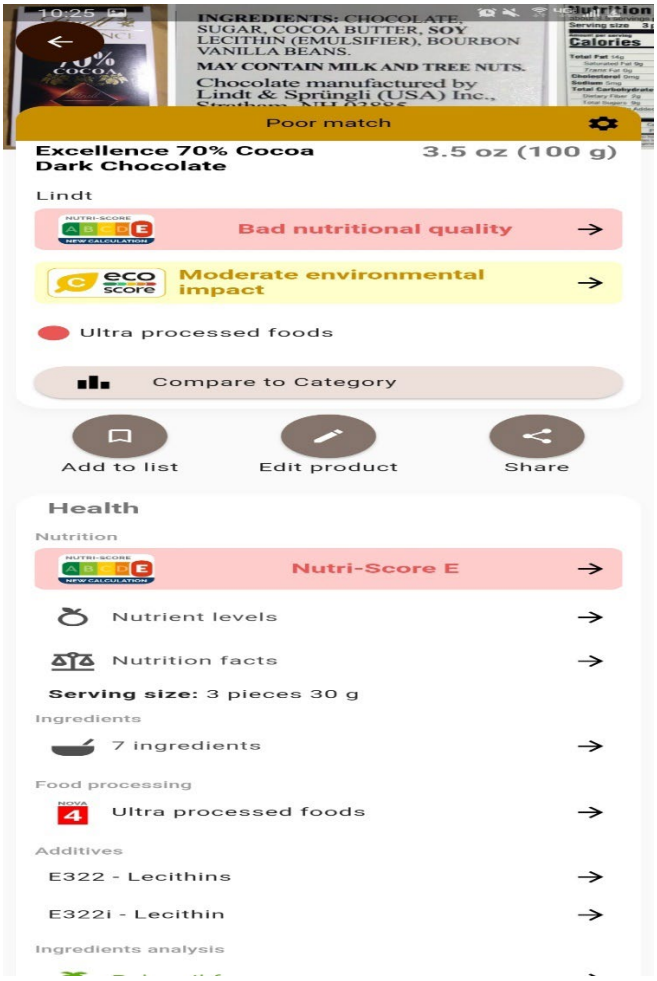
The "Open Food Facts" app features a section dedicated to allergens, allowing users to exclude certain allergens from their meal plans. By scanning food product labels, the app accumulates information and presents it in a manner consistent with manufacturers' allergen disclosures Its allergen information is supposed to provide the food manufacturer or provider's mandatory and voluntary allergen information. Instead of listing allergens, this app posts a disclaimer that reads: "*There is always a possibility that data about allergens may be missing, incomplete, incorrect, or that the composition of the product has changed. If you are allergic, always check the information on the actual product packaging."* The app refrains from

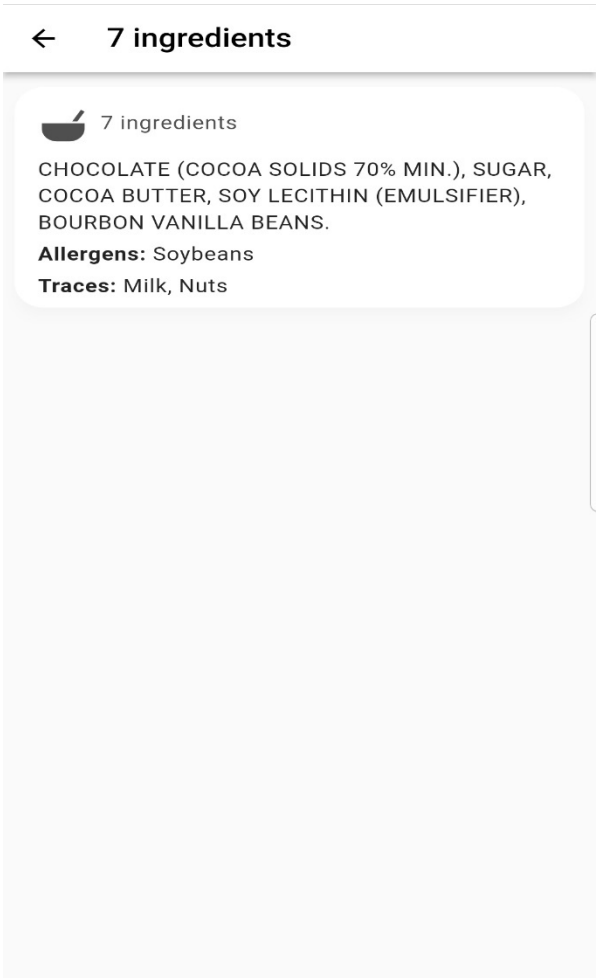
disclosing confidential personal data to third parties. The information displayed within the app is derived solely from voluntary submissions made by manufacturers or food producers to the application.

B. PAL Regulations

The information gathered by this application relies on data provided by food manufacturers and producers. The allergen information provided in the section of PAL is listed in a separate section. However, App uses its own term of “traces.”

Figure 12: Screen showing information captured from an app





The scanned food analyzer detected the PAL information and labeled voluntarily-disclosed allergens as "traces," while mandatory allergens were explicitly identified. Given that "traces" lacks a standardized legal definition, its use in food labeling may lead to consumer confusion, even when allergens are clearly listed in the product information.

C. Personal Information Sharing

The "Open Food Facts" application relies on user-submitted product data. When individuals access the platform, they contribute information about food items by scanning barcodes and capturing images of the product's front, ingredient list, and nutrition label. Food suppliers or manufacturers also provide details on packaging codes, the manufacturer's official website, and any other pertinent information.

The "Open Food Facts" website and the application's setup section detailed the user data gathered. This information included IP addresses and login credentials, IP addresses when using the mobile app to scan products, and dietary preferences for product sorting and identification. The "Open Food Facts" website outlined consumer rights, which encompassed the right to object, the right to data correction, and the right to data deletion.

5.2.11. Soosee-Allergy, Vegan-Glute

The ″Soosee-Allergy, Vegan, Glute” app is introduced as a “health and fitness” app. It is available on Android and iOS. It identifies gluten and identifies allergens in different and large colored fonts for consumers to more easily recognize allergens. Food labeling information is provided by scanning the ingredients and not the barcode. The appl allows users to utilize their smartphone's camera as a scanning device to read product labels. Once scanned, the system interprets the ingredient list from the package information. The scanning system supports 18

languages. The software employs a color-based classification system for different food groups. When users haven't specified allergens, the label-scanning function will analyze the product's packaging and present a comprehensive list of ingredients, with each component displayed in a unique color..

A. Mandatory Food Allergy Labeling Regulations

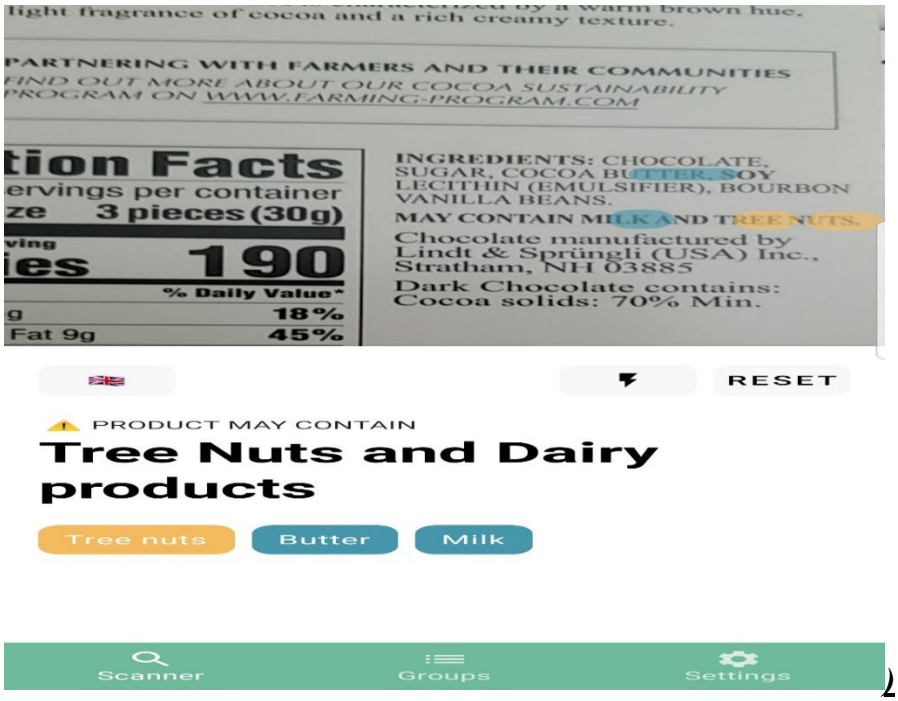
The app lists 31 categories, including different types or groups of allergens or selected food choices for pregnant people or gluten, including dairy products, peanuts, tree nuts, acidity regulators, anti-caking agents, additional additives, additives, alcohol, animal E-numbers, antibiotics, antioxidants, a separate list of food for pregnant people, celery, chicken egg, coloring, fish and shellfish, flavor enhancers, fruit & vegetables, general non-vegan, glazing agents, cases and sweeteners, gluten, lupin, meat, microplastics, palm oil, possibly Palm Oil, preservatives, sesame seed, soybean, sugar & sweeteners, sulfite, thickeners, stabilizers, emulsifiers. Each group of categorized names shows various versions of food names. The listed allergen group includes the nine regulated main allergens in the United States.[314]

B. PAL Regulations

As the app reads ingredients on packaged food labels, it does not distinguish voluntarily listed allergens from mandated allergens. Any item listed on the packaged label highlights all items that individual app users set to opt out of as risky allergens.

Figure 13: Screenshot of the food label using the app camera (A screenshot taken by the author from her phone

[314] The app, “Soose-Allergy, Vegan, Glute” suggests 31 categories: gluten, limit(pregnant), lupine, meat, microplastics, palm oil, peanut, possible animal e-numbers, possibly palm oil, preservatives, sesame seed, soybean, spices & Herbs, sugar & Sweetener, sulfite, thickeners/stabilizers/emulsifiers, and tree nuts (The group information is referred from the last visit of the app on May 16, 2024)



As an individual set to identify specific groups of food, the scanner reads food ingredients by highlighting the different color-coded words.

C. Personal Information Sharing

This app does not interact with an individual's health information. For the feedback form, the app provides the link to a Google form to submit customer feedback. While using the scanner, consumers can submit missing words if their scanner cannot find the words in the label description because of the wording or spelling of the food description. Because this app does not use individual or health information, it is not regulated under FTC-HIPAA regulations.

5.3. Summary

Different food allergy apps offer alternative ways for consumers to understand and read labels. Currently, food labeling apps are not categorized as medical devices to treat food allergies. Instead, the apps use data on mandatory and voluntary allergens collected from food manufacturers' labels. Some apps also can provide information about the ingredients on the menu

for restaurant food. Here, it is still risky for consumers to trust listed allergies in restaurant food; if the chef does not list the ingredients while cooking or handling food, digital food apps do not have any alternative ways to detect other allergens. Therefore, using digital apps is not a perfect solution for identifying allergens in restaurants and prepackaged food because identification is based on menu information or package labels.

The apps analyzed in this study were available in the U.S. Most digital apps list the nine U.S. regulated food allergens to detect or opt out of suggested meal plans or to read food allergy labeling codes.

CHAPTER 6: CONCLUSION

6.1 Analysis of Currently Used Digital Allergy Labeling

Research findings indicate that the development of a new legal framework for allergen identification should focus on the content provided by the app rather than on emerging technological innovations. This approach aligns with the theoretical framework that explores the interplay between legal systems and technology.[315] The examination of digital allergy labeling app content highlights the complexities of applying food allergy labeling legislation and privacy regulations from various countries, including the U.S. and EU, to oversee the digital food allergy applications currently on the market.

This dissertation found that digital food allergy labeling apps are introduced as wellness, meal plans, healthy diaries, and health plans. They can help consumers recognize food allergens from packaged food labels or avoid choosing allergens when they plan food choices. Apps offer various ways of identifying food allergens, including 1) pictures of the product (e.g., " Eat this Much"; 2) providing food allergy information to help the users choose meal plans from a suggested list that takes users' allergies into account (e.g., AllergyEats, Mealime Meal Plans & Recipes, SideChef, Tasty); 3) a scanner that takes a picture of a product barcode (e.g., Fig); 4) a scanner that takes a picture of the original product label (Soosee-Allergy, Vegan Glute); and 5) product information uploaded by consumers and/or provided by manufacturers (e.g., Open Food Facts). While not explicitly labeled as allergen detectors, food label apps often incorporate the functionality to screen for allergens when users provide supplementary information.

6.2. Research Question 1: How can digital informative food allergy labeling comply with the current food allergy laws and regulations?

[315] See supra note 61.

6.2.1. Implementation of Mandatory Food Allergen Requirements (Summary referring to Appendix 2)

Retailers' food packaging is controlled by the Code of Federal Regulations Title 21[316]. The U.S. food label is displayed, presented, shown, or examined under customary conditions of display for retail sale.[317] Regulations guide the detailed food labeling of mandatory allergens and also provide guidance for voluntary PAL labeling on packaged food labels.[318] Currently, U.S. food labels are required to list nine allergens on the food label.

The EU label regulation mandates the disclosure of 14 specific allergen foods, but the sub-ingredients classified under each required allergen do not correspond to the mandatory food items within each allergen category in the United States. This lack of alignment exists between the EU and U.S. labeling requirements for these designated allergenic substances.

This study found that digital health and wellness apps set the allergen section to allow consumers to choose their individual risky allergens before using the apps to go grocery shopping or receive meal plans. All food allergy apps were set up to screen nine mandatory allergens in the U.S. Despite the fact that most digital applications do not adhere to the US FDA guidelines for allergen screening, users can still customize app features to identify or filter out specific allergens of concern. This functionality applies to both pre-packaged food labels and suggested ingredients in meal plans accessed through these applications. The problem is that the listed allergens provided through food digital apps are inconsistent with the FDA standard guidelines. For example, "wheat" does not have the same meaning as gluten, the term that app developers use. Under US mandatory allergen regulations, gluten intolerance is not classified as an allergy. Gluten is a protein component found in wheat, barley, rye, and their crossbred grains.

[316] Code of Federal Regulations 21 CFR 101, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=101&showFR=1
[317] Id. at paragraph 101.1
[318] Id. At paragraph 101.2

Despite this, certain applications erroneously list gluten as the only allergen, even though the condition associated with gluten sensitivity, known as celiac disease, is not officially categorized as an allergen risk.. Moreover, according to FDA regulations, "gluten-free[319]" is a voluntary claim that manufacturers choose to describe on the label. In analyzing mobile apps' categories of allergens, three food allergen detectors included in this study showed that they mixed alerts for gluten with alerts for wheat. The FDA defines "gluten-free" foods as those containing less than 20 parts per million (ppm) of gluten or having no gluten at all. Although the FDA distinguishes between "gluten-free" and "wheat" categories, digital applications often misclassify wheat as an allergen. This misclassification leads to confusion, as gluten should be correctly identified as an intolerance rather than an allergen in food labeling.

Another example of digital apps' misleading allergen terminology concerns "dairy food." Although milk is commonly recognized as a dairy product, some digital app's dairy food category does not provide users with the option to specify allergens as specific as milk..[320]

The EU's adds five mandatory allergens - celery, mustard, sulfur, lupin, and mollusks – to the nine allergens in the U.S. The digital food apps analyzed in this dissertation show that some allergens are found in U.S. mobile allergen apps. Nevertheless, not every digital apps used in the United States is configured to identify or interpret the EU's mandatory allergens from food label descriptions. In general, these apps may or may not track the allergens required by EU regulations.

[319] Food and Drug Administration, Food Labeling; Gluten-Free Labeling of Foods, 21 CFR 101 (2013).
[320] According to 21 CFR 131.110, milk is the lacteal secretion, practically free from colostrum, obtained by the complete milk ing of one or more healthy cows. milk that is in final package form for beverage use shall have been pasteurized or ultrapasteurized, and shall contain not less than 8 1/4 percent milk solids not fat and not less than 3 1/4 percent milk fat. milk may have been adjusted by separating part of the milk fat therefrom, or by adding thereto cream, concentrated milk , dry whole milk , skim milk , concentrated skim milk , or nonfat dry milk . milk may be homogenized.

For the WHO's mandatory food allergens, manufacturers are required to declare allergens causing hypersensitivity on the label.[321] Most food digital allergy labeling apps analyzed in this dissertation had a "gluten list" in the allergen section. According to the definition of allergens in WHO Paragraph 4.2.1.4, "gluten" is described as cereals containing gluten (e.g., wheat and other Triticum species, rye and other Secale species, barley and other Hordeum species and their hybridized strains).[322] Digital apps that track dietary information often include gluten in their list of allergens, allowing users to opt out of monitoring it. However, these apps lack uniformity in their treatment of gluten, with each platform offering its own interpretation of gluten as an allergenic substance. This inconsistency in defining and categorizing gluten across various digital tools creates discrepancies in how it is presented to users.

The question arises whether digital allergen applications should adopt a standardized list of allergens to comply with the diverse mandatory allergen requirements across countries, as indicated in the literature review. The varying regulations between nations can lead to consumer confusion. It is likely that many app users are from different countries and would find a more extensive allergen list beneficial.

6.2.2. Implementation of Precautionary Food Allergen Requirements (Detailed Summary in Appendix 3)

The voluntary guidelines for Precautionary Allergen Labeling (PAL), established by the U.S. FDA under Section 403(w) of the FD &C Act, enable food manufacturers to notify consumers about the potential presence of substances other than the main ingredients in the final packaged food product.[323] FDA does not regulate the content of warnings about precautionary

[321] See supra note 125.
[322] FAO/WHO, Joint FAO/WHO Food standards programme codex committee on food labelling, CX/FL23/47/5, fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-714-47%252Ffl47_05e.pdf (2023).
[323] See Supra note 130.

allergens and allows manufacturers to voluntarily list allergens that could be present due to the food handling or manufacturing process. Nonetheless, most of the FDA's precautionary allergen statements follow the example of "may contain [allergen]" or "produced in a facility that also uses [allergen]." I found that most digital allergen apps do not strictly implement the US FDA's precautionary allergy labeling requirements.[324]

Moreover, as shown in Appendix 3, most digital food allergen labeling apps do not strictly follow the precautionary food guidelines. Many digital food apps offering "meal menus" with ingredient listings fail to incorporate a specific section for identifying allergens, whether they are voluntarily labeled or mandatorily declared. App users customize their allergen preferences by selecting specific allergens to monitor or ignore. This applies regardless of whether the allergens are mandatory ingredients, disclosed by manufacturers, or mentioned in precautionary warnings by food providers. The system allows users to tailor their allergen tracking based on individual needs, independent of the source or nature of the allergen information provided. Even though some digital apps have the ability to scan labels for prepackaged food, their digital allergy labels use inconsistent terms to inform users about precautionary allergy labeling warning statements. For example, one digital app treats precautionary allergens as mandatory and lists all allergens to warn consumers. Another digital app does not detect allergens under a precautionary statement. One digital food allergy app recognizes precautionary statements. Still, it uses the term "traces" instead of the US FDA's suggested statement of "may contain," or one(1) digital food allergy app highlights allergens under the precautionary statement. However, The app incorporates required allergens as well as those mentioned in cautionary declarations within the same entry..

[324] See supra note 129

Food manufacturers and suppliers selling pre-packaged products provide precautionary statements to warn consumers of allergens possibly present due to manufacturing processes. Manufacturer's labels have a unified format using the phrase "may contain [allergens]." Thus, The implementation of digital allergy labeling systems may inadvertently increase consumer confusion. This is because the software algorithms employed by app developers often fail to properly categorize and differentiate between main ingredients, potential allergens, and precautionary statements. As a result, these digital platforms tend to display all ingredient information in a uniform manner, without clear distinctions between various types of content.

Regarding to detect allergens for read-to-eat meal in restaurants, digital apps' meal plan features may protect app users by allowing them to scan the listed allergens on the restaurant menu or remove and avoid allergens from suggested meal plans by discussing with recommend experts though digital apps.

Lastly, none of the digital apps reviewed in this dissertation list any specific Reference Dose; their ingredient information is generally described as the amount per serving. As app users choose allergens in the settings, Reference Dose is considered impractical for people who want to prevent allergen reactions because the goal is to avoid allergen entirely not just have it in a limited quantity. .

6.3. Research Question 2: How can consumers be assured of protecting personal privacy information using digital informative food allergy labeling?

6.3.1. Data: Collecting, Storage, and Interacting through Digital Apps (Data Summary in Appendix 5)

App developers create apps that save and control personal health data, and some apps have features that interact with personal users and clinicians. Therefore, digital app data should

be reviewed subject to regulations that safeguard information and privacy to protect personal health and privacy. Most of the apps reviewed in this study collect, store, and share personal health information. Most digital apps require users to provide information about diet, allergic information, medical conditions, and food restrictions. Therefore, these results strongly suggest that these digital apps must be regulated under FTC-HIPAA regulations for non-covered entities. Moreover, some digital apps that interact with other parties, including clinicians, are likely to share personal health information with those third parties, including health insurance, personal stress level symptoms, digestion (heartburn, cramping, acid reflux, indigestion), tummy pain, bloated, medication taken, period, pain, health symptoms. Typically, digital apps are non-HIPAA-covered products that collect and store personal health information. Thus, the new 2024 FTC-HIPAA regulations may regulate food allergy labeling apps. Considering that apps do not yet refer to these rules in the consumer privacy information sections, regulation may need to state that apps state how health information is protected when users first sign up to use the apps.

6.3.2. Implementation of Private Policy Laws and Regulations (Analysis Summary in Appendix 6)

All apps researched in this study listed the California Consumer Privacy Act for Users in the U.S., the European Union's General Data Protection Regulation ("GDPR"), and other European data protection laws in their privacy protection guidelines before asking users to create their accounts to use their apps. As digital app developers understand the importance of protecting personal data, a privacy protection agreement is required when app users need to log in. Digital apps adhere to standard agreements by implementing privacy protection protocols, including consent mechanisms and notification policies, to ensure the ongoing safeguarding of consumer data during its utilization.. However, digital apps dealing with personal health information may be obligated to disclose FTC-HIPAA guidelines to users prior to app utilization. This

requirement, as examined in the section on managing personal health data, aims to shield such sensitive information from potential security breaches. Digital apps requesting users' personal health information for allergens generally lack comprehensive data protection policies. In fact, only one app, such as mySymptoms Food Diary, provides users with guidelines to understand and safeguard their health data. This suggests that apps offering allergen information should implement more stringent measures for collecting, storing, and sharing personal health information to ensure adequate protection under privacy policies.

6.4. Contribution and Implications

In the Food Digital Allergy Labeling Requirements section, the question is raised whether the same mandatory allergens should be regulated globally or intentionally. First, this study shows that digital apps located in the United States enable app users to clearly detect allergens and opt-out of or select risky allergens before choosing manufactured food or restaurant food. The implementation of the European Union's 14 allergen requirements on digital applications shows inconsistencies in the compilation of allergen lists set in the digital apps.. . The expansion of allergen detection capabilities in digital applications, coupled with consistent allergen reporting across platforms irrespective of location, could potentially lead to more detailed allergen listings on menus. This enhanced information might result in an increased range of dining options for consumers with dietary restrictions.

Second, regarding voluntary allergen requirements, digital allergy labeling does not have any separate setting for voluntary allergen descriptions. Moreover, owing to different ways of scanning food labeling, some digital apps distinguish mandatory from voluntary allergens. In contrast, some digital apps do not treat any differences from listed mandated allergens or ignore voluntary descriptions. If digital food allergen labeling is designed to provide more clarity,

digital app guidelines for voluntary allergen labeling should be consistent with the current FDA voluntary allergen labeling requirements.

Third, personal information protection or breach of personal data when using digital apps to read and detect allergens should inform the updated FTC‘s amended Health Breach Notification Rule (HBNR) effective on July 29, 2024, for users before they use their apps about new requirements of rules that includes new requirements for third-party service providers that support direct-to-consumer apps. While digital food allergy applications require users to input sensitive health information, such as allergy risks and other medical concerns, many of these apps offer limited privacy protection. They often apply general data protection guidelines to all information, failing to provide enhanced security measures for health-related data. Instead, these apps tend to treat health information with the same level of protection as general personal data rather than implementing stronger safeguards specifically for medical information.

Lastly, this study contributes to research as to how current apps apply FDA food regulations even though FDA allergy labeling requirements do not regulate digital health and wellness apps.

6.5. Future Research

This study analyzed the currently used digital apps to supplement paper allergy labeling descriptions. Future studies could evaluate whether the recently modified FTC-HIPAA guidelines for wellness apps effectively safeguard consumers' personal data by examining reported incidents. As individuals increasingly rely on mobile applications in their daily lives, they express growing concerns about the covert use of their information and the security measures outlined in privacy agreements. While the United States strives to regulate mobile health and wellness apps through FDA and FTC-HIPAA frameworks, the specific regulations for app usage under FDA oversight remain ambiguous and fail to fully protect certain groups, such as pregnant individuals or those with gluten sensitivities. This paper's focus on reviewing mobile

app compliance with existing regulations could be extended in future research by examining the implementation strategies of EU allergy regulations and privacy protection rules to enhance safeguards for app users in health and privacy matters.

Given that digital allergy apps are promoted as tools to simplify label reading for consumers, future studies may need to assess whether these apps effectively support users in making safe food choices for meals or packaged products without risking unexpected allergic reactions.

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RESOURCES

A good resource for information on federal laws and policies relating to food allergies is the U.S. Food and Drug Administration, Center for Food Safety & Applied Nutrition, http://vm.cfsan.fda.gov. The site has extensive information about the Food Allergen Labeling and Consumer Protection Act of 2004, which the FDA oversees. It regulates the full text of the act and numerous documents related to compliance and exemptions. It also has a collection of links to food allergy resources elsewhere in the federal government, primarily relating to health and nutritional issues.

Other sites with information on laws and policies related to food allergies :

• **AllergicChild.com, www.allergicchild.com.** Its site is a support group for parents, teachers, and others who deal with allergic children and has a page devoted to food allergy legislation. This information is reasonably minimal, and no updates have been made since 2005.

• **Asthma and Allergy Foundation of America, www.aafa.org.** AAFA is an asthma and allergy patient advocacy group whose mission is to help improve people's lives with asthma and allergies through education, advocacy, and research. Its website have a separate section explaining various food allergies and legal protection for allergy sufferers under the American Disabilities Act and food labeling laws.

• **Food Allergy Initiative, www.foodallergyinitiative.org**. The public policy section has information on federal labeling laws, current legislation, and 504 plans for schools to accommodate students with food allergies.

• **The Food Allergy Project, www.foodallergyproject.org**. This coalition of parents, researchers, educators, and others has increased federal and private funding for food allergy research. The site has some information on legislative initiatives related to its work in the news section.

• **Kids with Food Allergies.com, www.kidswithfoodallergies.org.** This nonprofit organization is dedicated to improving the lives of children with food allergies by sharing resources and tips. Access to most of the site's resources required an annual membership fee of $ 25. These resources deal mainly with nonlegal issues and reviews related information on federal food-labeling laws.

• **PeanutAllergy.com, www.peanutallergy.com.** Although this site has pages for "issues of concern," such as food labeling and schools, they are virtually empty. However, this site also has several active discussion boards. Of interest to legal professionals, these boards contain numerous stories of the legal challenges faced by those with peanut allergies in seeking accommodation in their schools and elsewhere. Many posts relate directly to negotiating and drafting 504 agreements with schools.

• **Peanut Aware, www.peanutaware.com**. The site was intended to provide information on allergy books, allergy-safe foods, and restaurants. Although its discussion forum has no direct information on legal or public policy matters, it has a section with postings on 504 plans and other school issues.

Appendix 1 : Massachusetts Allergy Poster Guideline

Food Allergies

What you need to know

Millions of people have food allergies that can range from mild to life-threatening.

Most Common Food Allergens

Always let the guest make their own informed decision.

When a guest informs you that someone in their party has a food allergy, follow the four R's below:

- **Refer** the food allergy concern to the department manager, or person in charge.
- **Review** the food allergy with the customer and check ingredient labels.
- **Remember** to check the preparation procedure for potential cross-contact.
- **Respond** to the customer and inform them of your findings.

Sources of Cross-Contact:

- Cooking oils, splatter, and steam from cooking foods.
- Allergen-containing foods touching or coming into contact with allergy-free foods (i.e. a nut-containing muffin touching a nut-free muffin).

Any food equipment used for the processing of allergy-free foods must be thoroughly cleaned and sanitized prior to use.

- All utensils (i.e.,spoons, knives, spatulas, tongs), cutting boards, bowls, pots, food pans, sheet pans, preparation surfaces.
- Fryers and grills.
- Wash hands and change gloves after handling potential food allergens.

If a guest has an allergic reaction, call 911 and notify management.

FAAN

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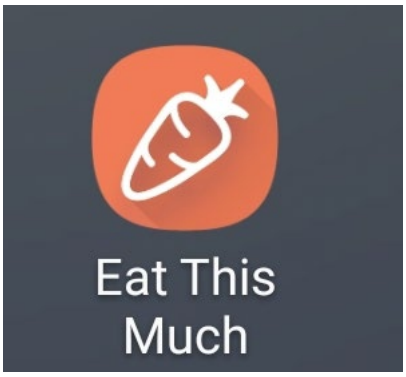
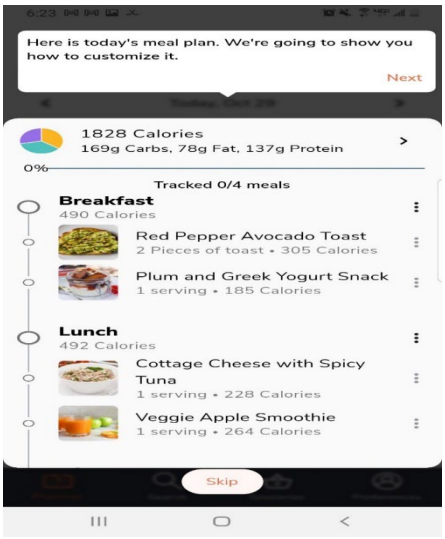
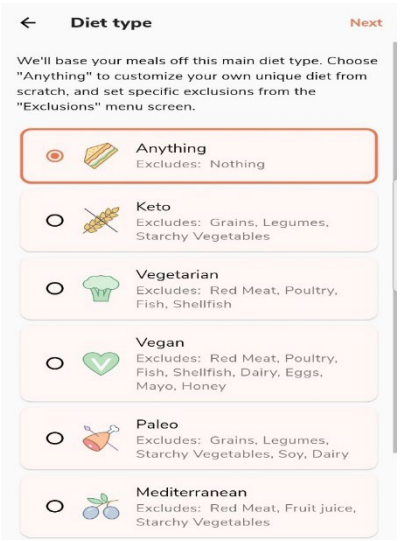
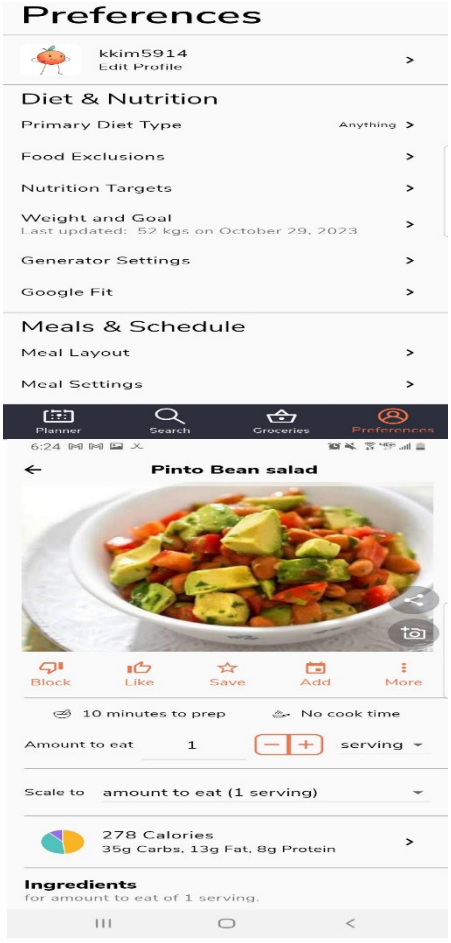
Appendix 2 Digital Apps Reviewed in This Study

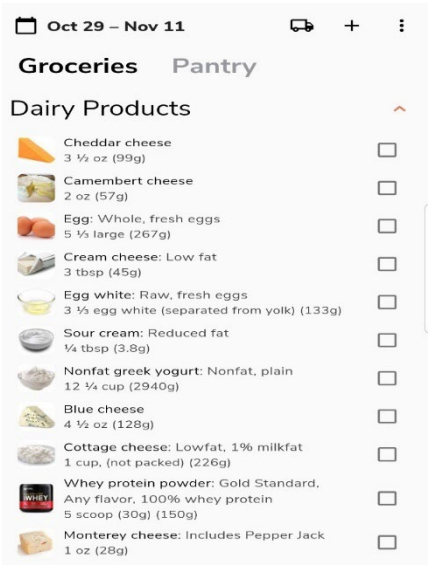
A. Eat This Much



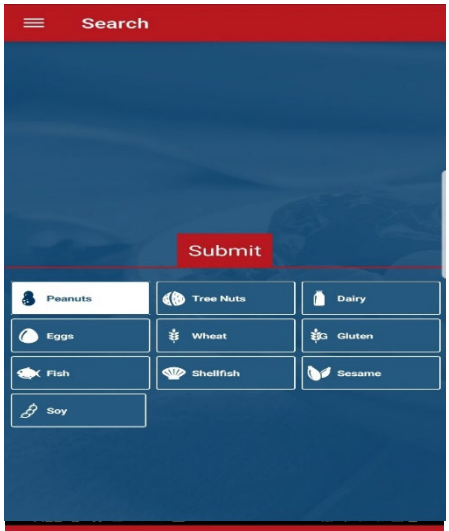


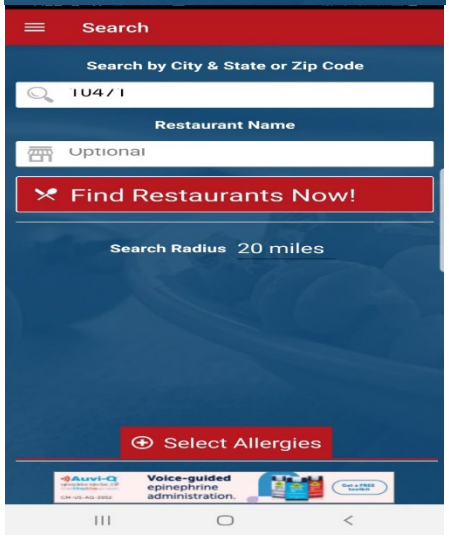


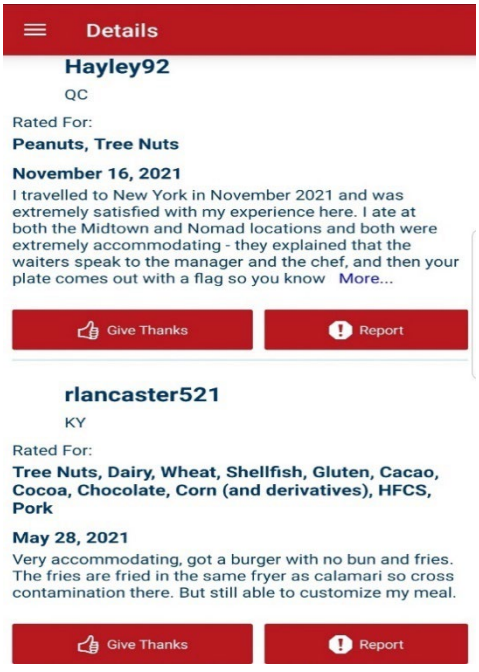


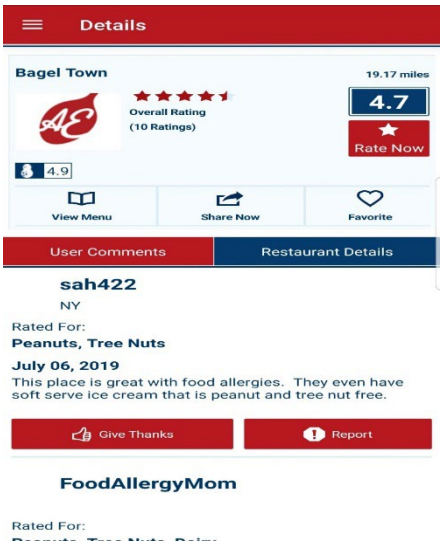


B. App, “Allergy Eats”

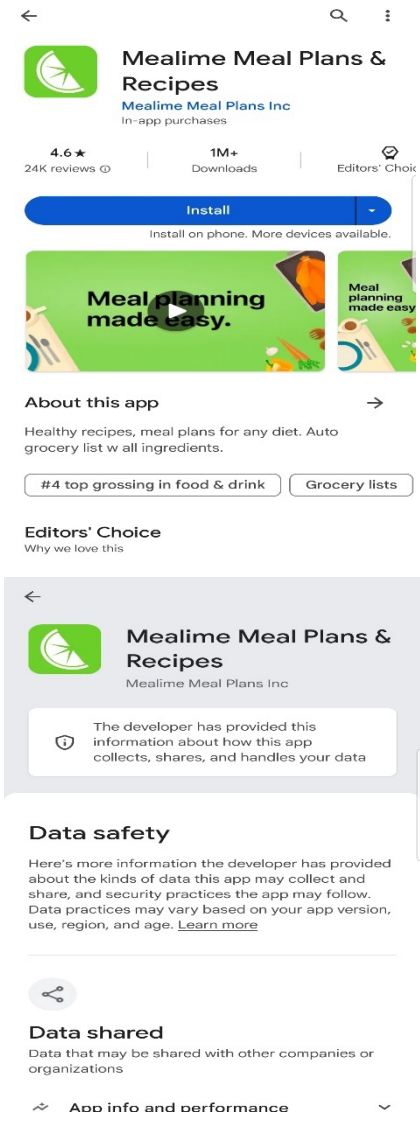




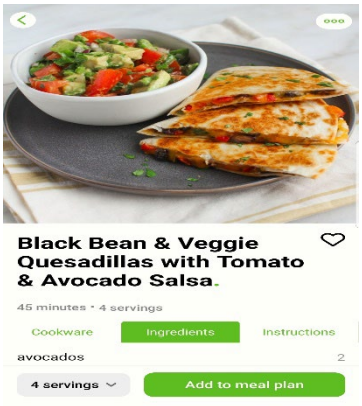


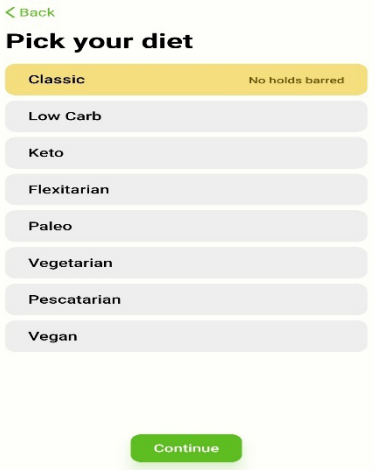


C. Meallime

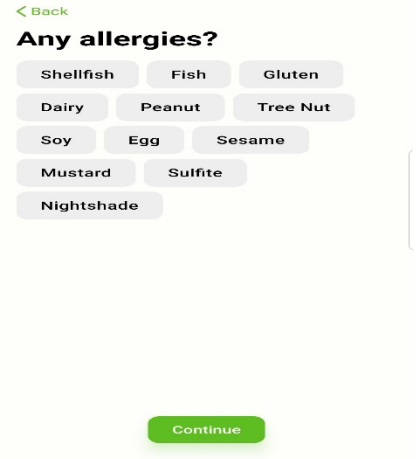

Mealime Meal Plans & Recipes
Mealime Meal Plans Inc
In-app purchases
4.6★
24K reviews
1M+
Downloads
Editors' Choic
Install
Install on phone. More devices available.
Meal planning made easy.
About this app
Healthy recipes, meal plans for any diet. Auto grocery list w all ingredients.
#4 top grossing in food & drink
Grocery lists
Editors' Choice
Why we love this

Mealime Meal Plans & Recipes
Mealime Meal Plans Inc
The developer has provided this information about how this app collects, shares, and handles your data
Data safety
Here's more information the developer has provided about the kinds of data this app may collect and share, and security practices the app may follow. Data practices may vary based on your app version, use, region, and age. Learn more
Data shared
Data that may be shared with other companies or organizations
App info and performance

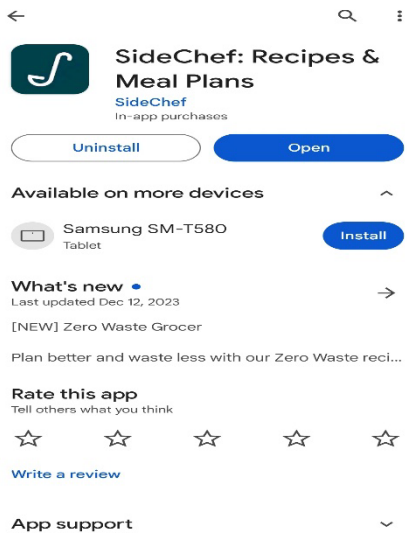

Black Bean & Veggie Quesadillas with Tomato & Avocado Salsa.
45 minutes • 4 servings
Cookware
Ingredients
Instructions
avocados
2
4 servings
Add to meal plan

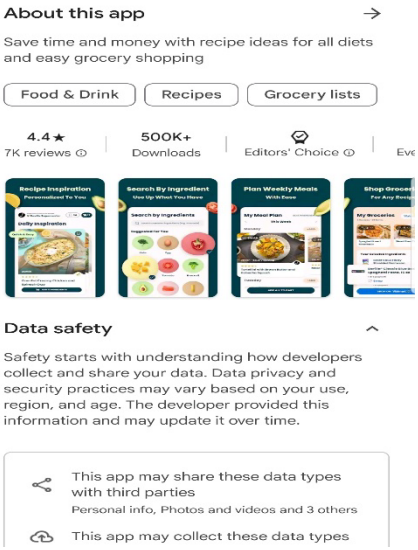

Back
Pick your diet
Classic
No holds barred
Low Carb
Keto
Flexitarian
Paleo
Vegetarian
Pescatarian
Vegan
Continue

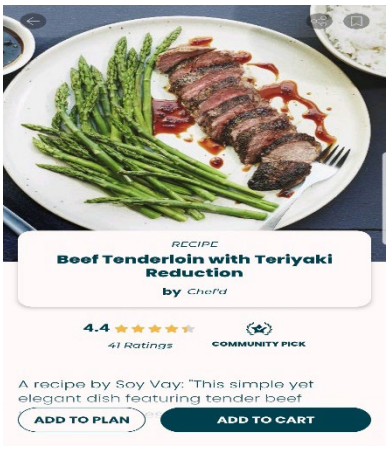

Back
See All
How about dislikes?
avocado
beef
beets
bell peppers
blue cheese
brussels sprouts
cauliflower
eggplant
goat cheese
lamb
mushrooms
olives
pork
quinoa
salmon
shrimp
tuna
turnips
Continue

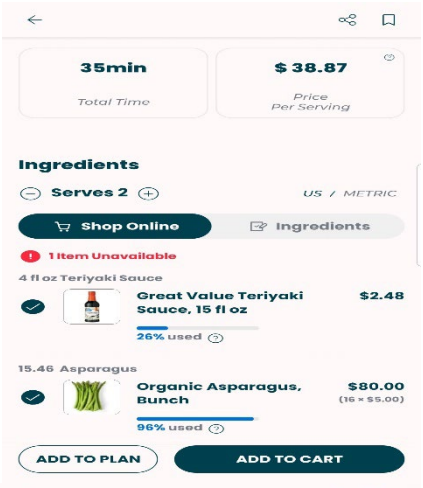

Back
Any allergies?
Shellfish
Fish
Gluten
Dairy
Peanut
Tree Nut
Soy
Egg
Sesame
Mustard
Sulfite
Nightshade
Continue

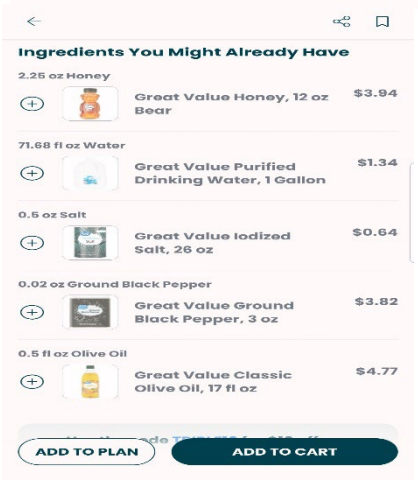
D. SideChef


SideChef: Recipes & Meal Plans
SideChef
In-app purchases
Uninstall
Open
Available on more devices
Samsung SM-T580
Tablet
Install
What's new
Last updated Dec 12, 2023
[NEW] Zero Waste Grocer
Plan better and waste less with our Zero Waste reci...
Rate this app
Tell others what you think
Write a review
App support

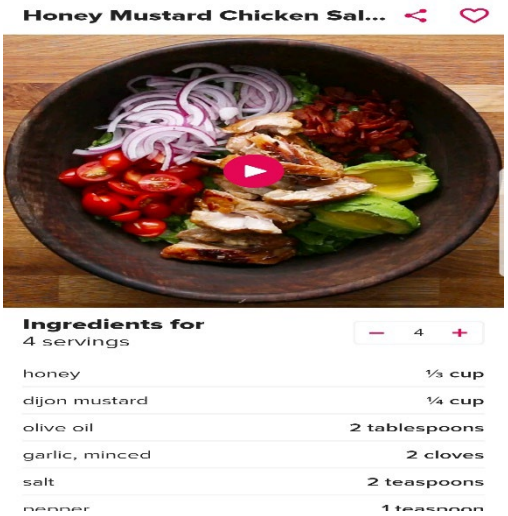

About this app
Save time and money with recipe ideas for all diets and easy grocery shopping
Food & Drink
Recipes
Grocery lists
4.4★
7K reviews
500K+
Downloads
Editors' Choice
Data safety
Safety starts with understanding how developers collect and share your data. Data privacy and security practices may vary based on your use, region, and age. The developer provided this information and may update it over time.
This app may share these data types with third parties
Personal info, Photos and videos and 3 others
This app may collect these data types

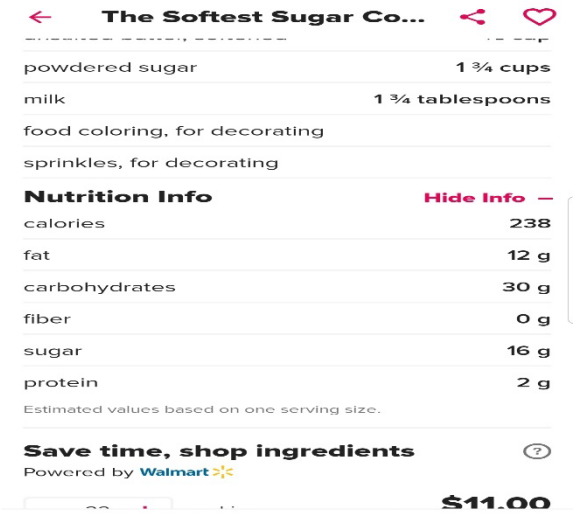

RECIPE
Beef Tenderloin with Teriyaki Reduction
by Chef'd
4.4
41 Ratings
COMMUNITY PICK
A recipe by Soy Vay: "This simple yet elegant dish featuring tender beef
ADD TO PLAN
ADD TO CART


35min
Total Time
$ 38.87
Price Per Serving
Ingredients
Serves 2
US / METRIC
Shop Online
Ingredients
1 Item Unavailable
4 fl oz Teriyaki Sauce
Great Value Teriyaki Sauce, 15 fl oz
$2.48
26% used
15.46 Asparagus
Organic Asparagus, Bunch
$80.00
(16 × $5.00)
96% used
ADD TO PLAN
ADD TO CART

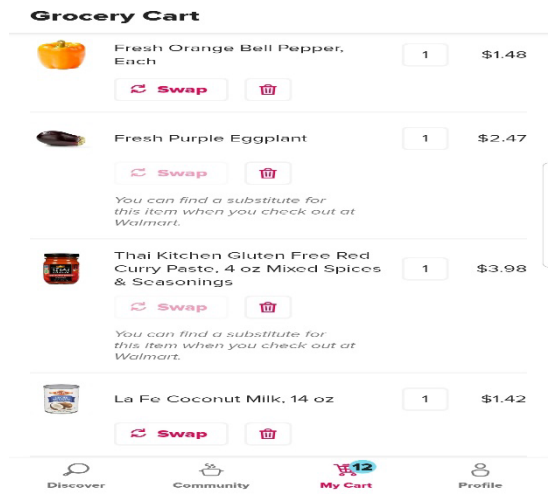

Ingredients You Might Already Have
2.25 oz Honey
Great Value Honey, 12 oz Bear
$3.94
71.68 fl oz Water
Great Value Purified Drinking Water, 1 Gallon
$1.34
0.5 oz Salt
Great Value Iodized Salt, 26 oz
$0.64
0.02 oz Ground Black Pepper
Great Value Ground Black Pepper, 3 oz
$3.82
0.5 fl oz Olive Oil
Great Value Classic Olive Oil, 17 fl oz
$4.77
ADD TO PLAN
ADD TO CART

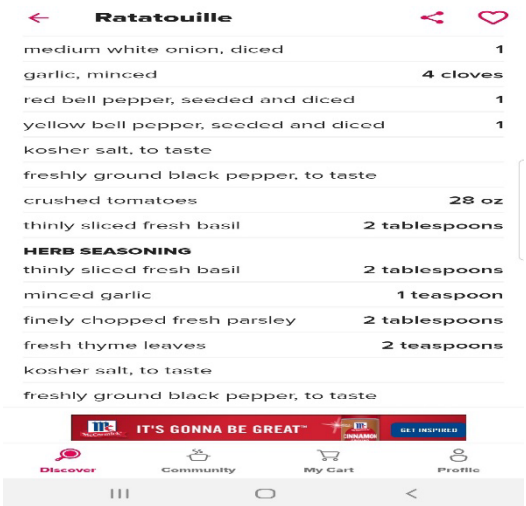
E. Tasty

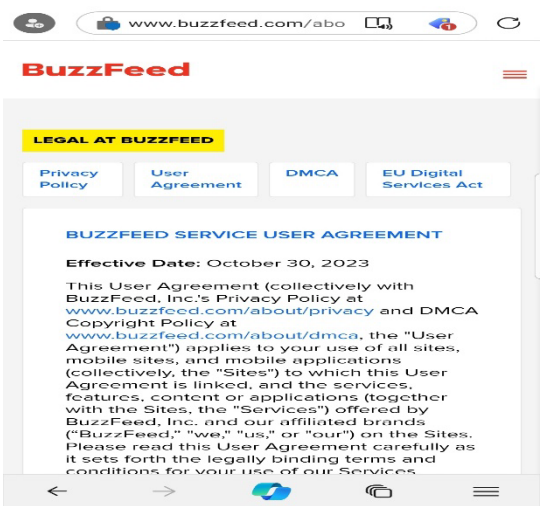

Honey Mustard Chicken Sal...
Ingredients for
4 servings
4
honey ⅓ cup
dijon mustard ¼ cup
olive oil 2 tablespoons
garlic, minced 2 cloves
salt 2 teaspoons


The Softest Sugar Co...
powdered sugar 1 ¾ cups
milk 1 ¾ tablespoons
food coloring, for decorating
sprinkles, for decorating
Nutrition Info
Hide Info
calories 238
fat 12 g
carbohydrates 30 g
fiber 0 g
sugar 16 g
protein 2 g
Estimated values based on one serving size.
Save time, shop ingredients
Powered by Walmart
$11.00

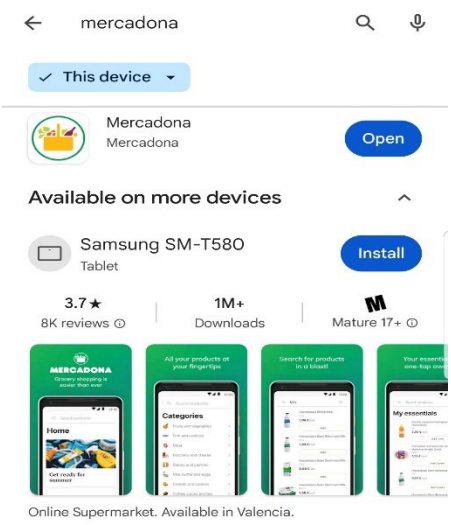

1 of 3
A few quick questions:
Are you a vegetarian?
Nope, show me all recipes
Yes, hide recipes with meat

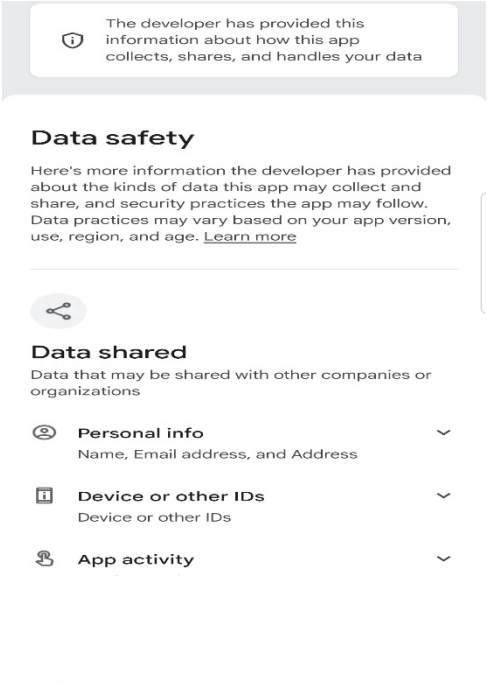

Grocery Cart
Fresh Orange Bell Pepper, Each 1 $1.48
Swap
Fresh Purple Eggplant 1 $2.47
Swap
You can find a substitute for this item when you check out at Walmart.
Thai Kitchen Gluten Free Red Curry Paste, 4 oz Mixed Spices & Seasonings 1 $3.98
Swap
You can find a substitute for this item when you check out at Walmart.
La Fe Coconut Milk, 14 oz 1 $1.42
Swap
Discover
Community
My Cart
Profile


Ratatouille
medium white onion, diced 1
garlic, minced 4 cloves
red bell pepper, seeded and diced 1
yellow bell pepper, seeded and diced 1
kosher salt, to taste
freshly ground black pepper, to taste
crushed tomatoes 28 oz
thinly sliced fresh basil 2 tablespoons
HERB SEASONING
thinly sliced fresh basil 2 tablespoons
minced garlic 1 teaspoon
finely chopped fresh parsley 2 tablespoons
fresh thyme leaves 2 teaspoons
kosher salt, to taste
freshly ground black pepper, to taste
IT'S GONNA BE GREAT
Discover
Community
My Cart
Profile

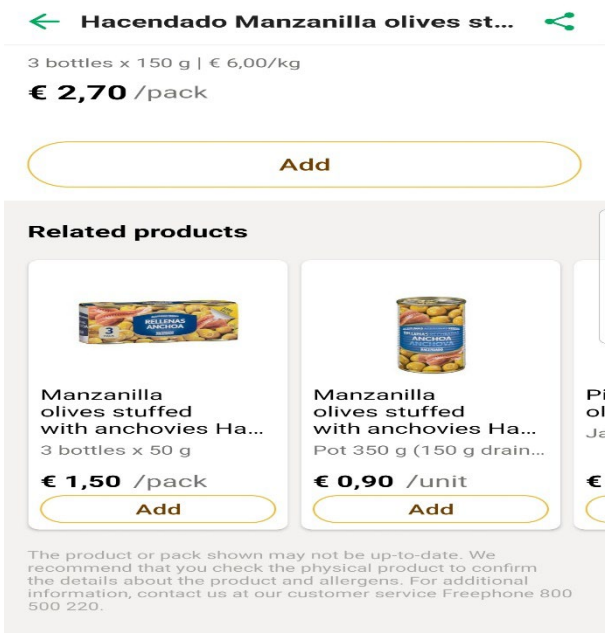

www.buzzfeed.com/abo
BuzzFeed
LEGAL AT BUZZFEED
Privacy Policy
User Agreement
DMCA
EU Digital Services Act
BUZZFEED SERVICE USER AGREEMENT
Effective Date: October 30, 2023
This User Agreement (collectively with BuzzFeed, Inc.'s Privacy Policy at www.buzzfeed.com/about/privacy and DMCA Copyright Policy at www.buzzfeed.com/about/dmca, the "User Agreement") applies to your use of all sites, mobile sites, and mobile applications (collectively, the "Sites") to which this User Agreement is linked, and the services, features, content or applications (together with the Sites, the "Services") offered by BuzzFeed, Inc. and our affiliated brands ("BuzzFeed," "we," "us," or "our") on the Sites. Please read this User Agreement carefully as it sets forth the legally binding terms and conditions for your use of our Services

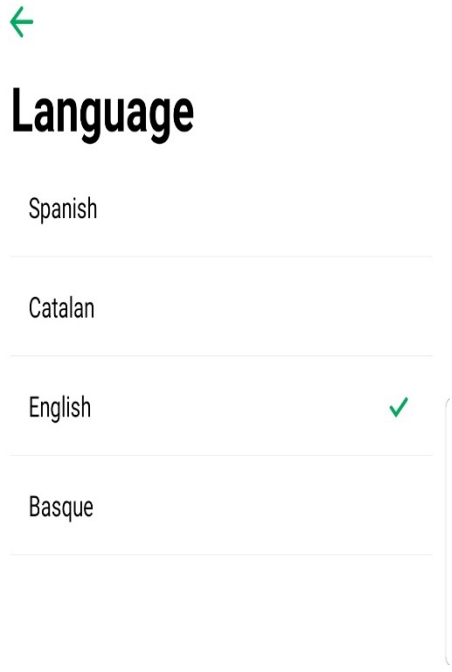
F. Marcadona – App information






Rebuenas
Hacendado Rebuena Chocolate filled Biscuits
Package 500 g | € 2,40/kg
€ 1,30 € 1,20 /unit
Add
Related products
MINI OREO
Chocominis


Hacendado Manzanilla olives st...
3 bottles x 150 g | € 6,00/kg
€ 2,70 /pack
Add
Related products
Manzanilla olives stuffed with anchovies Ha...
3 bottles x 50 g
€ 1,50 /pack
Add
Manzanilla olives stuffed with anchovies Ha...
Pot 350 g (150 g drain...
€ 0,90 /unit
Add
The product or pack shown may not be up-to-date. We recommend that you check the physical product to confirm the details about the product and allergens. For additional information, contact us at our customer service Freephone 800 500 220.


Language
Spanish
Catalan
English
Basque

Appendix 3: Summary Mandated Food Allergen in Digital Allergy Labeling Apps

	Name of Digital Apps	US Mandatory Food Allergen Detects	EU's Mandatory Allergen Detects	WHO's Codex Information
1	Eat This Much	8 allergens: milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanut, and soybeans Sesame is not on the list	8 allergens detected(US mandatory allergens)	Gluten is listed as a separate section, and sulphite information is listed in the food exclusion section but not in the allergen section.
2	AllergyEats	9 allergens detected: dairy, eggs, fish, shellfish, soy, tree nuts, wheat, peanuts and sesame	Celery, Mustard, suplhur, Lupin. Molluscs are not categorized separately. -but consumers can review the food menu individually.	Gluten is contained in the allergen section to screen.
3	Mealiime Meal Plans & Recipes	9 allergens: dairy, egg, fish, shellfish, peanut, tree nut, soy, gluten (instead of wheat)	Mustard are sulfite are screened	Gluten is listed in the allergen section.
4	SideChef	Allergen sections have 8 allergens listed: Gluten (Instead of Wheat), Dairy, Egg, Soy, Peanut, Tree Nut, Fish, and Shellfish.	EU's 14 allergens are not listed in the allergen section. However, the User controls to opt out of ingredients from the suggested.	Gluten is listed in the allergen section.
5	Tasty	In the allergen section, 2 allergens were detected: gluten and milk. However, manufactured food allergens can indirectly be detected in the US's mandatory allergens.	EU's 14 allergens are not separately categorized.	Gluten is listed in the allergen section.

6	Mercadona	Categories of food do not have a separate section for allergens. Among 26 categories, the consumers can check their favorite food items.	All products show the picture of the food label description. 14 EU allergens need to be read for alert.	Gluten cannot opt out by setting.
7	Cara Care: ODMAP, IBD, IBS Tr	Food choice does not have a separate section for allergy screening. Instead, Users can track individual food choices and their effect on the body.	**Lupin** is listed to screen in the allergen section.	It does not have any specific section for allergen screening.
8	Fig: Food Scanner & Discovery	All 9 allergens are screened.	In addition to 9 US-regulated allergens, Celery, Mustard, and Lupin are listed as screened allergens.	Not following WHO-required allergens for hypersensitivity.
9	mySymptoms Food Diary	All 9 allergens can be detected.	Depending on the Manufacturer's description	Depending on the Manufacturer's description
10	Open Food Facts	No special guideline: All 9 allergens can be detected.	Open source-voluntarily shared labeling information: Depending on the Manufacture's labeling information.	No Special guideline: open source-voluntarily shared labeling information: Depending on the Manufacture's labeling information.
11	Soose-Allergy, Vegan-Glute	All 9 allergens can be detected. (milk is listed under dairy product, egg is marked as the chicken egg. It does not specify wheat but in gluten)	Celery, Lupin, sulphur dioxides, and sulphites are listed as separate groups to be screened.	The Gluten section detects gluten from the label.

Appendix4: Summary of Precautionary Food Allergy Regulations in Digital Allergy Labeling Apps

	Name of Digital Apps	U.S. Voluntary Regulation-"Contain or May Contain"	Interaction with the food chef or food server (restaurant food)	EU's Reference Intake
1	Eat This Much	Does not recognize PAL allergen description	Not connected for interaction with food chef or food suppliers (but able to ask the ETM expert consulting individual meal plan and allergy concerns)	Information contained for each ingredient
2	AllergyEats	Can detect allergens from restaurants on the list	Can consult with restaurant chefs (by individual calling to the restaurant)	Completely opted out of concerned allergens (not having a section of reference dose)
3	Mealtime Meal Plans & Recipes	PAL for prepackaged food is not applied (but suggest with a warning symbol if an allergen may contain the suggested ingredients)	Listed chefs suggested meal plan/idea (not live discussion)	Each ingredient has a reference dose in general(but not for high-risk allergens)
4	SideChef	Among the suggested meal plan, pre-packaged food follows US PAL regulations (suggested ingredients for cooking do not have information on PAL)	NOT interacting, but individual users can opt out of unwanted ingredients from the suggested list.	Followed US system: nutrition per serving (NO reference dose for hypersensitive allergic reaction)
5	Tasty	NO specific PAL description for meal suggestion	Sharing own cooking recipes not specified for allergens	Followed US System: nutrition per serving (No Reference Does for hypersensitive allergic reaction)
6	Mercadona	Follow the PAL description from the food picture containing labeling information	Not applied (information is limited to packaged food)	Followed US System: nutrition per serving in the label(No

				reference does for hypersensitive allergic reaction)
7	Cara Care: ODMAP, IBD, IBS Tr	PAL is not applied (consumers can choose to opt-out in the default setting)	Interactive with the expert for alternative cooking ideas	Not specified for Reference Dose for hypersensitive allergic reaction
8	Fig: Food Scanner & Discovery	NOT separately set for the PAL section	NOT applied (only for prepackaged food with barcode information)	Not specified for Reference Dose for hypersensitive allergic reaction
9	mySymptoms Food Diary	Not separately set for the PAL section	Not applied (only for prepackaged food with barcode information)	Not specified for reference Dose for hypersensitive allergic reaction
10	Open Food Facts	Screened PAL description from Food allergy label	Can share allergen information with other users	Not specified for reference Dose for hypersensitive allergen reaction
11	Soose-Allergy, Vegan-Glute	Screened PAL description from Food Allergy Label	Not applied (only for prepackaged food with barcode information)	Not specified for reference Dose for hypersensitive allergen reaction

Appendix 5: Apps to be Covered for Pre-packaged Food or Ready-to-Eat Food

	Name of Digital Apps	Pre-Packaged Food	Ready-to-Eat Food (Restaurant or Bakery)
1	Eat This Much	Covered	Covered for suggested menu ingredients only (not restaurant or bakery)
2	AllergyEats	Not Covered	Covered (app guiding to call or check food menu of suggested restaurants)
3	Mealiime Meal Plans & Recipes	Covered (suggested ingredient connected to the food sold in retail stores including Albertsons, Safeway, Randalls, Tom Thumb, Jewel Osco, Instacart, Walmart, Kroger, HEB, Aldi, Giant Eagle, Hy-Vee, Meijer, Publix, Sprouts, Target and Amazon Fresh.	Cooking by app users by a suggested recipe (not Covered for restaurant or bakery)
4	SideChef	Covered for suggested pre-packed ingredients	Cooking by app users by a suggested recipe (not Covered for restaurant or bakery)
5	Tasty	Not-Covered for pre-packaged food (only food picture – not label information)	Cooking by app users by a suggested recipe (not Covered for restaurant or bakery)
6	Mercadona	Covered for Pre-Packed Food (pictures of labeling information)	Not covered (only for pre-packed food)
7	Cara Care: ODMAP, IBD, IBS Tr	Not covered for Pre-packed food	Cooking by app users following a suggested recipe (not covered for restaurant or bakery food)
8	Fig: Food Scanner & Discovery	Covered for pre-packed food	Covered (providing allergen information from the restaurant menu)
9	mySymptoms Food Diary	Covered for pre-packed food	Not covered for ready-to-eat food in restaurants or bakeries.
10	Open Food Facts	Covered for pre-packed food	Not covered for ready-to-eat food in restaurants or bakeries.
11	Soose-Allergy, Vegan-Glute	Covered for pre-packed food	Not covered for ready-to-eat food in restaurants or bakeries.

Appendix 6: Health information covered by HIPAA or General Information Privacy Protection Not Covered by HIPAA

	Name of Digital Apps	Health information	General Information(Collection, Store, Delete Rights)
1	Eat This Much	Diet type- allergic information, medical condition	Personal information- age, gender, weight, height, age, body fat
2	AllergyEats	Personal Allergy information	Personal information: Name, email address and password
3	Mealtime Meal Plans & Recipes	Allergy and Food restriction	Name, email address for sysm log phone number, payment information, Personal choice-ingrediets (dislike), favorit menu type,
4	SideChef	Allergy information, diet life style (high-feber, keto, low-calorie, low-carb, low-fat, low-salt, low-sugar, paleo, pescatarian, protein-packed, vegan, vegetarian)	4 categories of collecting personal data: visitors (no login required), registered users (login name, email address, no payment information), subscribers (name, email address, payment information), Content partners (name, email, personal recipes, cookbook, blog entries, payment information)
5	Tasty	Dietary Restriction	a.Account Data (Profile Data) - phone number, email b. Payment Data, purchase data, c. Purchase Data, d. Public Account Data e. Other Data-feedback, conuct search, post to community forum, participation in promotions
6	Mercadona	No requirement	a.Personal account information-name, email address; b. personal shopping information- personal order of products, quantity

7	Cara Care: ODMAP, IBD, IBS Tr	Health insurance, personal stress level, symptoms, digestion(heartburn, cramping, acid reflux, indigestion), tummy pain, bloated, medication taken, period, pain (headache, back, joint, muscles, injury, knee,bones, soreness)	a.Account contact information: contact form, email contact, b. favorie recipe
8	Fig: Food Scanner & Discovery	Diet information (Dairy-free, Egg-free), Allergy information	a.Account information-name, email address, b. scanned products, c) used restaurant information, c. Customer communication information,d. payment information, e. devicae information, f. location information-ip address, and zip code-physical location, g. camera access, h. user feedback
9	mySymptoms Food Diary	Dairy with clinician- allergy information, medication, exercise, supplement medicines, symptoms (nausea, vomiting, diarrhea, somach pain, headache, bloating, eczema, hayfever, asthma, heartburn, gas, and constipation)	a.Two categories of personal account: anonymous account, identified account
10	Open Food Facts	Nutrition quliaty (amount of salt, sugar, fat,satured fat) , allergen information, food processing, ingredients contained in food	Visit (IP., log, username, email address), contribution (country), scanning(IP address),
11	Soose-Allergy, Vegan-Glute	Allergy information	Account information (name, email address) , sanning-IP address

Appendix 7 : Listed Private Policy-Related Laws and Regulations under Each App Private Policy

	Name of Digital Apps	Listed Private Policy Law and Regulation (As of June 11,2024)
1	Eat This Much	The California Consumer Privacy Act of 2018 (“CCPA”) and other California privacy laws, The European Union’s General Data Protection Regulation (“GDPR”) and other European data protection laws
2	AllergyEats	any applicable privacy laws, including CAN-SPAM, Safe Harbor, PIPA, or other commercial privacy standards.
3	Mealtime Meal Plans & Recipes	f California, United States of America, according to "The California Consumer Privacy Act of 2018" (Users are referred to below, simply as “you”, “your”, “yours”), and, for such consumers, these provisions supersede any other possibly divergent or conflicting provisions contained in the privacy policy. This part of the document uses the term “personal information“ as it is defined in The California Consumer Privacy Act (CCPA)
4	SideChef	The California Consumer Privacy Act of 2018 (“CCPA”) and other California privacy laws, The European Union’s General Data Protection Regulation (“GDPR”) and other European data protection laws , the Children’s Online Privacy Protection Act, and US-EU and US-Swiss Privacy Shield and, in compliance with the Privacy Shield Principles
5	Tasty	The California Consumer Privacy Act of 2018 (“CCPA”) and other California privacy laws, The European Union’s General Data Protection Regulation (“GDPR”) and other European data protection laws
6	Mercadona	The Spanish Law Enforcement Forces and Agencies by virtue of the provisions set forth in the Law
7	Cara Care: ODMAP, IBD, IBS Tr	Health information Section listed as protection and insurance payment, the EU Data Protection Basic Regulation.
8	Fig: Food Scanner & Discovery	the Digital Millennium Copyright Act, 17 U.S.C. § 512 to confirm your obligations to provide a valid notice of claimed infringement, the laws of the State of California, the California Consumer Privacy Act
9	mySymptoms Food Diary	(i) in the UK including the retained EU law version of the General Data Protection Regulation ((EU) 2016/679) and the Data Protection Act 2018 (collectively the ‘UK GDPR’), and (i)

		and the Health Insurance and Accountability Act (‘HIPAA’) in the U.S. (“Applicable Data Protection Law”)
10	Open Food Facts	French Law, declared to the French commission "Computers and Freedom" (CNIL) under the number 1528436. Conforming to the French "Computers and Freedom" law (« informatique et libertés ») of January 6th 1978 and changed in 2004.
11	Soose-Allergy, Vegan-Glute	Listed that app does not collect any data, no network or no analytics