

Fresh from the Freezer: Exploring the “Knead” for Transparent Bread Labeling

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I. INTRODUCTION

Consider the stories of two bakers: Bryan, a small business owner, who has developed his affinity for baking into a livelihood, and Jim, an employee working in his local grocery store’s bakery department.

Bryan stumbles out of bed with the ringing of his 2:00 AM alarm still echoing in his ears. He rubs the fatigue from his eyes and begins to prepare for the day. Treading through the chilling night air, he arrives at the bakery doors. With the turn of a key, his daily routine begins. He starts up his industrial-sized oven; the roar of the massive baking machine overpowers the silence of the night.

He heads for his seventy-pound mixing bowl and pours in the warm water. Next, he delicately adds the yeast and stirs his mixture. The yeast begins its work as the murky water starts to foam. Next, Bryan wraps his arms around the bulky fifty-pound bag of flour. In an instant, he gracefully flings the bag onto his shoulder, slides over to the bowl, and watches as the flour tumbles into the yeasty water.

The dust cloud of flour descends around him as he continues to meticulously weigh the remaining ingredients: a few more pounds of flour, a handful or two of shortening, and just a scoop of salt. Bryan leans into the lever on his commercial mixer; the bowl slowly lifts from the ground, and the giant dough hook gradually vanishes into the mixture as it begins to rotate.

Over the next ten to fifteen minutes, the sticky concoction transforms into a smooth ball of dough. Bryan stops the mixer and thrusts his hand into the mass. The dough seeps between the gaps in his fingers.

Bryan takes his properly kneaded dough and heaves it onto his bench. His hands move like lightning as he slices the mountain of dough into loaf-sized pieces.

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Once he has transformed the fragments into loaves, they go into his proofer. There, they sit as the warm, humid conditions help them grow into fully formed loaves. Just before they go into the oven, Bryan takes a razor-sharp blade and pierces each one.

Now, hours after he began, the sun starts to rise over Bryan's city. Bryan removes a loaf from the oven. He slides it into a bag and places it on the shelf, ready to welcome people into his humble bakery. Finally, he prints out a label: "Fresh Bread \$3.99."

Next, consider Jim. He shuffles out of bed at 8 AM. He grabs his uniform and heads off to work in the bakery department of his local grocery store. Upon arriving, his first stop is the enormous walk-in freezer. He slogs deep into the frozen room and places some boxes on a cart. He pushes his cart full of cardboard over to an empty table to begin unpacking them.

One of the boxes is labeled "whole wheat bread." He tears it open. Jim removes something that looks more like a big, solid, brown ostrich egg than a loaf of bread. He lays it on the pan to thaw. Meanwhile, Jim sits down to relax. Once the loaf has thawed, Jim lets it rise and throws it in the oven.

Jim removes the finished product from the oven, lets it cool, and slides it into a bag. Finally, he prints out a label and affixes it: "Fresh Bread \$2.99."

Which loaf is "fresh"? Bryan's or Jim's? Technically, both are. However, according to the Food and Drug Administration's (FDA) regulation, food cannot be labeled as "fresh" if it was at any time frozen.¹ At first glance, this may lead one to believe that only Bryan's loaf could bear the label "fresh." Curiously, that is not the case. The FDA chooses not to apply this definition of "fresh" to bread because the term "fresh bread" is readily understood by the ordinary consumer as bread that just came out of the oven.²

FDA policies such as these continue to fall short of changing consumer expectations.³ And, to lead healthier lifestyles, modern consumers do not want to rely only on a word's ordinary meaning.⁴ Instead, consumers favor

1. 21 C.F.R. § 101.95 (2021).

2. *See id.*; Food Labeling: Definition of Terms, 58 Fed. Reg. 2302, 2403 (Jan. 6, 1993) (codified as amended at 21 C.F.R. § 101.95) (explaining that "the term 'fresh bread' does not imply that the food is unprocessed and in its raw state" because bread, by its nature, undergoes thermal processing).

3. *See* Nadia van der Colff et al., *Consumers' Prepurchase Satisfaction with the Attributes and Information of Food Labels*, 40 INT'L J. CONSUMER STUD. 220, 222 (2015). Modern consumers rely on a wide variety of factors when making purchasing decisions. These include past experiences, opinions of others, current promotions, and many other external considerations, *id.*, making it difficult for the FDA to continue to rely only on a word's ordinary meaning when establishing standards of quality. *See* Amy-Lee Goodman, *A "Natural" Stand Off Between the Food and Drug Administration and the Courts: The Rise in Food-Labeling Litigation & the Need for Regulatory Reform*, 60 B.C. L. REV. 271, 273-74 (2019).

4. Goodman, *supra* note 3, at 272-74.

transparent food labels to inform them about how manufacturers process food.⁵

The push toward increased transparency gradually arose in the United States from a desire to reduce the risk of obesity and its accompanying diseases.⁶ The COVID-19 pandemic reinvigorated this movement for healthier lifestyles.⁷ During the pandemic, as people have spent more time at home and in the kitchen, at-home baking has flourished.⁸

When baking at home, people have control over the ingredients they use and their method of preparation. In other words, people know exactly how they “processed” their final product. However, people often lack time to bake homemade, so they try to select comparable food options in the store. They look for production information on labels to find the foods that most closely resemble homemade processing.⁹ However, current FDA regulations regarding bread do not require producers to disclose the methods used to create the final product.¹⁰

The characteristics of bread change depending on the manufacturing process used.¹¹ Bread made from frozen dough is either a lower quality product or contains additives unknown to the consumer.¹² Yet, around the country, this type of bread is still labeled as “fresh.” As the above example

5. *Id.*

6. *Id.* at 283–84.

7. See Phil Lempert, *Food Trends Forecast 2021: Being Healthy in a Post Covid-19 World*, FORBES (Oct. 19, 2020, 12:46 PM), <https://www.forbes.com/sites/phillempert/2020/10/19/food-trends-2021-staying-healthy-in-a-post-covid-19-world/?sh=fb1a9e2485b3> [<https://perma.cc/GFH5-XH38>] (explaining how the COVID-19 pandemic has given people a new understanding of how what they eat affects their health and how shoppers yearn to understand what is in their food and from where it originated).

8. *Home Baking Is on the Rise, Thanks to Coronavirus Lockdowns*, ECONOMIST (Apr. 8, 2020), <https://www.economist.com/graphic-detail/2020/04/08/home-baking-is-on-the-rise-thanks-to-coronavirus-lockdowns> [<https://perma.cc/D94Q-VVFP>] (finding that searches for the DIY baking term “yeast” increased by 300% between March and April 2020, according to data retrieved from Google); see also Mary Ellen Shoup, *Home Baking Continues in 2021 Giving Rise to Comfort and Wellness Trends*, FOOD NAVIGATOR-USA (Mar. 22, 2021, 3:43 PM), <https://www.foodnavigator-usa.com/Article/2021/03/22/Home-baking-continues-in-2021-giving-rise-to-comfort-and-wellness-trends> [<https://perma.cc/CQZ5-AG3K>].

9. See Sergio Román et al., *The Importance of Food Naturalness for Consumers: Results of a Systematic Review*, 67 TRENDS FOOD SCI. & TECH. 44, 47 (2017) (finding that the production process is one of the key factors consumers consider when measuring “naturalness,” and how, according to consumers, less processing means more natural); Lauren Wicks, *Why It’s Actually Worth Buying Bread From a Bakery*, COOKINGLIGHT (Jan. 22, 2019), <https://www.cookinglight.com/eating-smart/nutrition-101/healthiest-bread-bakery-sugar-sodium> [<https://perma.cc/DK5M-QW45>].

10. See 21 C.F.R. § 136.110 (2021).

11. See *infra* Part III.B.

12. See *infra* Part III.B.

illustrates, when confronted with two loaves of bread, each labeled “fresh,” the rational consumer will purchase the cheaper option, wholly unaware that just hours before it was a frozen brick of dough. Armed with the full breadth of information, the consumer may make a different choice.¹³

This Comment will argue that labeling bread made from a frozen dough as “fresh” is misbranding under the Federal Food, Drug, and Cosmetic Act (FDCA) because such bread is either of a lower quality than truly fresh bread or contains additives not readily known to the ordinary consumer. Consumer demands for transparency and the continued mislabeling of frozen bakery products show that it is time for the FDA to establish a uniform standard for bread labeling in the United States. A uniform labeling requirement will provide consumers with the full breadth of information while allowing bread manufacturers to avoid costly litigation.

Part II explores how the history of food regulation in the United States has resulted in the legislature and courts going to great lengths to protect consumers’ safety, health, and well-being. Part III addresses the current FDA definition of “fresh,” its application to bread, and discusses how freezing affects the bread-making process. Finally, Part IV describes the need for further regulation regarding bread labels and provides a recommendation that will benefit bread producers and consumers. Part V briefly concludes.

II. HISTORY OF FOOD REGULATION IN THE UNITED STATES.

Modern food regulation results from over 100 years of adjustment to the increasingly industrialized food industry.¹⁴ When dangerous food products have brought about new crises, the federal power to regulate food has grown.¹⁵ Today, this growth means that consumers have come to rely on the federally regulated food labels to guide them in choosing which foods they purchase.¹⁶ When guidelines are unclear, consumers are left frustrated and confused.¹⁷ Section A of this Part explains the origins of food regulation in the United States and the Pure Food and Drug Act of 1906. Next, Section B discusses the Federal Food, Drug, and Cosmetic Act of 1938 and how its enforcement regulates food today. Finally, Section C explores how courts

13. See Goodman, *supra* note 3, at 283 n.61.

14. See RONALD HAMOWY, INDEP. INST., MEDICAL DISASTERS AND THE GROWTH OF THE FDA 2 (2010), https://www.independent.org/pdf/policy_reports/2010-02-10-fda.pdf [<https://perma.cc/2CHL-V56T>].

15. *Id.*

16. Andrea Maehara, *100% All Natural Ambiguity: A Comparative Approach to Food Labeling Requirements for the Term “Natural” by the Food and Drug Administration and the European Union*, 18 WASH. U. GLOB. STUD. L. REV. 263, 301 (2019).

17. *Id.* at 301–02.

have applied these acts to protect the public by removing misbranded products from the market.

A. *The Pure Food and Drug Act of 1906*

Today, the United States Food and Drug Administration is the Department of Health and Human Services agency responsible for regulating nearly everything Americans eat.¹⁸ The FDA employs over 18,000 employees and commands a budget of almost six billion dollars.¹⁹ However, food regulation in the United States started on a much smaller scale with one chemist in the Department of Agriculture, Harvey Washington Wiley.²⁰

Wiley grew up on a small farm in Indiana in the mid-1800s, where practically everything his family ate came from their farm.²¹ During the industrial revolution, he studied increasingly industrialized food production, which led to his appointment as the Division of Chemistry's chief chemist in the Department of Agriculture in 1882.²²

Under Wiley's direction, the Division of Chemistry became increasingly concerned with questionable food additives and their impact on health.²³ Wiley investigated and studied poisonous adulterants used as coloring and preserving agents, yet his reports received little public attention.²⁴ However, the public apathy towards food safety changed when Upton Sinclair published his 1906 book *The Jungle*, which exposed the horrors of the meatpacking industry.²⁵ As lobbyists began to push for federal reform, legislators introduced nearly 100 bills to Congress between 1879 and 1906 to regulate food and drugs.²⁶ These discoveries prompted Wiley to help draft the

18. *Fact Sheet: FDA at a Glance*, U.S. FOOD & DRUG ADMIN. (Nov. 18, 2020), <https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance> [<https://perma.cc/C24E-43KM>].

19. *Id.*; *How Many People Are Employed by FDA and in What Areas Do They Work?*, U.S. FOOD & DRUG ADMIN. (Jan. 8, 2021), <https://www.fda.gov/about-fda/fda-basics/how-many-people-are-employed-fda-and-what-areas-do-they-work> [<https://perma.cc/2SKA-7VYV>].

20. CLAYTON A. COPPIN & JACK HIGH, *THE POLITICS OF PURITY: HARVEY WASHINGTON WILEY AND THE ORIGINS OF FEDERAL FOOD POLICY* 3 (1999).

21. HARVEY W. WILEY, *AN AUTOBIOGRAPHY* 26 (1930).

22. See Anthony Gaughan, *Harvey Wiley, Theodore Roosevelt, and the Federal Regulation of Food and Drugs* 5 (2004) (unpublished manuscript), <https://dash.harvard.edu/bitstream/handle/1/8852144/Gaughan.pdf?sequence=1&isAllowed=y> [<https://perma.cc/7XXV-GZW7>].

23. Donna J. Wood, *The Strategic Use of Public Policy: Business Support for the 1906 Food and Drug Act*, 59 *BUS. HIST. REV.* 403, 405 (1985).

24. *Id.*

25. *Id.* at 403.

26. *Part I: The 1906 Food and Drugs Act and Its Enforcement*, U.S. FOOD & DRUG ADMIN. (Apr. 24, 2019), <https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/part-i-1906-food-and-drugs-act-and-its-enforcement> [<https://perma.cc/9MX9-6XQ8>].

Pure Food and Drug Act of 1906, which President Theodore Roosevelt signed into law on June 30, 1906.²⁷

Congress designed the Pure Food and Drug Act of 1906 to prevent “the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors.”²⁸ To do so, it provided the first definition for misbranding:

[T]he term ‘misbranded’ as used herein, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be *false or misleading in any particular*. . . .²⁹

Congress gave the Department of Agriculture the power to enforce the statute and promulgate other rules and regulations.³⁰ Wiley, as the head of the now renamed Bureau of Chemistry, was assigned these duties.³¹ However, differences between Wiley and the Secretary of Agriculture resulted in confusing policies that were difficult to enforce.³² Despite this confusion, food and drug regulation continued to grow in the United States; out of this regulation, the Bureau of Chemistry transformed into the modern FDA.³³

27. *Id.*; WILEY, *supra* note 21, at 226.

28. Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768, 768 (repealed 1938).

29. *Id.* at 770 (emphasis added).

30. *Id.* at 768–69.

31. *Part I: The 1906 Food and Drugs Act and Its Enforcement*, *supra* note 26. The Division of Chemistry was renamed the Bureau of Chemistry in 1901. See John P. Swann, *FDA's Origin*, U.S. FOOD & DRUG ADMIN. (Feb. 1, 2018), <https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/fdas-origin> [<https://perma.cc/YC8T-CWGX>].

32. See, e.g., Clayton Coppin, *James Wilson and Harvey Wiley: The Dilemma of Bureaucratic Entrepreneurship*, 64 AGRIC. HIST. 167, 177 (1990). Wilson attempted to restrain Wiley by establishing the Board of Food and Drug Inspection. *Id.* Wiley, despite being made chairman of the Board, took this as a personal affront and continuously attempted to undermine the other board members until his retirement five years later. *Id.* The most prominent dispute between Wiley and the Secretary of Agriculture revolved around the preservative benzoate of soda. *Id.* Before the passage of the Pure Food and Drug Act, Wiley had promised users of benzoate of soda that its usage would be permitted. *Id.* However, Wilson supported the Department outlawing its use in 1907. *Id.* For a detailed analysis of this disagreement which spanned from 1907 to 1912, see *id.* at 177–81.

33. See Swann, *supra* note 31. When regulation became a more centralized focus, the Bureau of Chemistry's name changed to the Food, Drug, and Insecticide Administration in 1927. *Id.* The name was shortened to the Food and Drug Administration three years later. *Id.* In 1940 the agency moved to the Federal Security Agency. *Id.* Then, in 1953, the agency moved again to the Department of Health, Education, and Welfare. *Id.* In 1980 the education function was dropped to create the Department of Health and Human Services, where the FDA currently resides. *Id.*

Despite the increase in regulation, widespread abuses of food packaging and quality persisted across the country.³⁴ To show Congress the need for stricter regulations, the FDA collected products that deceived the public or were outright dangerous to public health.³⁵ This collection became known as the American Chamber of Horrors because it brought to light all of the hazardous and deceptive food and drug products that escaped regulation under the 1906 law.³⁶

Finally, the tipping point came in 1937 when scientists discovered that sulfanilamide could treat streptococcal infections (strep throat or pneumonia).³⁷ In Tennessee, a pharmaceutical company was able to turn the drug into an elixir by mixing it with another compound.³⁸ The company shipped the elixir across the country without testing for toxicity.³⁹ When people began to die after ingesting the elixir, the FDA investigated and found that the compound used to turn the sulfanilamide into a liquid was diethylene glycol, a chemical commonly found in antifreeze and a deadly poison.⁴⁰ By the time the FDA could track down all of the elixirs, over 100 people had died, many of whom were children.⁴¹

34. *Part II: 1938, Food, Drug, Cosmetic Act*, U.S. FOOD & DRUG ADMIN. (Nov. 27, 2018), <https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/part-ii-1938-food-drug-cosmetic-act> [<https://perma.cc/S3YB-K2RF>].

35. *Id.*

36. *Id.* For example, plain noodles dyed yellow or wrapped in a yellow package and labeled as egg noodles; deceptive containers made of thick glass, elongated bottlenecks, or giant dimples in the bottom of some bottles; and giving items different names to avoid regulation, for instance, calling adulterated mayonnaise miracle whip. See RUTH DEFOREST LAMB, AMERICAN CHAMBER OF HORRORS 158, 160, 162–63 (1936), <https://archive.org/details/in.ernet.dli.2015.77374/page/n173/mode/2up?q=+> [<https://perma.cc/QS6A-7YTS>]; *The American Chamber of Horrors*, U.S. FOOD & DRUG ADMIN. (Jan. 30, 2018), <https://www.fda.gov/about-fda/histories-product-regulation/american-chamber-horrors> [<https://perma.cc/LYU6-46KC>].

37. HAMOWY, *supra* note 14, at 5.

38. *Id.* at 5–6.

39. *Id.* at 6.

40. *Id.*

41. FOOD & DRUG L. INST., A PRACTICAL GUIDE TO FDA'S FOOD AND DRUG LAW AND REGULATION 30 (Kenneth R. Piña & Wayne L. Pines eds., 6th ed. 2017). This tragedy resulted in the largest fine ever assessed under the Pure Food and Drug Act (\$24,600), and the chemist responsible ended up committing suicide. HAMOWY, *supra* note 14, at 7. It demonstrated the need for the FDA to require testing for safety *before* distribution to consumers. *Id.* at 9. In fact, the only reason the FDA was able to levy a fine against the Tennessee company was because the label “elixir” only applied if the solution contained alcohol and “Elixir Sulfanilamide” had none. FOOD & DRUG L. INST., *supra*.

B. The Federal Food, Drug, and Cosmetic Act of 1938

The sulfanilamide tragedy was the final push needed to get a new law through Congress, and on June 25, 1938, President Franklin D. Roosevelt signed the Federal Food, Drug, and Cosmetic Act.⁴² Through this act, Congress made it the mission of the FDA to “protect the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled.”⁴³

Given the 1906 law’s weaknesses, Congress purposefully extended the FDA’s authority to enforce the FDCA and imposed heightened penalties for disobeying the FDCA to ensure the law adequately protected the public.⁴⁴ This change allows the courts to consistently hold that the FDCA is not just a collection of words.⁴⁵ Instead, courts always interpret the FDCA with the underlying purpose of Congress in mind.⁴⁶ The FDA’s purpose under the FDCA is to protect members of the public who otherwise cannot defend themselves in an industrialized society.⁴⁷

To fulfill this purpose through the FDCA, Congress created the office of the commissioner of the FDA.⁴⁸ The commissioner works under the direction of the Secretary of Health and Human Services to ensure adequate enforcement of the Act.⁴⁹ Congress gave the FDA the power to regulate food quality and labels that producers introduce into interstate commerce.⁵⁰

Specifically, the FDCA provided that “[t]he Administration shall . . . protect the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled.”⁵¹ To accomplish this while ensuring public involvement in this process, Congress allows the FDA to promulgate regulations only after the public has had the opportunity to comment on the proposed regulation.⁵² In addition to these regulations, the FDA can also seize

42. Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–99i); see *Part II: 1938, Food, Drug, Cosmetic Act*, *supra* note 34.

43. 21 U.S.C. § 393(b)(2)(A).

44. *United States v. Dotterweich*, 320 U.S. 277, 280 (1943).

45. *Id.*

46. *See id.*

47. *Id.*; see also *Kordel v. United States*, 335 U.S. 345, 349 (1948) (“The high purpose of the [FDCA is] to protect consumers who under present conditions are largely unable to protect themselves in this field.”); *United States v. Sullivan*, 332 U.S. 689, 696 (1948) (stating that the FDCA protects consumers by applying its provisions to articles from the time they enter into interstate commerce until they are ultimately delivered to the consumer); *United States v. Bradshaw*, 840 F.2d 871, 874 (11th Cir. 1988) (stating that the overriding congressional purpose was to protect the public against misbranded or adulterated food, drugs, devices, or cosmetics).

48. § 393(d).

49. § 393(d)(2).

50. § 393(b)(2)(A).

51. *Id.*

52. § 371(e).

any adulterated or misbranded food and bring judicial actions to enforce the FDCA.⁵³

C. Misbranding Under the FDCA

One of the most potent tools Congress gave the FDA is the authority to police misbranded products. The FDCA provides that a food is misbranded if “its labeling is false or misleading in any particular.”⁵⁴ This language alone is identical to the language in the Pure Food and Drug Act of 1906, which producers continually abused.⁵⁵ Therefore, in the FDCA, Congress elaborated further on the term “misleading”:

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the articles to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.⁵⁶

In other words, the label must not only be clear on its face; it cannot omit critical details that could inform the ordinary consumer.⁵⁷ This definition envisions that a label can be misleading without being false.⁵⁸

When one combines such a definition with the explicitly announced purposes of the FDCA, the FDA can protect against labels that are likely to mislead even if they are technically truthful.⁵⁹ Thus began the FDA’s mission to police food labels to ensure consumers were purchasing what they believed they were buying.

When courts determine whether a food is mislabeled, they have not shied away from invoking the purpose of protecting the average consumer’s expectations. For example, one Supreme Court case in 1924 involved a manufacturer of apple cider vinegar who would dehydrate apples and then

53. See §§ 331–337.

54. § 343(a).

55. See *supra* notes 36–41 and accompanying text.

56. § 321(n).

57. *Id.*

58. *Van Liew v. United States*, 321 F.2d 664, 673 (5th Cir. 1963).

59. *Taylor v. United States*, 80 F.2d 604, 605–06 (5th Cir. 1935).

add water during the vinegar-making process so that it could still produce vinegar when apples were not in season.⁶⁰ The company subsequently labeled these vinegar bottles as “Sun Bright Brand apple cider vinegar made from selected apples.”⁶¹

During the trial, the district court judge tasted the vinegar from dehydrated apples and compared it to the vinegar made from apples without dehydration.⁶² He noted subtle differences in appearance and taste but concluded that both looked and tasted like apple cider vinegar.⁶³ Despite the two bottles of vinegar being nearly identical, the Supreme Court still held that labeling the apple cider vinegar made from dehydrated apples as “apple cider vinegar made from selected apples” constituted misbranding.⁶⁴

In doing so, the Court invoked the purpose of these consumer protection laws.⁶⁵ It determined that it made no difference whether the resulting vinegar from dehydrated apples was or was not inferior to apple cider vinegar.⁶⁶ The ordinary consumer would not expect an apple cider vinegar sporting that label to come from dehydrated apples.⁶⁷ In this case, the Court showed the strength of the purpose behind these misbranding laws; the quality of the resulting product is not necessarily a factor in determining what manufacturers should or should not include on a food label.⁶⁸

Moreover, courts have held that ordinary consumers should not be required to carefully analyze a product before purchasing it.⁶⁹ In Iowa, a company manufactured what it called a “fruit spread.”⁷⁰ This fruit spread was identical in appearance to jams, preserves, and other jellies.⁷¹ The manufacturer could not label these fruit spreads as jams because they

60. *United States v. Ninety-Five Barrels (More or Less) Alleged Apple Cider Vinegar*, 265 U.S. 438, 440 (1924).

61. *Id.* at 441.

62. *Id.* at 443.

63. *Id.*

64. *Id.* at 444–45.

65. *Id.* at 442–43.

66. *Id.* at 445.

67. *See id.* at 444.

68. *See id.* at 445.

69. *See United States v. 30 Cases, More or Less, Leader Brand Strawberry Fruit Spread, etc.*, 93 F. Supp. 764, 769 (S.D. Iowa 1950); *see also Libby, McNeill & Libby v. United States*, 210 F. 148, 150 (4th Cir. 1913) (holding that even if a label adheres with standards understood by the industry, a consumer is likely ignorant of that technical significance, meaning that when manufacturers use everyday words on a label, those words are given their ordinary popular meaning).

70. *30 Cases, etc.*, 93 F. Supp. at 766.

71. *Id.* at 767.

contained too much additional water to qualify as a “jam” under the existing regulation.⁷²

However, the Iowa district court did not entertain this circumvention.⁷³ Invoking the purposes behind the FDCA, the court concluded that Congress enacted the FDCA “to protect the public, the vast multitude which includes the ignorant, the unthinking, and the credulous who, when making a purchase, do not stop to analyze.”⁷⁴

The court held that the fruit spreads were misbranded because the ordinary consumer would believe them to be the same thing as a jam, and they were not, by definition, a jam.⁷⁵ Notably, the court conceded that consumers might have benefited from the sale of these fruit spreads since they were similar enough to jam and far less expensive.⁷⁶ Nonetheless, by classifying these actions as misbranding, the court showed that just because consumers may financially benefit when a company offers a less expensive option, the bargain cannot mask a reduction in quality.⁷⁷ The above examples demonstrate that when consumers are at risk of being confused or misled by a food label, the courts will protect consumer expectations even if the quality is the same or consumers save money.

III. THE FDA AND “FRESH BREAD”

Since the FDCA overwhelmingly aims to support consumers, the FDA has created specific guidelines that help producers avoid misbranding their products.⁷⁸ This Part begins with Section A, which discusses the FDA’s definition of “fresh” and its effect on the baking industry. Next, Section B explores the science behind bread and how freezing affects its production. Finally, Section C explores orange juice labeling requirements, how they compare to bread labeling requirements, and what they show about consumers’ expectations from the FDA.

72. *Id.* at 768. This case also demonstrates how the FDCA was used to close loopholes in the Pure Food and Drug Act of 1906. *Id.* Before the FDCA, companies would skirt regulation by calling a product by a different name; for example, see LAMB, *supra* note 36.

73. *30 Cases, etc.*, 93 F. Supp. at 770.

74. *Id.* at 769 (quoting *United States v. 62 Packages, More or Less, of Marmola Prescription Tablets*, 48 F. Supp. 878, 887 (W.D. Wis. 1943), *aff’d*, 142 F.2d 107 (7th Cir. 1944)).

75. *Id.* at 771.

76. *Id.*

77. *Id.*

78. *See generally* 21 C.F.R. pts. 1–190 (2021).

A. *The FDA Defines “Fresh”*

Considering Congress’s extensive efforts to protect consumers, producers may be left wondering what steps they can take to avoid having their products seized and condemned by the government. Anticipating this problem, Congress provided these guidelines to the FDA:

Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, [or] a reasonable standard of quality⁷⁹

Thus, since the enactment of the FDCA in 1938, the FDA has established many different guidelines to help protect consumers and ensure producers know how to label their products correctly.⁸⁰ Over the years, one term that confused consumers due to its continuous misuse was the label “fresh.”⁸¹ In 1993, due to this confusion, the FDA decided to set a reasonable standard of quality by defining the word “fresh.”⁸² Following a notice and comment process that produced numerous comments with very diverse views on the subject,⁸³ the FDA came up with this definition:

The term “fresh,” when used on the label or in labeling of a food in a manner that suggests or implies that the food is unprocessed, means that the food is in its raw state and has not been frozen or subjected to any form of thermal processing or any other form of preservation, except as provided in paragraph (c) of this section.⁸⁴

To accommodate the numerous comments regarding this definition, the FDA further clarified that this definition of fresh does not imply that all “fresh” food is unprocessed.⁸⁵ The regulation provides the example that milk producers can continue to label milk as “fresh” despite being pasteurized because consumers understand that milk is nearly always pasteurized.⁸⁶

When it comes to bakery items, the regulation is much less clear. In fact, when the FDA promulgated the regulation, the American Bakers Association

79. 21 U.S.C. § 341.

80. *See generally* 21 C.F.R. pts. 1–190 (2021).

81. Food Labeling: Definition of Terms, 58 Fed. Reg. 2302, 2401 (Jan. 6, 1993) (codified as amended at 21 C.F.R. § 101.95).

82. *Id.*

83. *Id.* at 2401–02.

84. 21 C.F.R. § 101.95 (2021). Paragraph (c) contains things like wax coatings, pesticides, mild chlorine washes, and treating food with approved ionizing radiation.

85. *Id.*

86. *Id.*

(ABA) was confused about how the definition would affect the baking industry.⁸⁷ Following the promulgation in 1993, various FDA officials interpreting the regulation told bakers to use the term “fresh baked” but not “fresh” if their bread contained a chemical preservative calcium propionate.⁸⁸ In the baker’s defense, the ABA brought various arguments explaining why bread should be labeled “fresh.”⁸⁹

The ABA’s primary argument was that “fresh bread” is commonly understood by the consumer and should be given the same exception to the regulation afforded to pasteurized milk or wax-coated vegetables.⁹⁰ The ABA relied on the dictionary, which includes “fresh bread” as an example under the definition of “fresh.”⁹¹ Eventually, in 2002, the ABA got clearance from the FDA to use the word “fresh” even if the bread contains the preservative calcium propionate.⁹²

A closer look at the FDA’s notice and comment process preceding the regulation in 1993 may have saved the ABA some time. Before officially publishing the rule, the FDA responded to concerns that the definition of “fresh” would be too narrow.⁹³ During that process, the FDA explained that the new definition of “fresh” would not apply to bread because “bread is not a food that exists in a raw state.”⁹⁴ Once informed of this exception in 2002, the ABA’s quarrel with the FDA over “fresh” came to an end.⁹⁵ Since the FDA’s clarification, bakers have broadly labeled bread as “fresh” over the past few decades.

Since this regulation’s promulgation nearly three decades ago, there have been relatively few challenges relying on this definition against things labeled “fresh.” This lack of litigation may be, in part, related to the structure of the FDCA. The FDCA does not allow private rights of action, meaning

87. Cindy Skrzycki, *FDA’s Fresh Stand on Rule Baffles Bakers*, WASH. POST (Oct. 15, 2002), <https://www.washingtonpost.com/archive/business/2002/10/15/fdas-fresh-stand-on-rule-baffles-bakers/56b5b1a4-5f85-4fb1-a6e7-692e71cd7738/> [<https://perma.cc/RNX2-B725>].

88. *Id.* Calcium Propionate is a commonly used food additive that the FDA has previously approved; it is added to baked goods to inhibit the growth of mold, thus extending the shelf life of these items. For more information about calcium propionate, see Ryan Raman, *What is Calcium Propionate, and Is It Safe?*, HEALTHLINE (Jan. 14, 2020), <http://healthline.com/nutrition/calcium-propionate> [<https://perma.cc/BS56-TX3K>].

89. *See* Skrzycki, *supra* note 87.

90. *Id.*

91. *Id.*; *see also* *Fresh*, MERRIAM-WEBSTER, <http://merriam-webster.com/dictionary/fresh> [<https://perma.cc/53M2-NAJT>].

92. *See* Skrzycki, *supra* note 87.

93. Food Labeling: Definition of Terms, 58 Fed. Reg. 2302, 2402 (Jan. 6, 1993) (codified as amended at 21 C.F.R. § 101.95).

94. *Id.* at 2403.

95. *See* Skrzycki, *supra* note 87.

consumers cannot bring claims under federal law when they feel they have been adversely affected by a label not meeting the federal standard.⁹⁶

Over the past decade, however, consumers have still felt deceived by bakery items advertised as “made fresh.”⁹⁷ They have had to rely on state laws and face enormous difficulties in bringing successful claims.⁹⁸ One class-action lawsuit failed because the plaintiffs could not allege particular signs and advertisements that had misled them when trying to prove that various bread and bakery items were frozen, even though the companies labeled them as “baked fresh in-store.”⁹⁹

Another class-action lawsuit failed when a California district court found that the plaintiffs lacked standing to bring a claim against various companies for unpurchased products incorrectly labeled as “made fresh.”¹⁰⁰ In that case, the court found it would have to make far too many contextual determinations concerning unpurchased products.¹⁰¹ These determinations included showing the products’ relative locations to the “made fresh” labels, the procedures used to prepare those products, and the type of product at issue.¹⁰²

These cases demonstrate just how vital FDA regulations are in ensuring that producers label foods correctly. Without an FDA regulation, consumers must rely on state consumer protection laws.¹⁰³ Some state consumer protection laws include various procedural hurdles that plaintiffs must overcome for a court even to allow the lawsuit.¹⁰⁴ These hurdles include complicated standing requirements and obligations to participate in alternative dispute resolutions before a plaintiff can file a complaint.¹⁰⁵ The United States may be the only party with the proper standing and resources to successfully bring a claim on behalf of consumers against bakeries who misuse the label “fresh.”

96. 21 U.S.C. § 337(a) (“[A]ll such proceedings for the enforcement, or to restrain violations of [the FDCA] shall be by and in the name of the United States.”).

97. See, e.g., *Mladenov v. Wegmans Food Mkts., Inc.*, 124 F. Supp. 3d 360, 367 (D.N.J. 2015); *Ang v. Bimbo Bakeries USA, Inc.*, No. 13-cv-01196-WHO, 2014 U.S. Dist. LEXIS 34443, at *32–34 (N.D. Cal. Mar. 13, 2014).

98. *Mladenov*, 124 F. Supp. 3d at 366–67; *Ang*, 2014 U.S. Dist. LEXIS 34443, at *33–34. For a discussion of why state law claims relating to food labeling face various complex legal hurdles, see April L. Farris, *The “Natural” Aversion: The FDA’s Reluctance To Define a Leading Food-Industry Marketing Claim, and the Pressing Need for a Workable Rule*, 65 FOOD & DRUG L.J. 403, 411–17 (2010).

99. *Mladenov*, 124 F. Supp. 3d at 367.

100. *Ang*, 2014 U.S. Dist. LEXIS 34443, at *33–34.

101. *Id.*

102. *Id.*

103. See Jennifer L. Pomeranz, *Litigation To Address Misleading Food Label Claims and the Role of the State Attorneys General*, 26 REGENT U. L. REV. 425, 435 (2014).

104. *Id.* at 435–36.

105. *Id.*

B. What Is Bread?

These recent challenges against bakeries suggest that, contrary to the ABA's assertions, perhaps "fresh bread" is not as commonly understood as it once was. One issue with the FDA's categorization of bread is that it rests on the premise that "bread" only exists once pulled from the oven.¹⁰⁶ Yet, bread's appearance, taste, and feel change depending on how the baker prepares it before it emerges from the oven.¹⁰⁷ When a company includes freezing in the process, it affects the resulting bread quality.¹⁰⁸

In 1993, when the FDA defined "fresh," it failed to consider the idea of bread in its raw state: dough.¹⁰⁹ Bread cannot be bread without first being dough.¹¹⁰ And the quality of the final bread depends heavily on what goes into the dough.¹¹¹ Therefore, any regulation about the quality of bread needs to account for the bread-making process.¹¹²

A basic bread formula consists of wheat flour, water, active dry yeast, salt, sugar, and margarine.¹¹³ Different ratios of these ingredients will produce various types of bread.¹¹⁴ Bread's extensive history and widespread cultural significance mean that hundreds of different kinds of bread exist worldwide.

Bakers mix, mold, proof, then bake the raw materials to turn these ingredients into bread.¹¹⁵ Each of the ingredients performs a critical role that makes bread unique in comparison to many other foods.¹¹⁶ The flour is responsible for the structure of the bread.¹¹⁷ When the flour mixes with water, two proteins, gliadin and glutenin combine to make gluten.¹¹⁸ Scientists still consider gluten one of the most complicated materials known.¹¹⁹

106. See Food Labeling: Definition of Terms, 58 Fed. Reg. 2302, 2403 (Jan. 6, 1993) (codified as amended at 21 C.F.R. § 101.95).

107. Cristina M. Rosell, *The Science of Doughs and Bread Quality*, in FLOURS AND BREAD AND THEIR FORTIFICATION IN HEALTH AND DISEASE PREVENTION 3, 5 (Victor R. Preedy et al. eds., 2011).

108. A. Le-Bail & D. Gabric, *Improving the Quality of Bread Made from Partially Baked, Refrigerated and Frozen Dough*, in BREADMAKING 661, 668 (Stanley P. Cauvain ed., 2d ed. 2012).

109. See Food Labeling: Definition of Terms, 58 Fed. Reg. at 2403.

110. See Virginia Giannou et al., *Quality and Safety Characteristics of Bread Made from Frozen Dough*, 14 TRENDS FOOD SCI. & TECH. 99, 100 (2003).

111. See *id.*

112. See *id.*

113. *Id.* at 100 tbl.1.

114. *Id.* at 100.

115. *Id.* at 101 fig.1.

116. *Id.* at 100–01, 104.

117. See *id.* at 100–01

118. *Id.* at 101.

119. K.H. Tipples et al., *Bread-Wheat Quality Defined*, in WHEAT PRODUCTION, PROPERTIES, AND QUALITY 25, 26 (W. Bushuk & V.F. Rasper eds., 1994).

Gluten's unique complex structure is what makes bread made from wheat flour so much more palatable than bread made from other flour substitutes.¹²⁰ This gluten structure gives dough the ability to stretch thin yet retain its shape while containing the yeast-created gasses.¹²¹

The yeast cells consume the sugars in the dough and produce carbon dioxide in the process.¹²² This carbon dioxide production gives most bread its volume.¹²³ In addition to enhancing volume, the yeast supports the gluten structure and is the source of baking bread's savory aroma.¹²⁴ Finally, water facilitates all of these processes.¹²⁵ It dissolves the salts and sugars, allowing the yeast to reach and consume the sugar.¹²⁶ Water is also responsible for activating the flour's proteins to make the gluten structure possible.¹²⁷ The science behind proper bread making requires skill and precision to craft a high-quality bread correctly.¹²⁸

Nowadays, restaurants, supermarkets, and catering businesses commonly use frozen bakery products worldwide.¹²⁹ The frozen products entered the market for good reason. Baking bread requires specially evolved skills and is very time and labor-consuming, and the resulting product has a relatively short shelf-life, often only a matter of days.¹³⁰ The introduction of frozen bakery products has allowed producers to meet consumer demands while reducing production expenses, resulting in a lower final product cost.¹³¹ However, the practicality of frozen bakery products comes with its own cost: a reduction in quality.¹³²

The freezing process affects many of the above-mentioned ingredients.¹³³ It decreases the yeast viability, resulting in a decrease in yeast gas

120. *Id.*

121. *Id.*

122. Giannou et al., *supra* note 110, at 101.

123. *Id.*

124. *Id.*

125. *Id.*

126. *Id.*

127. *Id.*

128. *See id.*

129. Virginia Giannou & Constantina Tzia, *Frozen Dough Bread: Quality and Textural Behavior During Prolonged Storage – Prediction of Final Product Characteristics*, 79 J. FOOD ENG'G 929, 929 (2006).

130. *Id.*

131. *Id.*; *see also* C.E. Stauffer, *Frozen Dough Production*, in *ADVANCES IN BAKING TECHNOLOGY* 88, 88 (B.S. Kamel & C.E. Stauffer eds., 1993).

132. *See* Abdelmagid Hamed et al., *Quality of Bread and Cookie Baked from Frozen Dough and Batter Containing β -Glucan-Rich Barley Flour Fraction*, 38 J. FOOD QUALITY 316, 316–17 (2015); Giannou & Tzia, *supra* note 129, at 929–30; Giannou et al., *supra* note 110, at 105.

133. Hamed et al., *supra* note 132, at 316–17; *see also* Giannou & Tzia, *supra* note 129, at 929–30; Giannou et al., *supra* note 110, at 105.

production.¹³⁴ The freezing also causes a build-up of ice crystals.¹³⁵ These ice crystals weaken the protein network and make the structure less capable of retaining carbon dioxide.¹³⁶ Overall, freezing results in a less stable dough.¹³⁷ The resulting bread can have a lower overall volume, a flattened top, and a courser internal structure.¹³⁸

To combat this deterioration, scientists alter standard bread recipes to include various additives and oxidizing agents to increase the final product's quality.¹³⁹ Thus, bread made from frozen dough is either of a lower quality or contains other additives when compared to its non-frozen counterpart.¹⁴⁰

C. Modern Labeling Techniques and Orange Juice

Manufacturers attempting to alter production methods of a preserved product to combat its lower quality is not a new practice in the food industry. For example, the American classic, orange juice, has also been subjected to alteration procedures.¹⁴¹ The dispute surrounding orange juice labeling offers an informative case study into modern society's concern for accurate food labels.¹⁴²

Unless orange juice is made directly by a store ("fresh-squeezed") and sold to a customer, the FDA requires that manufacturers process it in some way to maintain freshness.¹⁴³ The earliest such processing method involved using heat to pasteurize the juice.¹⁴⁴ Eventually, scientists discovered another technique that involved the creation of orange juice concentrate that, when

134. Giannou & Tzia, *supra* note 129, at 929–30 (finding that dough exhibited rapid deteriorating behavior in the first months of freezing then remained stable for at least nine months).

135. See Hamed et al., *supra* note 132, at 316.

136. *Id.*

137. See *id.* at 317.

138. *Id.* at 316.

139. *Id.* at 316–17 ("Examples of additives used in frozen dough and batter include soy ingredients, whey protein, polyols (sugar alcohol), carboxymethyl cellulose and gum Arabic, waxy wheat flour, locust bean gum, and xanthan gum."); see Xiangli Ding et al., *Effect of Barley Antifreeze Protein on Thermal Properties and Water State of Dough During Freezing and Freeze-thaw Cycles*, 47 *FOOD HYDROCOLLOIDS* 32, 32 (2015).

140. See Hamed et al., *supra* note 132, at 316–17.

141. Tove Danovich, *Is Your Juice Really 'Fresh'?*, *EATER* (Feb. 17, 2016, 2:30 PM), <http://eater.com/drinks/2016/2/17/11031894/what-is-fresh-juice-hpp-concentrate> [<https://perma.cc/B9PW-9NHG>].

142. See Goodman, *supra* note 4, at 273.

143. See U.S. FOOD & DRUG ADMIN., FDA-2002-D-0298, GUIDANCE FOR INDUSTRY: JUICE HAZARD ANALYSIS CRITICAL CONTROL POINT HAZARDS AND CONTROLS GUIDANCE (2004).

144. Danovich, *supra* note 141.

reconstituted, would taste just as good as “fresh” orange juice.¹⁴⁵ This discovery gave commercial orange juice producers three main options.¹⁴⁶ First, they can choose to pasteurize orange juice with heat.¹⁴⁷ Second, they can add water to orange juice concentrate to sell to consumers.¹⁴⁸ Third, they can sell the frozen concentrate directly to consumers.¹⁴⁹

Due to the strict FDA guidelines requiring processing, producers using each method wanted to label their products as “fresh” orange juice.¹⁵⁰ However, consumers complained that orange juice producers misused the term “fresh” by promoting commercially processed juice as “fresh.”¹⁵¹ To resolve this dispute, the FDA created independent, specific guidelines to protect producers and inform consumers.¹⁵²

First, the FDA required that producers heat-treating orange juice clearly label their juice as “pasteurized orange juice.”¹⁵³ Second, the FDA found it necessary to delineate between “frozen concentrated orange juice”¹⁵⁴ and “orange juice from concentrate.”¹⁵⁵ According to the FDA, “frozen concentrated orange juice” requires the consumer to add water at home to reconstitute the juice; “orange juice from concentrate,” on the other hand, is created when the manufacturer adds the water to reconstitute the juice before it is bottled and sold to the consumer.¹⁵⁶

With pasteurization and either type of concentrate method, the FDA requires that orange juice manufacturers label their products so that consumers know where it comes from and how it is made, regardless of any significant difference in quality.¹⁵⁷

The strict labeling requirements imposed on orange juice are an example of the modern trend of consumers being particularly concerned with how manufacturers make their food.¹⁵⁸ The nutritional properties of pasteurized

145. *Id.*

146. *Id.*

147. *Id.*

148. *Id.*

149. *Id.*

150. *Id.* For an in-depth discussion of the nature of this dispute, see ALISSA HAMILTON, SQUEEZED: WHAT YOU DON’T KNOW ABOUT ORANGE JUICE 50–72 (2009).

151. Warren E. Leary, *Citing Labels, U.S. Seizes Orange Juice*, N.Y. TIMES (Apr. 25, 1991), <https://www.nytimes.com/1991/04/25/us/citing-labels-us-seizes-orange-juice.html> [<https://perma.cc/KYU5-TSK8>].

152. 21 C.F.R. §§ 146.135–.154 (2021).

153. § 146.140.

154. § 146.146.

155. § 146.145.

156. §§ 146.145–.146.

157. *See id.*

158. *See* Goodman, *supra* note 4, at 273.

orange juice and concentrated orange juice are the same.¹⁵⁹ And “not from concentrate” orange juice often undergoes the same amount of processing as concentrated orange juice.¹⁶⁰ Although manufacturers claim that the processing is “natural,” consumers continue to bring lawsuits.¹⁶¹ Why? Because they want the label to tell them what the manufacturers do to their orange juice.¹⁶²

As obesity rates rise in the United States, consumers desire transparency in the food-making process to make informed decisions about their health.¹⁶³ Consumers continue to demand definitions that adhere to their basic expectations rather than the industries’ standards.¹⁶⁴ In line with consumer expectations, some studies suggest that people will even pay a premium for foods they consider healthier or more “natural.”¹⁶⁵

Moreover, consumers have become accustomed to relying on food labels when making decisions.¹⁶⁶ And recent history shows that consumers feel like the FDA is not adequately protecting their interests when they fail to issue formal rules regarding new labeling recommendations.¹⁶⁷ The lack of confidence in the FDA results from current FDA policies about food biotechnology, food irradiation, antibiotic use, and “natural” food claims not meeting consumer expectations.¹⁶⁸ In each of these instances, consumers continue to ask for clear guidelines, and the FDA fails to provide any.¹⁶⁹

159. Karen McCarthy, *Juice Nutrition: From Concentrate vs. Not from Concentrate*, LIVESTRONG (Oct. 11, 2019), <https://www.livestrong.com/article/397693-juice-nutrition-from-concentrate-vs-not-from-concentrate/> [<https://perma.cc/J26R-3DCF>].

160. Megan Griffith-Greene, *Orange Juice: Is ‘Premium’ Juice Actually More Natural?*, CBC (Jan. 16, 2015), <https://www.cbc.ca/news/business/orange-juice-is-premium-juice-actually-more-natural-1.2902004> [<https://perma.cc/29GJ-APMH>]. See generally HAMILTON, *supra* note 150 and accompanying text.

161. Griffith-Greene, *supra* note 160; Danovich, *supra* note 141.

162. Griffith-Greene, *supra* note 160; Danovich, *supra* note 141.

163. Goodman, *supra* note 4, at 272.

164. *Id.* at 313 & n.237 (citing Markham Heid, *Experts Say Lobbying Skewed the U.S. Dietary Guidelines*, TIME (Jan. 8, 2016), <http://www.time.com/4130043/lobbying-politics-dietary-guidelines/> [<https://perma.cc/7F6B-VKK6>]).

165. *Id.* at 283 n.61.

166. Maehara, *supra* note 16, at 301.

167. *Id.* at 275–77. For example, in a 2019 poll, 53% of people expressed only a “fair amount” of confidence in the federal government to ensure the safety of the food supply, and 32% had “not much” or no confidence at all. *Gallup Historical Trends: Nutrition and Food*, GALLUP, <https://news.gallup.com/poll/6424/nutrition-food.aspx> [<https://perma.cc/RBL2-EJWV>].

168. For a summary of the misalignment between FDA policies and consumer expectations, see Brett M. Paben, *Lack of Interest in Consumer Interests: FDA’s Narrow Perspective on Food Labeling and Label Statements Undermines a Century of Agency Leadership*, 13 RUTGERS J.L. & PUB. POL’Y 174, 178–86 (2015).

169. *Id.*

Additionally, some corporations facing lawsuits over labeling disputes have become increasingly vocal in asking the FDA to issue clear guidelines.¹⁷⁰ With Americans consuming hundreds of millions of loaves weekly, bread is even more of a staple than orange juice; it follows that Americans will be even more concerned over the proper labeling of bread than orange juice.¹⁷¹

IV. ANALYSIS & RECOMMENDATION

The FDA must set specific bread labeling guidelines to prevent the continued misbranding of bread made from frozen dough. Clear and concise labeling requirements have benefited both producers and consumers in the past.¹⁷² They help consumers make informed decisions and help producers reduce liability.¹⁷³ The confusion surrounding the FDA's definition of "fresh" as it applies to bakery items has left consumers not fully aware of what they are buying when purchasing various bakery items labeled "fresh." Section A of this Part begins by addressing the shortcomings of the FDA's current understanding of "fresh" related to bread. Section B explains why the consumer is in the best position to choose between fresh bread and bread made from frozen dough. Section C discusses how stricter guidelines from the FDA will also benefit producers by helping them avoid future litigation. Section D looks to Europe's method of handling frozen food labels by requiring descriptive terms to accompany words like "fresh." Lastly, Section E provides a recommendation that would require adding a few words to each label, thus giving the consumer the most straightforward choice when purchasing bread.

170. Maehara, *supra* note 16, at 291–92.

171. See *U.S. Population: Usage of Bread from 2011 to 2024*, STATISTA (July 2, 2021), <https://www.statista.com/statistics/281971/us-households-usage-of-bread-trend/> [<https://perma.cc/UN9Y-EQDC>] (exhibiting that ~98% of Americans reported consuming bread in 2020); Charlotte Atchly, *Three Bread Trends Shaping American Diets*, WORLD-GRAIN.COM (Sept. 21, 2017), <https://www.world-grain.com/articles/8702-three-bread-trends-shaping-american-diets> [<https://perma.cc/8CEP-3CL7>] (noting that, in 2017, Americans consumed around thirty-seven pounds of bread per capita); see also *Orange Juice Domestic Consumption in the United States from 2008/09 to 2020/21*, STATISTA (Sept. 14, 2021), <https://www.statista.com/statistics/297320/us-fruit-juice-consumption/> [<https://perma.cc/HYF9-HV8F>] (tracking a sharp decline in orange juice consumption in the U.S. since 2008).

172. Maehara, *supra* note 16, at 302.

173. *Id.* at 301–02.

A. A “Common” Understanding of Bread

When the FDA defined “fresh” in 1993, it based its reasoning for exempting bread on two premises, both of which are no longer valid.¹⁷⁴ First, during the notice and comment process, the FDA emphasized that the definition of “fresh” cannot apply to bread because “bread is not a food that exists in a raw state.”¹⁷⁵ Neither the FDA’s comments nor arguments from the ABA acknowledge dough as bread in its raw state.¹⁷⁶ Bread cannot exist without first being dough, and the quality of that dough will have a distinct effect on the resulting bread.¹⁷⁷ Therefore, the FDA has yet to fully address how labeling requirements relate to bread made from frozen dough.

Second, the FDA’s definition of “fresh” acknowledges that some “fresh” foods may still be processed or preserved.¹⁷⁸ Speaking on behalf of bakers, the ABA argued that the average consumer commonly understands the term “fresh bread” as the product she buys at the bakery regardless of how the baker made it.¹⁷⁹ Perhaps the FDA confirmed this statement in 1993; yet, modern trends show that consumers are concerned, not just with the ingredients in the food, but also with transparency in the labeling process.¹⁸⁰ As mentioned above, consumers have attempted at least two class-action lawsuits against the baking industry seeking to achieve transparency regarding labeling.¹⁸¹

The average consumer has no way of knowing just by looking at the product which bread, if any, came directly from dough and which has been frozen. The bread that originates from the frozen dough will either be a lower quality bread or be filled with additives to counter the freezing process’s adverse effects.¹⁸² The difference is meaningful and warrants disclosure to the public on the label.

When all bread bears the label “fresh,” whether or not it originates from frozen dough, the modern consumer may be misled into paying more for a bread he or she believes is “fresh” despite the presence of additives needed in frozen dough.¹⁸³ The modern consumer confusion, along with the FDA’s previously misunderstood ideas about the nature and science of bread, signals

174. *See supra* notes 86–96 and accompanying text.

175. Food Labeling: Definition of Terms, 58 Fed. Reg. 2302, 2403 (Jan. 6, 1993) (codified at 21 C.F.R. § 101.95).

176. *Id.*

177. *See supra* notes 110–128 and accompanying text.

178. 21 C.F.R. § 101.95 (2021).

179. *See* Skrzycki, *supra* note 87.

180. For a summary of the modern trends, *see supra* notes 158–171.

181. *See supra* notes 97–105 and accompanying text.

182. *See supra* notes 132–140 and accompanying text.

183. *See* Goodman, *supra* note 4, at 283 n.61.

a need for further clarification regarding what bakery items bakers are allowed to label as “fresh.” Such clarification would help consumers make an informed choice about the food they are purchasing.

B. Letting the Consumer Make the Choice

Consumers should be afforded the choice between paying more for bread that is genuinely fresh or paying less for bread that was simply baked from frozen dough. Even if one assumes the bread’s quality is unchanged by the freezing process, consumers should decide for themselves, armed with the full breadth of information regarding the product’s history.

The FDA has signaled a willingness to enact such a regulatory scheme; it has already done so with orange-juice products.¹⁸⁴ Consumers can choose to buy frozen orange-juice concentrate, orange juice from concentrate, pasteurized orange juice, or fresh-squeezed orange juice. Despite scientists finding no difference in nutritional value or quality, the FDA determined that the label should provide the consumer with the full breadth of information regarding its processing.

Similarly, a consumer can choose to buy frozen dough¹⁸⁵ and bake it herself at home, buy bread baked by a manufacturer that started as frozen dough, or buy fresh bread. The issue, however, is that the bread labels are not required to provide the same breadth of information as are orange-juice labels. Orange-juice manufacturers include—on the label—information about who added the water and how they processed the juice despite no change in the nutritional value or quality. Bread manufacturers should provide consumers with the same information about who applied the heat to their dough and how it is processed when those methods *do* change the quality of the final bread product.

Producers can better meet consumer expectations of transparency by allowing consumers to make an informed choice.¹⁸⁶ Modern consumers value transparency in labeling—this transparency often guides their purchasing

184. See *supra* notes 143–157 and accompanying text.

185. See, e.g., RHODES BAKE N SERV, <https://rhodesbakenserv.com/> [<https://perma.cc/A5AX-5EAV>].

186. LABEL INSIGHT, HOW CONSUMER DEMAND FOR TRANSPARENCY IS SHAPING THE FOOD INDUSTRY 6 (2016), https://www.labelinsight.com/hubfs/Label_Insight-Food-Revolution-Study.pdf [<https://perma.cc/M3PH-AQNV>] (finding that 94% of people surveyed want more transparency from manufacturers and 83% would value more in-depth product information).

decisions.¹⁸⁷ Not only does transparent labeling increase brand loyalty, but consumers will pay more for this transparency.¹⁸⁸ Stricter labeling requirements mean that bread manufacturers producing truly fresh bread will gain increased loyalty to their brand and can justify higher prices for a higher quality product.

Producing truly fresh bread is often more expensive than using frozen dough.¹⁸⁹ Armed with an informed choice, consumers can choose to compensate those producers—often small businesses—that elect to invest the labor and skills needed to craft a higher quality fresh bread.¹⁹⁰ In addition to encouraging investment in the smaller businesses, stricter guidelines will also benefit larger bread producers by limiting potential liability.

C. *Strict Labeling Requirements Protect Producers*

Finally, even if the FDA declines to provide more straightforward labeling guidelines, companies should nonetheless be wary of labeling bread from a frozen dough as “fresh” to avoid potential liability for misbranding. The FDA has noted that just because the new definition of “fresh” may not apply to particular food items, the FDA retains the authority to determine on a case-by-case basis if using the term “fresh” on a food item is false or misleading under the FDCA.¹⁹¹ And the FDCA jurisprudence shows that labeling bread from frozen dough the same as fresh bread constitutes misbranding.

When confronted with apple cider vinegar made from fresh and dehydrated apples nearly identical in taste and appearance, the Supreme Court still relied on the purpose of these consumer protection laws to draw an essential distinction between the two types of vinegar.¹⁹² It declared the

187. *Id.* at 9; see Keith Nunes, *Consumers Expectations Moving Beyond the Label*, FOOD BUS. NEWS (Dec. 10, 2019), <https://www.foodbusinessnews.net/articles/14977-consumer-expectations-moving-beyond-the-label> [<https://perma.cc/Z2XU-BZSS>].

188. *Product Labels Still Not Meeting Consumer Expectations for Clarity*, NUTRACEUTICALS WORLD (Sept. 22, 2020), https://www.nutraceuticalsworld.com/contents/view_breaking-news/2020-09-22/product-labels-still-not-meeting-consumer-expectations-for-clarity/ [<https://perma.cc/QZ73-SDYR>]; Goodman, *supra* note 4, at 283 n.61; *Gallup Historical Trends*, *supra* note 167 (finding that 64% of people surveyed would pay more for products labeled “natural”).

189. See Giannou & Tzia, *supra* note 129, at 929.

190. See, e.g., Jim Woodruff, *Baking Industry Analysis*, CHRON (Mar. 19, 2019), <https://smallbusiness.chron.com/bakery-industry-analysis-64831.html> [<https://perma.cc/RUK5-ZKVG>].

191. Food Labeling: Definition of Terms, 58 Fed. Reg. 2302, 2403 (Jan. 6, 1993) (codified at 21 C.F.R. § 101.95).

192. See *United States v. Ninety-Five Barrels (More or Less) Alleged Apple Cider Vinegar*, 265 U.S. 438, 442–43 (1924). For a more in-depth analysis of this case, see *supra* notes 60–68 and accompanying text.

vinegar made from the dehydrated apples was misbranded even though it was not inferior to the vinegar made from the fresh apples.¹⁹³ Similarly, manufacturers of frozen dough can alter it to resemble bread made from scratch.¹⁹⁴ The ordinary consumer would not expect a product labeled as “fresh bread” to have come from a frozen brick of dough, just as consumers did not expect vinegar “made from fresh apples” to have come from dehydrated apples.¹⁹⁵ These consumer expectations are what the FDCA aims to protect.¹⁹⁶

Furthermore, simply because the frozen dough has resulted in a reduced final product cost,¹⁹⁷ the consumer’s financial benefit is not a justification for falsely mislabeling products. When the district court in Iowa faced watered-down jam masquerading as fruit spread, the fact that the “fruit spread” was considerably less expensive than regular “jam” was not sufficient to allow the company to mislead consumers into buying a product that was not, by law, “jam.”¹⁹⁸ Similarly, the advent of frozen dough has allowed the baking industry to keep the final purchase price low while keeping up with increased consumer demands.¹⁹⁹ However, the consumer’s financial benefit should not be enough to allow these industries to mask their products’ origin and content. Even if the consumers are saving money, and even if the quality were equal, labeling a bread made from a frozen dough as “fresh” is still misleading and confusing.

The likelihood of consumers attempting to bring a lawsuit against bread manufacturers has also increased in the last decade.²⁰⁰ The lack of uniform food labeling standards across the country has led to a movement of “regulation by litigation.”²⁰¹ When the FDA steps in and exercises its power to establish uniformity in the market, the judicial branch tends to defer to the

193. *Ninety-Five Barrels*, 265 U.S. at 445.

194. See Stauffer, *supra* note 131, at 88–95.

195. *Ninety-Five Barrels*, 265 U.S. at 444.

196. 21 U.S.C. § 321(n).

197. See Stauffer, *supra* note 131, at 88.

198. *United States v. 30 Cases, More or Less, Leader Brand Strawberry Fruit Spread, etc.*, 93 F. Supp. 764, 767 (S.D. Iowa 1950).

199. See Stauffer, *supra* note 131, at 88; Michelle Smith, *Bread Is on a Roll*, FOOD BUSINESS NEWS (Aug. 11, 2021), <https://www.foodbusinessnews.net/articles/18685-bread-is-on-a-roll> [<https://perma.cc/JY9R-KGC9>].

200. NICOLE E. NEGOWETTI, BROOKINGS, FOOD LABELING LITIGATION: EXPOSING GAPS IN THE FDA’S RESOURCES AND REGULATORY AUTHORITY 1 (Christine Jacobs & Beth Stone eds., June 2014), https://www.brookings.edu/wp-content/uploads/2016/06/Negowetti_Food-Labeling-Litigation.pdf [<https://perma.cc/M6K6-SWPC>]; Paben, *supra* note 168, at 175.

201. NEGOWETTI, *supra* note 200, at 1.

FDA to avoid overstepping the FDA's authority to execute the law.²⁰² This deference to the FDA provides an avenue for food manufacturers to avoid costly lawsuits by adhering to the FDA standard.

D. Europe's Solution to Frozen Food Labeling

The best way to protect the consumer's interests and protect the producers from further litigation would be to alter current regulations and set a uniform standard for the country.²⁰³ Some already consider the United States behind the times when it comes to regulating ingredients allowed in bread.²⁰⁴ Many additives still allowed in bread in the United States have been outlawed in other countries.²⁰⁵ Regarding labeling, the European Union has issued guidelines outlining, for its member countries, mandatory descriptive terms that should accompany the name of the food:

(1) The name of the food shall include or be accompanied by particulars as to the physical condition of the food or the specific treatment which it has undergone (for example, powdered, refrozen, freeze-dried, quick-frozen, concentrated, smoked) in all cases where omission of such information could mislead the purchaser.

(2) In the case of foods that have been frozen before sale and which are sold defrosted, the name of the food shall be accompanied by the designation 'defrosted.'

This requirement shall not apply to the following:

- (a) ingredients present in the final product;
- (b) foods for which freezing is a technologically necessary step of the production process;

202. Glenn G. Lammi, Wash. Legal Found., *FDA Action Should Take the Juice out of Some Food Labeling Class Actions*, FORBES (Mar. 4, 2014, 2:08 PM), <https://www.forbes.com/sites/wlf/2014/03/04/fda-action-should-take-the-juice-out-of-some-food-labeling-class-actions/?sh=40ca75e64098> [https://perma.cc/B99Y-7GBW] (providing examples from then-ongoing litigation involving "evaporated cane juice" of how courts dismissed plaintiff's lawsuits once the FDA started its administrative proceedings).

203. See NEGOWETTI, *supra* note 200, at 2.

204. Troy Farah, *Banned Bread: Why Does the US Allow Additives That Europe Says Are Unsafe?*, GUARDIAN (May 28, 2019, 2:00 AM), <https://www.theguardian.com/us-news/2019/may/28/bread-additives-chemicals-us-toxic-america> [https://perma.cc/YU2D-HRG6].

205. Examples of these additives include Potassium Bromate, an oxidizer that helps the bread rise, and Azodicarbonamide, a chemical used to bleach and leaven dough. *Id.* Both chemicals are still allowed and used in the United States despite causing cancer to lab animals in studies. *Id.*

(c) foods for which the defrosting has no negative impact on the safety or quality of the food.

This point shall apply without prejudice to point 1.²⁰⁶

In other words, the European Union’s guidelines provide that when producers include on the label the specific treatment the food has undergone, it reduces the likelihood that the label will mislead the consumer. These guidelines specifically mention various types of freezing that need to be disclosed if such freezing affects the safety or quality of the final product.

For example, in 2018, Italy promulgated a regulation that applied the European Union’s descriptive terms to bread.²⁰⁷ The Italian regulation specifies that bread may only be labeled “fresh” “if the entire ‘continuous’ production—except the leavening process—does not take more than 72 hours from start to sale to the customer.”²⁰⁸ Italy crafted the new regulation to help small and medium businesses add value to their products and keep Italian consumers fully informed.²⁰⁹ This type of specific regulation from the European Union has allowed its courts to easily classify “fresh bread.”²¹⁰

By drafting a new regulation, using the European Union regulation as a guideline, the FDA would allow bakers to continue to label their bread as “fresh” while conforming with the FDCA’s intended purpose to protect consumers from misleading product labels. As the regulation currently stands, consumers have no way of knowing what type of bread they are buying when they pick out a loaf of “fresh bread.” A requirement that manufacturers must label bread according to the specific treatment it has undergone would remove this confusion.

206. Regulation 1169/2011, of the European Parliament and of the Council of 25 October 2011 on the Provision of Food Information to Consumers, annex VI, 2011 O.J. (L 304) 18, 48.

207. Gill Hyslop, *Italy Enforces Fresh Bread Labeling Law*, BAKERYANDSNACKS (Dec. 19, 2018, 8:44 AM), <https://www.bakeryandsnacks.com/Article/2018/12/18/Italy-enforces-fresh-bread-labeling-law> [<https://perma.cc/DDN9-SK7D>].

208. *Id.*

209. *Id.*

210. A review of EU case law from 2011–present fails to disclose any opinion in which the court had trouble interpreting the regulations governing the labeling of “fresh bread.” Additionally, these guidelines were not met with much controversy in the EU as they had a basis in older cases. See, for example, Case C-416/00, *Morellato v. Comune di Padova*, 2003 E.C.R. I-9343. In this case, a judge ruled that companies must relabel and separate “fresh bread” from bread made from partially baked dough. *Id.* The case offered no discussion of whether or not partially baked bread qualified as “fresh bread;” instead, it simply assumed that bread made from partially baked dough did not qualify as “fresh.” *Id.*

E. Recommendation

The FDA is the leading food regulatory agency in the United States and is responsible for removing confusion surrounding food labels.²¹¹ Yet its policies continue to come up short of consumer expectations.²¹² This Section provides a guideline for the FDA and producers to follow to avoid bread’s continued misbranding. Also, this Section discusses the importance of considering the food industry’s interests whenever crafting new labeling guidelines.

1. The Recommendation

The FDA should require producers of bread to label their products as follows:

Table 1: Proposed Labeling Requirements

Descriptive Term	Application
“Fresh”	Bakery items that are mixed, molded, leavened, baked, and packaged without any additional processing.
“Defrosted”	Bakery items that are frozen following the baking process, then thawed and sold to customers.
“Baked Fresh from Frozen Dough” <i>or</i> “Thawed then Freshly Baked”	Bakery items made from dough or another batter that has been frozen.

a. Fresh

This recommendation is based on the average consumer’s understanding of the word “fresh.” As Americans continue to lead healthier lifestyles, words like “fresh” or “natural” are the most influential words found on a label.²¹³ As such, consumers purchasing bread labeled “fresh” should be confident that the purchased bread is as fresh as it would be if they made it themselves.

The proposed recommendation also has the benefit of administrative efficiency. The current FDA regulation defining “fresh” already sets the

211. See *Fact Sheet*, *supra* note 18.

212. Paben, *supra* note 168, at 178–86.

213. INT’L FOOD INFO. COUNCIL, 2020 FOOD & HEALTH SURVEY 60 (2020), <https://foodinsight.org/wp-content/uploads/2020/06/IFIC-Food-and-Health-Survey-2020.pdf> [<https://perma.cc/BW9B-NLB3>].

standard that fresh food should be, for the most part, unprocessed.²¹⁴ Therefore, all that the FDA would need to do to implement this recommendation would be to reinterpret its own rule and stop exempting bread from its definition of “fresh.” Suppose the FDA wished instead to engage in the formal rulemaking process. In that case, a description of “fresh” could be explicitly crafted with bread in mind, including a time restriction similar to the Italian regulation.²¹⁵

b. Defrosted

This recommendation follows the example of the European Union regulation.²¹⁶ When Italy promulgated stricter bread labeling requirements, it did so, in part, to help those small and medium-sized businesses that choose to continue to provide consumers with genuinely fresh products.²¹⁷ It does this by forcing producers to be more transparent with their labels. The term “defrosted” acts as a window into the manufacturing process. It allows consumers to know more about how their bread was processed just by looking at the label.

If the FDA only defines “fresh,” then bakeries using frozen items will merely avoid the word “fresh” while continuing to mask their production methods. The inclusion of a “defrosted” labeling requirement compels those who sell frozen products to be upfront about their processing methods. This recommendation is one step towards satisfying growing consumer demand for increased transparency.²¹⁸

c. Baked Fresh from Frozen Dough or Thawed then Freshly Baked

This recommendation acknowledges that given the widespread use of frozen dough in the baking industry today, it may be unrealistic to ask that everyone remove “fresh” entirely from the label. After all, as the ABA pointed out in the early 2000s, “fresh bread” is the dictionary’s example of

214. The current regulation states that food cannot be subject to “any form of thermal processing.” 21 C.F.R. § 101.95(a) (2021). Technically speaking, the baking of the bread itself could be considered a thermal process. It could be argued that it would be impossible to make bread in a way that conforms with the current regulation. However, consumers commonly understand that dough is “treated” with heat to become bread, thus still allowing the other provisions of the regulation to apply to bread labels. *Id.*

215. Hyslop, *supra* note 207.

216. Regulation 1169/2011, of the European Parliament and of the Council of 25 October 2011 on the Provision of Food Information to Consumers, annex VI, 2011 O.J. (L 304) 18, 48.

217. Hyslop, *supra* note 207.

218. INT’L FOOD INFO. COUNCIL, *supra* note 213, at 20 (finding that half of Americans want to know if manufacturers process their food and 43% say that processing methods have a more significant impact on their purchasing decision now than they did ten years ago).

“fresh.”²¹⁹ And some bakers using frozen dough may still believe they are providing a “fresh” product.

Instead of banning the word “fresh” altogether from these items, this recommendation aims to allow producers to continue to use the word “fresh.” However, it also provides the consumer with crucial information about how producers treat the dough before it becomes bread. As with the European Union regulation, this recommendation is not setting a strict definition; instead, it lets consumers know what “specific treatment [the bread] has undergone” and leaves it to them to choose which bread to purchase.²²⁰

1. Implementation

Implementing such regulations would empower the public with the information necessary to make a fully informed decision when choosing which breads to purchase. In addition to helping consumers, producers could make the small change of adding a few words to a label to avoid the movement of regulation by litigation.

This proposal requires only a small effort from the producers. Admittedly, however, it involves the imposition of yet another regulatory barrier for an already heavily regulated market. Despite the added regulation, this change is advantageous because the baking industry will benefit from increased transparency resulting in increased consumer loyalty and fewer labeling-related lawsuits.

The food industry spends millions of dollars every year lobbying Congress to avoid these barriers.²²¹ While this lobbying is generally successful, recent cultural changes have caused consumer advocacy groups to push back with hundreds of class-action lawsuits against the food and beverage industry.²²² When the FDA sets a national standard, courts tend to dismiss some of these lawsuits in favor of Congress’s attempts to establish uniformity.²²³

Enacting a uniform national standard is the most efficient way to guarantee that the labels fulfill the purpose of clearly and accurately informing

219. See *supra* note 91 and accompanying text.

220. Regulation 1169/2011, of the European Parliament and of the Council of 25 October 2011 on the Provision of Food Information to Consumers, annex VI, 2011 O.J. (L 304) 18, 48.

221. *Industry Profile: Food & Beverage*, OPENSECRETS, <https://www.opensecrets.org/federal-lobbying/industries/summary?cycle=2019&id=N01> [<https://perma.cc/PPR2-WSH8>].

222. NEGOWETTI, *supra* note 200, at 1.

223. Lammi, *supra* note 202.

consumers.²²⁴ In pursuit of uniformity, Congress amended the FDCA to include a preemption provision regarding certain kinds of food labels.²²⁵ This preemption means that state and local governments generally can only set food labeling requirements identical to the national standard.²²⁶

Due to FDA inaction, states have responded to consumer advocacy groups' pressure by setting state standards for food labeling.²²⁷ This inconsistent collection of state standards has only resulted in increased confusion and litigation for manufacturers.²²⁸ Big industries tend to turn to federal preemption provisions as weapons to get these state-law-based lawsuits dismissed.²²⁹ The food industry is no exception.²³⁰

Though the baking industry likely has the lobbying power to dissuade the FDA from implementing this recommendation, a national definition of "fresh" would be a tool for the baking industry. If promulgated by the FDA, this recommendation would carry with it the preemption power of the FDCA. It will be far easier for bakers to rely on one national standard for "fresh," enforceable only by the FDA, than it would be to face the sweeping consumer advocacy movement of regulation by litigation.

Finally, this recommendation answers the question posed in Part I: which baker, Bryan or Jim, baked "fresh" bread? As this Comment has demonstrated, only Bryan can truthfully label his bread as "fresh." And by differentiating Bryan's "fresh" bread from Jim's "thawed then freshly baked" bread, consumers can more confidently choose which baker to support and what quality of bread to purchase.

224. See Jake Tyner, *A Federal Standard: Solving the State-by-State Patchwork of Product Labeling Laws*, U.S. CHAMBER COM. (June 8, 2018, 10:15 AM), <https://www.uschamber.com/article/federal-standard-solving-the-state-state-patchwork-of-product-labeling-laws> [<https://perma.cc/ZE6B-W9NF>].

225. 21 U.S.C. § 343-1.

226. *Id.*

227. See *A Growing Problem: Inaccurate Labels on the Rise*, COAL FOR ACCURATE PROD. LABELS, <https://www accuratelabels.com/> [<https://perma.cc/45K6-YEEH>] (noting that sixty-two proposals across seventeen different states would require warning labels that go beyond the national standard).

228. NEGOWETTI, *supra* note 200, at 1; Tyner, *supra* note 224.

229. When Congress established a comprehensive scheme to regulate cigarette advertising, the tobacco industry used preemption to get out of lawsuits brought under state laws. See, e.g., *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 571 (2001); *Rowe v. N.H. Motor Transp. Ass'n*, 552 U.S. 364, 377 (2008).

230. Lindsay F. Wiley, *Deregulation, Distrust, and Democracy: State and Local Action To Ensure Equitable Access to Healthy, Sustainably Produced Food*, 41 AM. J.L. & MED. 284, 303 (2015). See generally Sylvia Zarski, Comment, *Can You Judge Your Food by Looking at Its Cover? How Courts' Application of Federal Preemption Allows Misleading Food Labeling To Slip Through the Regulatory Cracks*, 64 DEPAUL L. REV. 1119 (2015).

V. CONCLUSION

The overwhelming purpose of the FDCA is to protect consumers who cannot protect themselves.²³¹ Transparent labeling practices provide consumers with the necessary information to choose for themselves which foods they consume. When companies label bread from a frozen dough as “fresh,” consumers are misled into thinking it is of comparable quality to truly “fresh” bread.

With the COVID-19 pandemic as a catalyst, United States consumers continue to push for healthier lifestyles. Meanwhile, producers are left to predict consumer expectations. They have struggled to keep up with this transparent labeling movement and now face hundreds of lawsuits.²³² The FDA has the power to intervene and provide producers with clear guidelines to follow. The FDA needs to engage in formal rulemaking and establish a uniform standard for “fresh bread” to protect consumers, producers, and bread, one of the oldest foods known to humankind.²³³

231. *Kordel v. United States*, 335 U.S. 345, 349 (1948).

232. NEGOWETTI, *supra* note 200, at 1.

233. See Lina Zeldovich, *14,000-Year-Old Piece of Bread Rewrites the History of Baking and Farming*, NPR: THE SALT (July 24, 2018, 11:57 AM), <https://www.npr.org/sections/thesalt/2018/07/24/631583427/14-000-year-old-piece-of-bread-rewrites-the-history-of-baking-and-farming> [<https://perma.cc/SC7L-RRJJ>].