UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MARK MCAFEE 7221 So. Jameson Fresno, CA 93706, and **FARM-TO-CONSUMER LEGAL DEFENSE FUND** 8116 Arlington Blvd, Ste. 263 Falls Church, VA 22042 Plaintiffs, v. **U.S. FOOD AND DRUG ADMINISTRATION,** White Oak Building 1, 10903 New Hampshire Avenue Silver Spring, MD 20993, Defendant.	)	Civil Action No. 19-3161 **SECOND AMENDED COMPLAINT**

INTRODUCTION

1. Plaintiffs Mark McAfee and Farm-to-Consumer Legal Defense Fund (collectively, "Plaintiffs") bring this Second Amended Complaint to challenge the United States Food and Drug Administration's ("FDA's") denial of Plaintiffs' Citizen Petition.

2. Congress granted the FDA broad authority to promulgate regulations establishing definitions, standards of identify, and standards of quality for foods pursuant to 21 U.S.C. § 341. Under the same statute, Congress explicitly excluded butter from the FDA's authority, stating: "No definition and standard of identity and no standard of quality shall be established for . . . butter." 21 U.S.C. § 341.

3. Instead, butter became one of the few foods defined by Congress via statute. According to 21 U.S.C. § 321(a), butter is "the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for."

4. For decades, consistent with Congress' statutory mandate, the FDA promulgated pasteurization regulations for dairy and dairy products that excluded butter, including the requirements under the Pasteurized Milk Ordinance ("PMO") and the Federal Food, Drug, and Cosmetic Act ("FDCA") that "milk and cream" be pasteurized. Cheese was similarly excluded from regulation under the PMO and the FDCA. Like cheese, butter is naturally acidic and lower in moisture than fluid milk, and, consequently, pathogens have more difficulty growing in cheese and butter than they do in milk.

5. Yet in 1992 the FDA began promulgating standards for butter under provisions of the Public Health Service Act ("PHSA") that control communicable diseases and by extending the FDCA regulations concerning adulterated foods. Pursuant to 21 C.F.R. 1240.61, the FDA required that all "milk products" transported or sold in interstate commerce must be pasteurized or made from pasteurized milk or cream that is heated pursuant to FDA specifications. The FDA definition of "milk products" went further than the previous pasteurization regulations had gone and, for the first time, included butter. 21 C.F.R. 1240.3(j). Through these actions, the FDA banned the interstate transportation of commercially prepared raw butter.

6. Though these regulations reference cheese—in addition to butter—as a milk product, the FDA excluded aged, raw-milk cheese from the definition of milk products and, by extension, from the prohibition on interstate transportation.

7. Incongruous with its treatment of cheese, the FDA did not consider raw butter as an independent product or make regulations specific to raw butter or to its different types, some of which involve fermentation and aging and are processed using methods that make pathogen growth unlikely.

8. On June 22, 2016, Plaintiffs petitioned the FDA to reverse its ban on the interstate transport of raw butter by: (1) amending the definition of "milk products" in 21 C.F.R. 1240.3(j) to exclude butter; and (2) amending 21 C.F.R. 1240.61(a) to explicitly exclude raw butter from the prohibition on interstate transport of unpasteurized "milk or milk products."

9. After more than three years without a response from the FDA, Plaintiffs sued the FDA on October 22, 2019 to compel the FDA to act on Plaintiffs' Citizen Petition. After a stipulated stay of this action, the FDA denied the requests in Plaintiffs' Citizen Petition on February 27, 2020.

10. In its final response to Plaintiff's Citizen Petition, the FDA acknowledged the low likelihood of pathogen presence and levels, and microbiological growth, especially in cultured butter, as well as the low risk of illness—regardless of microbiological growth—to most consumers. Even after acknowledging that the type of butter may influence the risk, the FDA arbitrarily lumped all raw butter types together without explanation. The FDA then cited to data that failed to distinguish between pasteurized and unpasteurized butter to explain the prohibition on raw butter.

11. The FDA also failed to consider the organic similarities between raw butter and raw cheese or explain why the FDA's inclusion of raw butter in these two provisions, particularly in light of its exclusion of raw cheese, was not arbitrary.

12. The FDA claimed that the presence of *any* pathogen in raw butter is unacceptable regardless of: (1) whether pathogens could actually grow in each type of raw butter given the types' different levels of microbiota; or (2) whether the level of pathogen would cause negative health consequences if consumed. The FDA's position as to raw butter is unsupported by its own studies in addition to being inconsistent with its position on the other food products it regulates.

13. The FDA ignored the Center for Disease Control's ("CDC's") outbreak data related to raw butter for the 15 years preceding Plaintiff's Citizen Petition. Instead, the FDA substituted outbreak data from the United States and Europe that did not distinguish between pasteurized and unpasteurized butter and did not isolate the different types of butter (e.g. cultured, salted, whipped, etc.). Even so, the FDA's research efforts did not locate a single outbreak or illness linked to raw butter in nearly two decades—the last outbreak listed in the FDA's chart having occurred during an event in England in 2003.

14. Under the FDA's own data, therefore, raw butter is a low-risk product that does not merit the regulatory restrictions imposed by the FDA—restrictions that are inconsistent both with Congress' intent and express statutory mandate and with the FDA's own positions regarding the relative safety of raw cheese and other similarly-manufactured products created from raw milk.

15. The FDA acted arbitrarily, and without a reasoned basis, and contrary to law when it amended the definition of "milk products" in 21 C.F.R. 1240.3(j) to include butter and when it refused to act on Plaintiffs' Citizen Petition because, *inter alia*: (1) the FDA has no authority to define or augment the standards of identity or quality for butter; (2) the FDA had no reasoned or scientific basis for creating conflicting definitions of "milk products" that include butter in the case of some regulations while exempting both butter and cheese in others; (3) the

FDA has consistently excluded cheese—a similar product in terms of composition and safety—from the definition of "milk products," and the FDA failed to consider whether a similar exemption for butter is appropriate; and (4) the FDA had no scientific or data-driven reason to include butter in the definition of "milk products" in 21 C.F.R. 1240.3(j).

16. The FDA's final response to Plaintiffs' Citizen Petition is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law, in violation of the FDCA and the APA, 5 U.S.C. § 706(2).

PARTIES

17. Plaintiff Mark McAfee is the founder of Organic Pastures Dairy Company ("OPDC"), which was established in 1999 in Fresno, California. OPDC is a Grade A licensed raw[1] dairy that sells cultured and sweet cream butter throughout California. There have been no reported foodborne illnesses from OPDC's butter.

18. Plaintiff Farm-to-Consumer Legal Defense Fund ("FTCLDF") is a grassroots, nonprofit organization based in Virginia with members located across the country. Founded in 2007, FTCLDF protects the rights of farmers and consumers to engage in direct commerce while working to create a food system in which consumers are able to obtain the foods of their choice from the sources of their choice. FTCLDF's members include small farms located all over the United States that have been negatively impacted by the interstate ban on raw butter.

19. Defendant FDA is a federal government agency within the Department of Health and Human Services ("HHS"). The FDA is responsible for implementing most of the provisions

[1] Plaintiffs use the term "raw" dairy to refer to unpasteurized dairy to remain consistent with Plaintiffs' Citizen Petition and with the terminology used by producers and consumers of raw butter and other raw milk products.

of the FDCA, including the provisions regarding definitions and standards for food (except as to butter), along with food safety protocols.

JURISDICTION

20. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1361.

21. This Court may award Plaintiffs declaratory relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and may award all necessary and appropriate injunctive relief compelling or setting aside agency action, findings, and conclusions pursuant to the APA, 5 U.S.C. § 706(2).

22. Venue is proper in this District under 28 U.S.C. § 1391(e).

FACTS

I. Congress defines "butter" and precludes the FDA from revising the definition or standard of identity for butter.

23. Congress, by the FDCA, has authorized the FDA to issue regulations establishing quality standards and standard-of-identity requirements for most foods. *See* 21 U.S.C. § 341 ("Definitions and standards for food"). Specifically, the FDA can "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, a reasonable standard of quality, or reasonable standards of fill of container." *Id.*

24. However, the FDCA limits the FDA's ability to change the definition or standard of identity for butter: "No definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, **or butter**, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons." *Id.* (emphasis added).

25. This is consistent with Congress' earlier decision to define butter explicitly by statute. Title 21 of United States Code § 321(a) (adopted in 42 Stat. 1500 (1923)) provides:

> For the purposes of the Food and Drug Act of June 30, 1906 (Thirty-fourth Statutes at Large, page 768) "butter" shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for.

26. Congress does not include a separate definition or separate requirements for butter that is in final package form or otherwise prepared for consumers. *Id.*

27. The statutory definition of butter does not mandate that it be made with pasteurized or ultrapasteurized milk or cream.

28. The FDA has defined "milk" as "the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows." 21 C.F.R. 131.110. The definition addresses milk for consumers, requiring that "[m]ilk that is in final package form for beverage use shall have been pasteurized or ultrapasteurized." *Id.*

II. By its very composition, as defined by Congress, butter—whether pasteurized or raw—poses a low risk of foodborne illness.

29. Pathogens do not grow in properly-produced butter, contrary to prior FDA assumptions that are not supported by advancements in microbiology and post-1985 scientific studies. (*See* Plaintiffs' Citizen Petition ("Pet.") at 12 (internal citations omitted).)

30. Moreover, pathogen contamination of commercial butter is rare in current practice, and, when pathogens *are* present, pathogen counts are too low to cause illness (<100 *L. monocytogenes/g*). (*Id.*)

31. For several reasons, the physical and microbial nature of raw butter creates hurdles for pathogens, rendering raw butter a poor medium for the growth of bacteria.

32. *First*, hardened butterfat inhibits the growth of bacteria. As Congress specified by statute, butter must be at least 80% fat by weight. (*Id.* at 12.) This fat is in the continuous phase, and a small amount of water in the form of droplets are dispersed in the fat. (*Id.*) Bacterial growth is understood to be restricted to the water droplets originally colonized during the manufacture because migration of bacteria between water droplets is restricted by fat. (*Id.* at 13.) When butter is "well-worked," as it is in commercial production, the water droplets become too fine to support bacterial growth. (*Id.*)

33. *Second*, butter's slightly acidic pH level limits or prevents pathogen growth. (*Id.*)

34. *Third*, the low temperatures at which butter is recommended to be stored (either refrigerated or frozen) reduce or eliminate bacterial growth. (*Id.*)

35. *Fourth*, in the case of salted butters, the dispersion of salt inhibits bacterial growth. (*Id.*)

36. *Fifth*, raw butters have a microbiota enriched in lactic acid bacteria that outcompete potential pathogens by direct and indirect mechanisms that may promote healthy gut and immune systems as well as prevent or minimize disease.

37. The FDA has acknowledged these principles as recently as 2017 in a draft guidance report that it prepared: "Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry." This guidance not only confirms that *Listeria monocytogenes* do not grow when "food is formulated to contain a combination of factors scientifically demonstrated to be effective in preventing growth (the 'hurdles' concept)," but it also cites low water activity and pH levels as cause for the lack of *Listeria monocytogenes* growth. In responding to Plaintiffs'

Citizen Petition, however, the FDA did not cite to this 2017 guidance, or to the underlying peer-reviewed references cited in it, or to its own recommendations for preventing or limiting pathogen growth.

38. Another 2017 publication whose authors included members of the FDA Center for Food Safety and Applied Nutrition ("CFSAN") reported that unsalted retail butter (without specification as to raw or pasteurized status) was considered a "cultured" commodity along with dairy-based dips. (Luchansky, *et al.*, 2017.) Only 1 of 468 samples in the cultured dairy group tested positive for *Listeria monocytogenes* at the limit of detection (<0.036 most probable number ("MPN") per gram). While it is unclear whether the single positive sample among 467 negative samples of retail cultured dairy products was butter, the FDA had access to this data, and the overwhelming results of this study, and chose not to present it as part of the scientific body of evidence relevant to what the FDA posited as butter risks in responding to the Citizen Petition.

39. Similarly, in a 2001 FDA report, food microbiota is described as an intrinsic factor of foods that limits the growth of pathogens. In their Citizen Petition, Plaintiffs point to numerous studies on microbiota that comport with the FDA's earlier determinations regarding the importance of microbiota. (*See e.g.*, Pet. at 16–17; 20–22.) In responding to the Citizen Petition, however, the FDA did not address this 2001 report or the impact of microbiota.

40. The FDA also failed to address modern studies that have shown: (1) *Listeria* can be found in even higher quantities in pasteurized butter than are found in unpasteurized butter when both are inoculated and tested; and (2) the mere presence of *Listeria* at low levels does not necessarily pose a risk, especially as the gut microbiota of healthy humans provides colonization resistance against many pathogens. (*Id.* at 20–21.)

III. In 1973, the FDA begins requiring pasteurization of milk and cream.

41. In 1973, the FDA adopted a regulation that required pasteurization as part of the standard of identity for raw milk and certain specific raw-milk products transported interstate. *See* 38 Fed. Reg. 27924 (Oct. 10, 1973).

42. Consistent with the FDCA, the 1973 pasteurization regulation was limited to "milk and cream" and included a definition of cream (*see id.* § 18.1) along with a standard of identity for each of the following: milk (*id.* § 18.2), lowfat milk (*id.* § 18.10), skim milk (*id.* § 18.20), half-and-half (*id.* § 18.30), light cream (*id.* § 18.501), light whipping cream (*id.* § 18.511), heavy cream (*id.* § 18.515), evaporated milk (*id.* § 18.520), concentrated or condensed milk (*id.* § 18.525), sweetened condensed milk (*id.* § 18.530), and various types of nonfat dry milk (*id.* § 18.540). It did not define or identify butter or other manufactured milk products.

43. Shortly thereafter, in 1974, the FDA stayed the effect of the 1973 pasteurization order as to certified raw milk, stating that it would hold a public hearing to resolve the factual dispute over the safety of certified raw milk while the pasteurization requirement went into effect for all non-certified raw milk. *See* 39 Fed. Reg. 42351 (Dec. 5, 1974).

44. No further action was taken on the stay until 1985, when suit was brought to compel action on a citizen petition asking the FDA to ban all domestic sales of raw milk, including certified raw milk. *See Public Citizen v. Heckler*, 602 F. Supp. 611 (D.D.C. 1985) ("*Heckler I*"). The district court ordered the FDA to issue a regulation addressing certified raw milk. *Id.* at 614.

45. The FDA then denied the citizen petition. *See Public Citizen v. Heckler*, 653 F. Supp. 1229, 1235 (D.D.C. 1986) ("*Heckler II*"). As part of its rationale, the FDA stated: "[T]here is no reason to believe that unpasteurized milk marketed in interstate commerce represents a

greater source of risk than unpasteurized milk marketed intrastate." *Id.* The FDA further noted its lack of authority to prohibit intrastate activity. *Id.*

46. The petitioners sued again, in *Heckler II*, to challenge the denial of their citizen petition and to seek a ban on the sale of unpasteurized milk in the United States.

47. The district court agreed with the petitioners, stating: "There is no longer any question of fact as to whether the consumption of raw milk is unsafe." *Id.* at 1241.

48. The district court only discussed the safety of certified and non-certified raw milk, and ordered the FDA to "approve a rule banning the interstate sale of all raw milk and all raw milk products, both certified and non-certified, based on the now completed rulemaking proceedings and consistent with the opinion herein." *Id.* at 1242.

49. The district court did not define "milk products" to include butter or any other manufactured dairy product. Moreover, the issues and discussion presented in *Heckler II* did not involve butter but, rather, focused exclusively on raw milk. *See, e.g., id.* at 1233 ("In accordance with the Secretary's first letter to Dr. Wolfe, on October 11 and 12, 1984, an informal hearing was held by HHS on two issues: (1) whether the consumption of raw milk is a public health concern; and (2) if so, whether requiring pasteurization of all raw milk is the most reasonable regulatory option.").

50. At the time that *Heckler II* was considered and decided, the FDA had not included butter or cheese within its definition of "milk and milk products" in its 1978 Pasteurized Milk Ordinance ("PMO").

51. Moreover, the *Heckler II* court was addressing the petitioners' request to implement the standard of identify for milk to require pasteurization. The FDA could not have

amended or adopted a similar standard of identify for butter because of the prohibition in 21 U.S.C. § 341.

IV. The FDA defines "milk products" to include butter and requires that all butter transported interstate be made from pasteurized milk or cream.

52. The FDA's 1987 regulation implementing the *Heckler II* decision was included in the regulations for "control of communicable diseases." Without any precedent, and without providing any explanation or justification, the FDA included butter, cheese, and other manufactured dairy products in this regulation. *See* 21 C.F.R. Part 1240.

53. Rather than interpreting "milk products" to include only actual milk and cream items—the subject of the litigation—the FDA's rulemaking extended to products manufactured from raw milk products, including butter and cheese. *Id.*

54. The FDA defined "Milk products" in 21 C.F.R. 1240.3(j) to include:

> Food products made exclusively or principally from the lacteal secretion obtained from one or more healthy milk-producing animals, e.g., cows, goats, sheep, and water buffalo, including, but not limited to, the following: lowfat milk, skim milk, cream, half and half, dry milk, nonfat dry milk, dry cream, condensed or concentrated milk products, cultured or acidified milk or milk products, kefir, eggnog, yogurt, butter, cheese (where not specifically exempted by regulation), whey, condensed or dry whey or whey products, ice cream, ice milk, other frozen dairy desserts and products obtained by modifying the chemical or physical characteristics of milk, cream, or whey by using enzymes, solvents, heat, pressure, cooling, vacuum, genetic engineering, fractionation, or other similar processes, and any such product made by the addition or subtraction of milkfat or the addition of safe and suitable optional ingredients for the protein, vitamin, or mineral fortification of the product.

55. The FDA also included within this regulation a prohibition on the interstate sale of any milk product as defined by 21 C.F.R. 1240.61(a):

> No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package form for direct human consumption unless the product has been pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized, except where

> alternative procedures to pasteurization are provided for by regulation, such as in part 133 of this chapter for curing of certain cheese varieties.

56. The FDA, referring to prior regulations that allowed for the interstate sale of raw-milk cheeses that had been aged, permitted exclusion of these cheeses in both the definition of milk products and, by extension, from the prohibition on interstate sale of milk products.

57. In the case of butter, the FDA did not include in 21 C.F.R. 1240.3(j) the same parenthetical language regarding 21 U.S.C. § 341's definition of butter nor did the FDA explain why it treated raw butter—designated as unique by statute—the same way it treated other dairy products despite treating cheese differently.

V. In addition to contravening the FDCA, the prohibitions enacted by the FDA do not reasonably relate to the actual rates of illness linked to raw butter.

58. Hundreds of millions of pounds of butter are consumed by Americans annually. The United States Department of Agriculture ("USDA") estimates that butter was produced and consumed at a rate of 834,000 metric tons in the United States in 2016 alone. (*See* USDA, Foreign Agricultural Service, *Dairy: World Markets and Trade*, 17 (July 2019).) That number rose to 870,000 metric tons in 2018. (*Id.*)

59. As noted by the FDA in its final response to Plaintiffs' Citizen Petition, even after the FDCA prohibited interstate transportation of raw butter, numerous states passed laws allowing for the production and sale of raw butter intrastate.

60. According to the CDC Foodborne Outbreak Online Database ("FOOD Tool"), which provides information on foodborne outbreaks reported to the CDC from 1998 forward, there were few or no reported foodborne illness outbreaks linked directly to butter commercially prepared from raw milk from 1998 to 2016 (the year that Plaintiffs submitted their Citizen Petition) anywhere in the Unites States. (*See* Pet. at 10–11.)

61. And only a small number of outbreaks have been linked to butter at all—commercial or homemade—during the same timeframe. (*Id.*)

62. The FOOD Tool listed only 10 outbreaks between 1998 and 2016 in which butter was *one* of the listed "food vehicles" for the outbreak. (*Id.*) In most of these outbreaks, other food vehicles were also listed that were of higher risk and more likely to have been the source of the outbreak—such as seafood or pork. (*Id.*)

63. Even in the unlikely event that butter was responsible for all of these outbreak cases, the worst-case scenario reflects only 242 illnesses over a period of 18 years, or an average of fewer than 14 illnesses per year. (*Id.*) These numbers include butter made from both pasteurized and raw milk, and butter that was both homemade and prepared commercially. (*Id.*)

64. The CDC database lists only one outbreak during the timeframe of 1998 to 2016 involving butter produced from raw milk. (*Id.*) Based on the Utah Health Department's description of that outbreak in 2007, these products appear to have been homemade and were not commercially prepared and sold. (*Id.*)

65. Plaintiff McAfee's dairy, OPDC, by way of example, sold over 2 million pounds of butter from 2001 to April 2016, and not a single foodborne illness was linked to these sales. (*Id.* at 11.) Since April 2016, he has sold another 290,000 pounds of butter without any reported illness or recalls.

66. The CDC National Outbreak Reporting System ("NORS") is a web-based platform that launched in 2009, as a successor to the Food Tool, to enable all local, state, and territorial health departments in the United States to report all waterborne and foodborne disease outbreaks and enteric disease outbreaks to the CDC. While NORS differentiates between raw and cooked meats, for instance, and different kinds of cheeses (e.g., soft and hard or cheddar and

blue cheeses), as well as pasteurization status, NORS does not differentiate between the different types of butter (e.g., whipped, cultured, or sweet cream), nor does it differentiate between pasteurized and unpasteurized butter.

VI. The FDA's pasteurization regulations conflict with other regulations recognizing the low risks of raw butter as compared to raw milk.

67. The USDA has recommended that differing requirements be imposed on milk used for manufacturing purposes—including butter—and milk created for fluid consumption. (Pet. at 23.) For the former, the quality standards for both the milk itself and for the farms on which it is produced are lower than are the standards for fluid consumption. (*Id.*)

68. Similarly, the PMO, established by the FDA, sets a limit of 300,000 bacteria per milliliter for fluid milk. (*Id.*) The requirements for milk for manufacturing purposes, by contrast, permit up to 500,000 bacteria per milliliter. (*Id.*) Recognizing the safety of both raw butter and raw cheese, the FDA's PMO specifically excludes *both* butter and aged cheese from the definition of "milk and milk products." (*Id.*)

69. Raw milk cheeses that have been aged for at least 60 days are a low-risk product that have resulted in only a small handful of outbreaks over the last two decades. As discussed above, raw butter has been linked to—at most—one outbreak over that same period. (*Id.*)

70. The FDA similarly excludes aged raw cheese from the pasteurization requirements of 21 C.F.R. 1240.61. (*Id.*) Yet without any stated rationale or scientific support, the FDA did not take the same approach, and apply the same exclusion in the case of butter.

71. While the FDA makes it legal to sell raw cheeses in interstate commerce, the FDA does not allow butter to be sold in interstate commerce. The different treatment of these two manufactured dairy products is not based on any scientific evidence or outbreak data.

72. Moreover, the FDA and the USDA recognized in these above-referenced regulations that bacteria can be safely present in milk and milk products and that the level of acceptable bacteria should vary depending on the manner of consumption. Yet in responding to the Citizen Petition, the FDA took the position that *any* bacteria or pathogen presence in raw butter would make it unsafe, contrary to its other regulations concerning pasteurized and unpasteurized milk and milk products.

VII. The FDA's pasteurization regulations conflict with its own assessments and reports.

73. The 2001 FDA report referenced above specifically considered whether butter was a potentially hazardous food. This report concluded that butter is a medium-risk food, based on data available prior to 2001. The report lists the following process controls for butter in Table 4-1: "production/raw ingredient quality control, moisture droplet size in the water-in-oil emulsion, water phase salt, $a_{w.}$" (Water activity that would apply to both pasteurized and unpasteurized butter, although raw butter is not referenced.)

74. Under the FDA's own risk assessment in 2003 and recalculations in 2008, even though both pasteurized milk and the "high fat and other dairy products" group—which included butter—were classified as "high-risk products," the assessment acknowledged the low rates of contamination and low predicted risk-per-serving in these products. (FDA, *Interpretive Summary: Quantitative Assessment of the Relative Risk to the Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods,* Sept. 2003 at 23.)

75. The 2003 report acknowledged that its risk assessment was not consistent with the United States epidemiological record—meaning that while the report labeled these commonly-consumed commodities as "high-risk," very few outbreaks and illnesses were actually associated with any of these products. Due to these inconsistencies, the report stated that these product

classes are priorities for further scientific investigation to "confirm risk assessment predictions or identify the factors not captured by the 2003 model that reduce risk." (*Id.* at 24.)

76. Yet the FDA has not completed further investigation in the nearly two decades since its 2003 report. Instead, the FDA continues to treat butter as a high-risk food, even though its own risk-assessment data does not support such a classification. This is especially arbitrary in that other foods deemed high-risk, such as pasteurized milk, are regularly produced and transported interstate, and in that the FDA has refused to promulgate rules regarding processing or testing or acceptable pathogen levels for butter as it has done for other foods.

77. Moreover, in the 2003 assessment, data for presence and levels of pathogens in butter were insufficient to warrant treating butter as a stand-alone commodity. The FDA, therefore, chose to group butter with "high fat dairy products" (cream, half-and-half, chocolate milk, pudding, milkshakes, dip, eggnog, whipping cream (*id.* at App. 7)) whose characteristics differ markedly from butter, resulting, in the case of butter, in misapplication of data related to risk estimation.

78. Additionally, raw butter contains microbiota enriched in lactic acid bacteria and other intrinsic properties that minimize growth of pathogens, but the FDA failed in the assessment to consider this unique characteristic as the FDA did not isolate and evaluate butter or raw butter specifically.

79. In responding to Plaintiffs' Citizen Petition, the FDA also failed to cite to its 2017 guidance regarding RTE foods such as butter. The FDA's "Control of *Listeria monocytogenes* in Ready-To-East Foods: Guidance for Industry" states the following, citing Tienungoon, *et al.*, 2000, and other peer-reviewed references:

a. "It is well established (Ref. 12, Ref. 15, and Ref. 17 through Ref. 20) that *L. monocytogenes* do not grow when:

i. The pH of the food is less than or equal to 4.4;

ii. The water activity of the food is less than or equal to 0.92; and

iii. The food is formulated to contain a combination of factors scientifically demonstrated to be effective in preventing growth (the 'hurdles' concept)."

80. In its response to the Citizen Petition, however, the FDA cited to neither its own 2017 draft guidance report nor to the key study on predictive microbiology and dependencies of growth on lactic acid concentrations in food by Tienungoon, *et al.*, 2000.

81. Further, the 2017 FDA guidance includes two appendices relevant to identifying the risk associated with raw butter:

a. Appendix 1 lists four pathogen sources, analysis of which is essential to risk-assessment for butter and other RTE foods: 1) processing materials such as ice or brine for cooling in processing facilities; 2) contact surfaces, such as containers; 3) surfaces that do not usually contact foods, such as sanitation equipment; and 4) plant environment such as drains, ceilings, and floors; and

b. Appendix 2 of the 2017 FDA guidance described 21 pathogen sources unrelated to potential contamination of incoming raw ingredients.

82. The FDA failed to consider any of the recognized pathogens or contamination sources in these two appendices in responding to the Citizen Petition.

83. Further, the FDA's response to the Citizen Petition was inconsistent with peer-reviewed analysis updating the FDA/FSIS 2003 assessment. (Buchanan, *et al.*, 2017.) In the analysis, Dr. Robert Buchanan, the former FDA CFSAN Science Advisor (who served in this

role during the preparation and completion of the FDA/Food Safety and Inspection Service ("FSIS") assessment in 2003) observed that due to the low incidence of listeriosis despite frequent exposures to the pathogen in foods, both FDA/FSIS (2003) and WHO/FAO (2004) presumed that high pathogen doses were necessary to cause illness. (The World Health Organization/Food and Agricultural Organization of the United Nations ("WHO/FAO") had determined in its assessment of listeriosis for Ready to Eat ("RTE") foods (WHO/FAO, 2004) that competition by food microbiota can lower risk estimates for listeriosis as compared to simulations based on assumptions of optimal pathogen growth representative of pure cultures in media such as heat-treated foods.)

84. The FDA/FSIS 2003 assessment used mathematical functions anchored to epidemiological evidence in modeling dose-response. But as Dr. Buchanan pointed out, the 2003 dose-response model did not include several factors that may influence the virulence of pathogen strains. Two such factors that Dr. Buchanan noted the 2003 dose-response model should have included were: (1) gut microbiota of healthy and susceptible humans; and (2) plausibility of threshold models to replace outdated assumptions of non-threshold linear low-dose behavior where no data exist to validate model shape in the low-dose region. In its response to Plaintiffs' Citizen Petition, however, the FDA ignored this research and failed to take into consideration these two factors that Dr. Buchanan identified as capable of influencing the virulence of pathogen strains.

VIII. Plaintiffs petition the FDA to exclude raw butter from the existing raw-milk prohibitions.

85. In their Citizen Petition submitted pursuant to 5 U.S.C. § 553(e), 21 C.F.R. 10.20, 10.30, and the First Amendment of the Federal Constitution, Plaintiffs requested that the FDA take two actions.

86. *First*, Plaintiffs requested that the FDA amend the definition of "milk products" in 21 C.F.R. 1240.3(j) by striking "butter" and adding this sentence to the end: "This definition shall not include butter meeting the standard established by 21 USC 321a."

87. *Second*, Plaintiffs requested that the FDA amend 21 C.F.R. 1240.61 to allow for interstate sales of unpasteurized butter by adding the bolded text as follows: "No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product . . . unless the product has been pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized, except where alternative procedures to pasteurization are provided for by regulation, such as in part 133 of this chapter for curing of certain cheese varieties **or except for butter meeting the standard established by 21 USC 321a**."

88. In support of its Citizen Petition, Plaintiffs provided both the text of the FDCA and the legal background of butter's definition to demonstrate that the FDA contravened both the FDCA and legal precedent by including butter in the restrictions referenced above. Additionally, Plaintiffs provided: (1) significant research compiled using a CDC database and other government data to demonstrate the low likelihood that any outbreaks in the U.S. in a nearly two-decade period could be attributed to raw butter; and (2) information about the microbial ecology of raw butter demonstrating that raw butter—by its microbial make-up—presents a low risk of contamination and does not promote the growth of bacteria. Plaintiffs also cited to

numerous other conflicting provisions from the FDA and other government agencies regarding butter and other low-risk manufactured milk products such as cheese to demonstrate that butter was improperly included in the restrictions referenced above

89. An agency may change its interpretation of a statute as long as it provides a "reasoned analysis" explaining its altered stance. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 42 (1983) ("An agency must be given ample latitude to adapt their rules and policies to the demands of changing circumstances.") (quoting *Permian Basin Area Rate Case*, 390 U.S. 747, 784 (1968)).

90. FDA regulations require the agency to respond to each citizen petition within 180 days of receipt. *See* 21 C.F.R. 10.30(e)(2). The response must either approve the citizen petition, deny the citizen petition, dismiss the citizen petition as moot, or provide a tentative response explaining why the agency has been unable to reach a decision. *Id.*

91. The plain language of 21 U.S.C. § 341, the administrative record, and other government data and evidence directly or indirectly considered by the FDA provide sufficient grounds for the FDA to amend the regulations as Plaintiffs' Citizen Petition requests.

92. Since the date that Plaintiffs submitted their Citizen Petition, June 22, 2016, numerous studies and reports have reiterated the benefits and low health risks associated with raw butter.

93. In its final response to Plaintiffs' Citizen Petition, which came more than three years after the FDA received the Citizen Petition, the FDA, despite denying Plaintiffs' request, acknowledged both the low likelihood of pathogen or microbiological growth in at least some butters and the low risk of illness regardless of microbiological growth to most individuals.

94. The FDA failed to even consider or address Plaintiffs' substantive research regarding the benefits of raw butter—including the FDA's own reports and research.

95. Rather than address the CDC's data and research regarding actual outbreaks related to butter, the FDA questioned the validity of the CDC's data and substituted its own, purportedly to permit it to argue for high risks associated with raw butter. Thus, as modern information and statistics provided by the federal government demonstrate the low risk of outbreak or illness from raw butter, the FDA was forced to rely upon information that: (1) is over a century old; and (2) includes outbreak information from outside the United States. Even using this geographically and temporally foreign information, the FDA's research efforts could not locate a single outbreak or illness linked to raw butter in nearly two decades—the last outbreak listed in the FDA's chart having occurred in an event in England in 2003—and the FDA could only identify 6 possible deaths linked in any way to raw butter over the past 112 years. Those 6 deaths all occurred in 1913, and the FDA could not definitively state whether the outbreak arose from unpasteurized or pasteurized butter.

96. Moreover, the pathogens causing diseases, including typhoid fever, diphtheria, and tuberculosis, which the FDA attributes to butter in its data in Table 1 are not listed as pathogens of concern in butter in an independent report prepared for the FDA by the Institute of Food Technologists ("IFT") (FDA/IFT, 2001). Instead of using this study and others available to the FDA, or peer-reviewed publications regarding well-characterized outbreak investigations, the FDA relied on summaries in chapters in an outdated encyclopedia of food microbiology, a trade newsletter, and a lawyer's website for references to "illnesses and deaths associated with butter not known to be pasteurized" in its Table 1.

97. After ignoring Congress' specific prohibition on changing the standards of identity for butter in the FDCA—a prohibition that precludes the FDA from acting in this area (at all—erroneously or not) the FDA has erred further by failing to act on Plaintiffs' request despite the wealth of government data and medical information demonstrating that raw butter is safe for consumer use and despite the FDA's own regulations recognizing that raw butter presents lower risks than raw milk does.

98. The FDA's decisional process is unreasonable in light of the nature and extent of the interests addressed in the Citizen Petition and the statutory limitations imposed by Congress. The public, as well as producers of raw butter, are being harmed by the FDA's delay in addressing its arbitrary and capricious prohibition.

99. The FDA's final response to Plaintiffs' Citizen Petition is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law, in violation of the FDCA and the APA, 5 U.S.C. § 706(2).

FIRST CLAIM FOR RELIEF

100. Plaintiffs incorporate by reference all preceding paragraphs.

101. The FDA included butter without qualification within the definition of "milk products" in 21 C.F.R. 1240.3(j) and prohibited the interstate transportation of raw butter in 21 C.F.R. 1240.61(a).

102. Congress prohibited the FDA from creating standards of identify or standards of quality for butter in 21 U.S.C. § 341.

103. Moreover, Congress defined butter by statute as a product made from milk or cream without: (1) reference to or requirement of pasteurization or ultrapasteurization; (2) any

standards for pasteurization; or (3) any requirements or limitation on the production or the interstate transportation of butter. *See* 21 U.S.C. § 321(a).

104. Consequently, the FDA's inclusion of butter within the definition of "milk products" in 21 C.F.R. 1240.3(j) disregards or modifies the statutory definition of butter, and creates a standard of identity or standard of quality for butter, by requiring that butter be pasteurized.

105. Moreover, the FDA's prohibition on the interstate transportation of raw butter in 21 C.F.R. 1240.61(a) conflicts with the clear command of 21 U.S.C. § 341 and the definition and standard of butter contained in 21 U.S.C. § 321(a).

106. For this reason, and all the reasons discussed above, the FDA's actions in including butter without qualification within the definition of "milk products" in 21 C.F.R. 1240.3(j) was contrary to or prohibited by law.

107. For this reason, and all the reasons discussed above, the FDA's action in banning the interstate transportation of raw butter is contrary to or prohibited by law.

SECOND CLAIM FOR RELIEF

108. Plaintiffs incorporate by reference all preceding paragraphs.

109. The FDA, through the FDCA, created a prohibition on the interstate transportation of unpasteurized milk and cream in 1973. The FDA had previously defined milk and milk products in the FDCA and the PMO as excluding butter. But in 1992 the FDA began to characterize butter among "milk products" for purposes of 21 C.F.R. 1240.3(j), and the FDA extended the prohibition on interstate transportation to raw butter without rationally explaining, or providing any basis for, its changed position and undertaking to regulate butter.

110. The FDA also failed to rationally explain its decision to include all forms of butter in the definition of "milk products," banning the interstate transportation of all forms of raw butter without any consideration for, or analysis of, different forms of butter, or the manner of production of these various forms of butter; nor did the FDA attempt to justify its decision—inconsistent with its treatment of all forms of butter—to exclude aged raw-milk cheeses in 21 C.F.R. 1240.3(j).

111. The FDA failed to consider scientific information, public safety and health data, or the FDA's own reports in responding to Plaintiffs' Citizen Petition.

112. The FDA's denial of Plaintiffs' Citizen Petition is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law under the APA, 5 U.S.C. § 706(2)(A).

REQUEST FOR RELIEF

Plaintiffs request that this Court enter judgment against the FDA as follows:

A. Declaring that the FDA's inclusion of butter within the definition of "milk products" in 21 C.F.R. 1240.3(j) and the FDA's ban on the interstate transportation of raw butter in C.F.R. 1240.61(a) are contrary to law;

B. Declaring that the FDA's denial of Plaintiffs' Citizen Petition is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law, in violation of the FDCA, 21 U.S.C. § 341, and the APA, 5 U.S.C. § 706(2);

C. Setting aside the FDA's denial of the Citizen Petition;

D. Awarding Plaintiffs their reasonable costs and attorneys' fees; and

E. Granting such other and further relief as the Court deems just and proper.

Respectfully submitted,

Dated: May 25, 2020

/s/ Samantha J. Ellingson

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