UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MARK MCAFEE, *et al.*,	:	
	:	
Plaintiffs,	:	Civil Action No.: 19-3161 (RC)
	:	
v.	:	Re Document Nos.: 15, 17
	:	
U.S. FOOD AND DRUG ADMINISTRATION,	:	
	:	
Defendant.	:	

MEMORANDUM OPINION

DENYING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

Federal regulations require those who sell dairy products across state lines to pasteurize their products. But the plaintiffs in this case claim that those regulations should not apply to butter. They say that the government lacked authority to mandate pasteurization of butter and that such a requirement makes little sense anyway. They are wrong. Not only does the pasteurization requirement fit well within the federal government's broad power to combat the spread of infectious diseases, but there is also a great deal of scientific research showing that pasteurization is effective at doing so. The government is thus entitled to summary judgment.

II. BACKGROUND

Pioneered in the 1860s, pasteurization is the process of heating up milk for a period of time to kill potentially harmful bacteria. J.A. 1073, 1116. The technique did not become common in the United States until the late 1940s and early 1950s. J.A. 1089 n.15. Initially, the federal government encouraged pasteurization but did not mandate it. *See, e.g.*, U.S. Public

Health Service, Fed. Security Agency, *Milk Ordinance and Code* 96–97 (1939), http://resource.nlm.nih.gov/101528318 (remarking that "[t]he public-health value of pasteurization is unanimously agreed upon by health officials" but noting that some local opposition existed).

In 1972, the Food and Drug Administration ("FDA") proposed a rule requiring pasteurization for milk and related products traded in interstate commerce. Proposed Revision of Existing Standards and Establishment of New Identity Standards, 37 Fed. Reg. 18,392 (Sept. 9, 1972). It finalized the rule the next year, concluding that a pasteurization requirement would "assure[] the destruction of pathogenic bacteria that may be present" in milk products. 38 Fed. Reg. 27,924, 27,924 (Oct. 10, 1973). In response to objections from industry, however, the agency stayed the requirement as it applied to certified raw milk pending a public hearing. Identity Standards for Milk and Cream; Order Staying Certain Provisions ("Stay Rule"), 39 Fed. Reg. 42,351, 42,351 (Dec. 5, 1974).

For nearly a decade, the FDA "collected and evaluated scientific and medical information to determine if the outbreak of certain diseases was associated with the consumption of certified raw milk." *Pub. Citizen v. Heckler (Pub. Citizen II)*, 653 F. Supp. 1229, 1232 (D.D.C. 1986). The agency eventually "conclude[d] that the consumption of certified raw milk and all forms of raw milk and raw milk products was linked to the outbreak of serious disease," so it "began drafting a proposed regulation banning the interstate sale of all raw milk and raw milk products." *Id.* Debates within the FDA's parent agency, the Department of Health and Human Services ("HHS"), and a public hearing followed. *Id.* at 1232–34. After delays in acting on the proposal, a court ultimately ordered HHS and the FDA to promulgate it. *Id.* at 1234–35, 1242.

The agencies complied. A final rule, published in 1987, banned the delivery into interstate commerce of "any milk or milk product" that was not pasteurized. Requirements

Affecting Raw Milk for Human Consumption in Interstate Commerce ("Pasteurization Rule"), 52 Fed. Reg. 29,509, 29,514 (Aug. 10, 1987) (to be codified at 21 C.F.R. § 1240.61(a)). A few years later, the FDA issued a "technical amendment" to clarify that the pasteurization rule "applie[d] to the dairy ingredients of certain dairy products, such as . . . butter" by including butter in the definition of "milk products." Control of Communicable Diseases; Definition of Milk and Milk Products ("Definition Rule"), 57 Fed. Reg. 57,343, 57,343 (Dec. 4, 1992) (to be codified at 21 C.F.R. § 1240.3(j)). The current version of the regulation bars from 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." 21 C.F.R. § 1240.61(a).

Plaintiffs Mark McAfee and the Farm-to-Consumer Legal Defense Fund ("Plaintiffs") want to change that regulation. They filed a citizen petition with the FDA asking it to remove butter from the definition of milk products and make an exception to the pasteurization requirement for butter. J.A. 3. According to Plaintiffs, the FDA lacks statutory "authority to require pasteurization of butter," J.A. 7, and "there is no sound scientific basis" for doing so, J.A. 9. The agency denied their petition. J.A. 1072. Plaintiffs then filed a complaint claiming that the denial violated the Administrative Procedure Act ("APA"). *See* Am. Compl., ECF No. 6. Now, both sides move for summary judgment. *See* Mem. P & A Supp. Pls.' Mot. Summ. J. ("Pls.' Mot."), ECF No. 15-2; Combined Mem. Supp. Def.'s Cross-Mot. Summ. J. and Opp'n Pls.' Mot. Summ. J. ("Def.'s Mot."), ECF No. 17-1. The Court grants the FDA's motion and denies Plaintiffs' motion.

III. LEGAL STANDARD

The usual standard for deciding summary judgment motions does not apply when reviewing an agency action under the APA. *See Rempfer v. Sharfstein*, 583 F.3d 860, 865 (D.C. Cir. 2009). Because the agency's job is "to resolve factual issues" in reaching an administrative decision, the court's concomitantly limited role is merely to ensure that evidence in the record supports that decision. *Roberts v. United States*, 883 F. Supp. 2d 56, 62 (D.D.C. 2012), *aff'd*, 741 F.3d 152 (D.C. Cir. 2014). The court thus "sits as an appellate tribunal" and treats "[t]he 'entire case' on review [as] a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001); *see also Marshall Cty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993) ("[The] complaint, properly read, actually presents no factual allegations, but rather only arguments about the legal conclusion to be drawn about the agency action."). Plaintiffs bring two APA challenges that require assessment under different—but related—standards. Both are unavailing.

IV. ANALYSIS

A. The FDA Had Statutory Authority to Issue the Pasteurization Rule

Plaintiffs first assert that the FDA lacked statutory authority to require pasteurization of butter. Pls.' Mot. at 9–13. In APA terms, they argue that the agency acted "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). Courts review that kind of claim using the two-step *Chevron* framework. *See Pharm. Rsch. & Mfrs. of Am. v. FTC*, 790 F.3d 198, 204 (D.C. Cir. 2015). The first step is to determine whether Congress already answered the "precise question at issue." *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984). If so, "that is the end of the matter." *Id.* If not, the

court proceeds to the second step, which asks whether the "agency's answer" to the question "is based on a permissible construction of the statute." *Id.* at 843.

When the FDA promulgated the pasteurization rule, it purported to do so under the Public Health Service Act ("PHSA"). *See* Pasteurization Rule, 52 Fed. Reg. at 29,510, 29,514; *see also* Definition Rule, 57 Fed. Reg. at 57,343–44. That Act authorizes the FDA "to make and enforce such regulations as in [its] judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession." 42 U.S.C. § 264.[1] The term "communicable diseases" is liberally defined by regulation. It encompasses "[i]llnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment." 21 C.F.R. § 1240.3(b). Aside from the pasteurization rule, the FDA has used its authority under the PHSA to regulate the interstate transport of shellfish, *id.* § 1240.60, turtles, *id.* § 1240.62, psittacine birds, *id.* § 1240.65, and human food waste used to feed to swine, *id.* § 1240.75.

Plaintiffs do not dispute that, on its own, the PHSA would seem to give the FDA authority to mandate pasteurization. *See* Pls.' Mot. at 10–13. Nor could they. The PHSA "grant[s] broad, flexible powers to federal health authorities . . . to protect the public against the spread of communicable disease." *Louisiana v. Mathews*, 427 F. Supp. 174, 176 (E.D. La. 1977). And pasteurization eliminates "numerous . . . harmful microorganisms" that transmit

[1] Although the PHSA grants regulatory power to the Surgeon General and the Secretary of Health and Human Services, those officials have delegated their authority to the FDA. *See* J.A. 1073 n.3; *United States v. Regenerative Scis., LLC*, 878 F. Supp. 2d 248, 257, 262 (D.D.C. 2012), *aff'd*, 741 F.3d 1314 (D.C. Cir. 2014); *Indep. Turtle Farmers of La., Inc. v. United States*, 703 F. Supp. 2d 604, 619 (W.D. La. 2010).

infectious diseases. Pasteurization Rule, 52 Fed. Reg. at 29,512. The PHSA's application thus appears straightforward. *See Pub. Citizen v. Heckler (Pub. Citizen I)*, 602 F. Supp. 611, 613 (D.D.C. 1985) (explaining that "both the Public Health Service Act's authorization for regulations to control communicable diseases and the Food, Drug and Cosmetic Act's provisions for the control of adulterated foods" provided the FDA "ample legal authority" to ban interstate sales of raw milk (citations omitted)).

But Plaintiffs argue that another law comes into play where butter is concerned. They say that a provision in the Food, Drug and Cosmetic Act ("FDCA") prohibits any mandate that butter be pasteurized. Some background on that Act helps to understand their argument. Among other things, the FDCA permits the FDA to set "a reasonable definition and standard of identity" for foods if doing so would "promote honesty and fair dealing in the interest of consumers." 21 U.S.C. § 341. A standard of identity might list the ingredients a food can contain or provide acceptable proportions of those ingredients. J.A. 1074–75. The purpose is to "eliminate a source of confusion" to consumers who can have difficulty "determin[ing], solely on the basis of informative labeling, the relative merits of a variety of products superficially resembling each other." *Fed. Sec. Adm'r v. Quaker Oats Co.*, 318 U.S. 218, 230–31 (1943). Importantly, however, the statute that grants the FDA authority to set standards of identity carves out an exception for butter. *See* 21 U.S.C. § 341 ("No definition and standard of identity . . . shall be established for . . . butter . . . ."). Another provision in the FDCA defines butter's standard of identity as "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." *Id.* § 321a.

That statutory definition for butter is the foundation of Plaintiffs' claim. Whatever the PHSA might seem to permit, they say, it does not allow the FDA to issue a regulation that sets a standard of identify for butter that differs from the FDCA's statutory definition. *See* Pls.' Mot. at 12–13. And by requiring the pasteurization of all butter in interstate commerce, Plaintiffs continue, the FDA essentially makes pasteurization a part of butter's definition. *See id.* Along the same lines, Plaintiffs assert that the specific statutory definition of butter supplants the more general delegation of power that the PHSA gives the FDA to protect against communicable diseases—at least when it comes to butter. *See id.* at 10–11. They are mistaken.

Plaintiffs perceive a conflict between the PHSA and FDCA where there is none. Out of respect for the separation of powers, a court faced with two statutes "allegedly touching on the same topic" must "strive to give effect to both." *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1624 (2018) (internal quotation marks and citation omitted). The party who asserts that one statute displaces another thus "bears the heavy burden of showing a clearly expressed congressional intention that such a result should follow." *Id.* (internal quotation marks and citation omitted). That "intention must be 'clear and manifest.'" *Id.* (citation omitted). And only when statutes are "irreconcilably conflicting" can a more specific one take precedence over the more general one. *See Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 698 (D.C. Cir. 2014) (quoting *Detweiler v. Pena*, 38 F.3d 591, 596 (D.C. Cir. 1994)).

There is no reason to suggest that the FDCA's statutory definition of butter blocks the PHSA's operation as Plaintiffs say it does. The two statutes hardly "touch[] on the same topic," *id.*, much less conflict in such a way that one would have to supersede the other. While the PHSA is concerned with containing the spread of infectious diseases regardless of the means of transmission, standards of identity are meant to ensure that customers know what foods they are

buying. Rarely do statutes with such different purposes and scopes conflict. *See Watt v. Alaska*, 451 U.S. 259, 267 (1981) ("We must read the statutes to give effect to each if we can do so while preserving their sense and purpose."); *see also Radzanower v. Touche Ross & Co.*, 426 U.S. 148, 157 (1976) (explaining that there was no conflict between a statute that "was enacted primarily to halt securities fraud" and one that "regulate[d] banks"). If Congress wanted to exempt butter from the PHSA's reach, it could have said so. *See Hall v. United States*, 566 U.S. 506, 516 (2012) ("We assume that Congress is aware of existing law when it passes legislation . . . ."). In fact, it did just that when it passed the FDCA and withheld from the FDA authority to create a standard of identity for butter different from the preexisting statutory one. *See* 21 U.S.C. § 341.[2]

Plaintiffs' argument rests on the false premise that the pasteurization rule works a change to butter's standard of identity. They offer no statute, regulation, or case to back that position. Their only support is a misreading of history. *See* Pls.' Mot. at 12–13; Pls.' Reply at 2–3. When the FDA first required pasteurization in 1973, it did so by altering the standards of identity for milk and related products (but not butter). *See* 38 Fed. Reg. at 27,924 ("In the matter of revising existing standards and establishing new identity standards for milk and cream . . . ."). Then, the agency gradually changed tack. In the rule staying the pasteurization requirement for certified raw milk, the agency noted that it was now requiring pasteurization under the PHSA in addition to the FDCA. *See* Stay Rule, 39 Fed. Reg. at 42,351. And after a court ordered the FDA to issue a new rule, it grounded the rule—the one at issue here—solely in the PHSA; it did not purport to modify the affected milk products' standards of identity. *See* Pasteurization Rule, 52 Fed. Reg.

[2] Congress enacted the statutory definition for butter in 1923. *See* Act of Mar. 4, 1923, Pub. L. No. 67-519, 42 Stat. 1500. It incorporated that definition into the FDCA when it passed the Act in 1938. *See* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 902, 52 Stat. 1040, 1059 (1938) ("[T]he Act of March 4, 1923 . . . defining butter and providing a standard therefor . . . shall remain in force and effect and be applicable to the provisions of this Act.").

at 29,510 ("The provisions of the Public Health Service Act that relate to communicable disease . . . form the legal basis for the final rule." (citations omitted)); Definition Rule, 57 Fed. Reg. at 57,343 (similar); *see also Pub. Citizen II*, 653 F. Supp. at 1232 (explaining that, before the court-ordered promulgation of the current rule, the FDA proposed issuing a pasteurization rule under the PHSA because it "would provide a more uniform and efficient regulatory mechanism than a standard of identity proceeding, to assure public health protection"). The new rule did "not apply to milk and milk products for which an alternative to pasteurization is established in a standard of identity regulation." Pasteurization Rule, 52 Fed. Reg. at 29,513.

It is difficult to follow Plaintiffs' argument as to how that history shows the FDA cannot require pasteurization under the PHSA without changing a product's standard of identity. But what discernable points they make are baseless. To begin, there was no problem with the FDA using its standard-of-identity authority to issue one rule and then using its PHSA authority to issue another. In the same way that an agency can choose between rulemaking or adjudication to pursue its policy aims, it is free to choose which of its applicable statutory authorities should form the basis of an administrative action. *Cf. Friends of Animals v. Bernhardt*, 961 F.3d 1197, 1208–09 (D.C. Cir. 2020) ("[A]n agency has broad discretion to choose whether to use rulemaking or adjudication—assuming both options are authorized by the agency's organic statutes."). Moreover, the latest rule's exception for food products whose standards of identity already include "an alternative to pasteurization" does not mean that a pasteurization mandate necessarily affects standards of identity. The exception merely accounted for the fact that the FDA had previously used another tool—the standard-of-identity authority—to approve safe pasteurization substitutes for some foods. Finally, the FDA's decision not to require pasteurization for butter earlier does not suggest that the agency "lacked authority to do so." *See*

Pls.' Mot. at 13. Even though the FDA recognized as early as 1974 that it could require pasteurization through the PHSA, "[n]othing prohibits federal agencies from moving in an incremental manner." *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 522 (2009).

Their historical argument unfounded, Plaintiffs cannot show that Congress clearly and manifestly meant for the FDCA's statutory definition of butter to limit the FDA's authority under the PHSA. Just because the FDA cannot alter the standard of identity for butter does not mean the agency cannot regulate butter for other purposes under other statutes. *See N.Y. Shipping Ass'n, Inc. v. Fed. Mar. Comm'n*, 854 F.2d 1338, 1367 (D.C. Cir. 1988) ("[T]here is no anomaly if conduct privileged under one statute is nonetheless condemned by another; we expect persons in a complex regulatory state to conform their behavior to the dictates of many laws, each serving its own special purpose."). The PHSA grants the FDA authority to combat infectious diseases apart from the authority the FDCA gives the agency to set standards of identity. Those separate authorities do not conflict here.

Absent a conflict with the FDCA, the PHSA comfortably authorizes the pasteurization rule. The requirement that butter be pasteurized to eradicate disease-causing pathogens is a textually reasonable interpretation of the broad power the PHSA gives the FDA "to make . . . regulations . . . necessary to prevent the introduction, transmission, or spread of communicable diseases." *See* 42 U.S.C. § 264. Plaintiffs' first claim fails.

B. The FDA Did Not Arbitrarily Deny Plaintiffs' Citizen Petition

Plaintiffs next attack the pasteurization rule as scientifically unsupported. This second claim asserts that the rule is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Judicial review under the arbitrary or capricious standard is "highly deferential," *AT&T, Inc. v. FCC*, 886 F.3d 1236, 1245 (D.C. Cir. 2018)

(citation omitted), especially when evaluating an agency's "scientific judgment within its 'area of expertise,'" *Rempfer*, 583 F.3d at 867 (citation omitted). The basic requirement is that the agency "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks and citation omitted).

The target of Plaintiffs' arbitrariness challenge is the FDA's denial of their citizen petition. FDA regulations require the agency to promulgate a rule proposed in a citizen petition if the petition (1) "contains facts demonstrating reasonable grounds for the proposal;" and (2) "substantially shows that the proposal is in the public interest and will promote the objectives of the [relevant organic statute] and the agency." 21 C.F.R. § 10.40(a)(2); *see also id.* § 10.30(b)(3) (providing that a petition should cite the "relevant statutory sections . . . of the . . . [FDCA] or [PHSA] or any other statutory provision for which authority has been delegated to" the FDA). Nevertheless, judicial review of an agency's refusal to promulgate a rule in response to a citizen petition is "extremely limited" and "highly deferential." *Massachusetts v. EPA*, 549 U.S. 497, 527–28 (2007) (citation omitted); *see also Defs. of Wildlife v. Gutierrez*, 532 F.3d 913, 919 (D.C. Cir. 2008) ("[A]n agency's refusal to institute rulemaking proceedings is at the high end of the range of levels of deference we give to agency action under our arbitrary and capricious review." (internal quotation marks and citation omitted)). The agency is entitled to such great deference because it has "broad discretion to choose how best to marshal its limited resources and personnel to carry out its delegated responsibilities." *Massachusetts*, 549 U.S. at 527. Furthermore, review "is limited to the 'narrow issues as defined by the denial of the petition for rulemaking.'" *NLRB Union v. Fed. Lab. Rels. Auth.*, 834 F.2d 191, 196 (D.C. Cir.

1987) (emphasis omitted) (quoting *Pro. Drivers Council v. Bureau of Motor Carrier Safety*, 706 F.2d 1216, 1217 n.2 (D.C. Cir. 1983)).

In denying Plaintiffs' citizen petition, the FDA articulated the basic rationale behind its pasteurization rule. The agency explained that "[t]he main ingredient in butter was cream" and that "[r]aw cream may be contaminated with pathogens capable of causing disease." J.A. 1077. Creating butter from raw cream does not destroy those pathogens, the agency continued, but pasteurization does. *Id.* Accordingly, pasteurization would help combat the spread of foodborne illnesses. *See, e.g.*, J.A. 1082 ("[W]e have determined that your Petition does not establish that the chemical and biological characteristics of raw cream butter are sufficient to prevent the presence of pathogenic organisms at levels that may cause human illness.").

The FDA also rejected each of the substantive grievances that Plaintiffs raised in their petition. *See* J.A. 1075–86; *see also* J.A. 9–23. Plaintiffs first asserted that "all butter, including that made from raw milk," must "pose[] a very low risk of foodborne illness" because there had been no outbreaks of disease linked specifically to raw butter in the previous eighteen years. J.A. 10. In response, the FDA pointed out that it had required pasteurization for butter shipped in interstate commerce during that time period. J.A. 1076. It then provided a list detailing outbreaks linked to butter "not known to be pasteurized" from 1908 to 2003. J.A. 1089. One outbreak that stemmed from raw butter caused over 200 people to fall ill and occurred as recently as 2001 and 2002. J.A. 1076.

Next, Plaintiffs claimed that butter is "rarely contaminated with pathogens at levels necessary to cause human disease" because of its "chemical and biological characteristics." J.A. 12. They said that pathogen counts in contaminated butter are "low" and, to illustrate the point, offered a threshold for *Listeria* of less than 100 colony-forming units per gram. *Id.* ("[W]hen

present, pathogen counts are low (<100 *L. monocytogenes*/g)."). The FDA countered that its list of butter-related outbreaks undermined Plaintiffs' claim. J.A. 1077. Moreover, despite Plaintiffs' focus on *Listeria*, the agency explained that raw butter was known to host *Salmonella*, *Staphylococcus*, and *E. coli* too. J.A. 1077–80. The FDA then delved into a review of the studies Plaintiffs cited, arguing that they did not support Plaintiffs' position. J.A. 1077–82. It said that one study drew on research that found *Listeria* in raw butter at levels above Plaintiffs' "low" threshold of 100 colony-forming units per gram. J.A. 1078–79. It also stated that some studies had traced disease outbreaks to bacteria levels below that threshold. J.A. 1078. One study Plaintiffs cited even warned that "butter should not be manufactured from raw cream or, if it is, it should be used only for cooking where it will receive adequate heat treatment," *i.e.*, pasteurization. J.A. 1081 (quoting J.A. 512). The agency concluded that the petition did "not establish that the chemical and biological characteristics of raw cream butter are sufficient to prevent the presence of pathogenic organisms at levels that may cause human illness." J.A. 1082.

Plaintiffs further argued that, when butter is contaminated with pathogens, "its natural properties limit or eliminate growth." J.A. 18. Once again, the FDA took a different view of the scientific studies that Plaintiffs relied on. It said that some were not directly applicable. For instance, one study tested cultured butter instead of raw butter. J.A. 1082. The agency also pointed out that Plaintiffs misconstrued other studies that had, in fact, detected bacterial growth. *Id.* One study indicated that its results were consistent with another study that had concluded: "[T]o produce Listeria-free butter, cream must be properly pasteurized and post-pasteurization contamination must be avoided." J.A. 1083.

Seemingly reiterating their second argument, Plaintiffs next contended that the scientific literature shows that "butter is a low-risk product." J.A. 20. They cited more studies, but the FDA again retorted that the studies did not provide the support that Plaintiffs said they did. J.A. 1083–86. In addition, the agency clarified that, while low levels of pathogens "may not cause illness in all individuals," research shows that even low levels "can cause illness in susceptible individuals" such as pregnant women. J.A. 1084. Because the agency's "regulations are intended to protect, not just healthy individuals, but also people who may be more susceptible," the FDA determined that Plaintiffs had not "provide[d] a basis for modifying the existing regulations." *Id.*[3]

Finally, Plaintiffs asserted that various regulatory agency's treatments of butter "reflect" its "relatively low risk." J.A. 23. According to the FDA, however, the regulatory standards Plaintiffs relied on were inapplicable because they were "measurement[s] of quality and not safety." J.A. 1086. And responding to Plaintiffs' point that some states permit the sale of raw dairy products including butter, J.A. 23, the FDA observed that many of those states nevertheless "warn of the danger of consuming raw milk and raw milk products and emphasize that State regulation does not ensure that raw milk is safe and free of pathogens." J.A. 1087.

Before this Court, Plaintiffs renew their attack on just two grounds. *Cf. Noble Energy, Inc. v. Salazar*, 691 F. Supp. 2d 14, 23 n.6 (D.D.C. 2010) (finding that a party forfeited an argument it made in its complaint but not in summary judgment briefing). Neither is persuasive.

[3] Plaintiffs fault the FDA for not specifically discussing two studies they cited. *See* Pls' Reply at 11–12. But an agency does not need to "directly address every study" that a petition mentions." *Nat'l Ass'n of Mfrs. v. EPA*, 750 F.3d 921, 924–25 (D.C. Cir. 2014). It was enough that the FDA responded—with evidence—to Plaintiffs' general argument that the pathogens found in butter are usually dangerous only at high levels.

First, Plaintiffs argue that the FDA justified its pasteurization rule with the irrational assumption that the pathogens found in butter are unsafe in any amount. *See* Pls.' Mot. at 15–18. Recall that, in support of their argument that butter usually carries low levels of pathogens, Plaintiffs gave an illustrative threshold for *Listeria* of less than 100 colony-forming units per gram. J.A. 12. The FDA remarked in response that its standard for detecting *Listeria* is "negative by test" and cited its Bacteriological Analytical Manual, J.A. 1079 n.8, which provides that the agency confirms the presence of *Listeria* when there is at least 1 colony-forming unit per gram, J.A. 1392. Plaintiffs interpret that language as suggesting that the FDA believes that any amount of a pathogen presents a health risk. Pls. Mot. at 15–16. They reiterate that low levels of *Listeria* do not cause disease. *Id.* at 15–17. And they add that even pasteurized milk products can be contaminated by pathogens and cause illness. *Id.* at 16–18. It is arbitrary, they conclude, for the FDA to ban raw butter on the basis that the mere presence of pathogens is dangerous when low levels do not cause illness and pasteurization cannot eliminate all pathogens anyway. *Id.* at 17–18.

The argument completely misses the mark. When promulgating the pasteurization rule, the FDA explained that its aim was to address "documented health risks" such as "the transmission of disease" that "epidemiological evidence" had "repeatedly" linked to raw dairy products. Pasteurization Rule, 52 Fed. Reg. at 29,511. Nowhere did the agency claim that it required pasteurization because the presence of *any* amount of a pathogen would cause illness. It certainly said no such thing in its passing remark (in a footnote) about its listeria testing procedures.[4] Moreover, even though "[a]ll information available to the [FDA] documents that

[4] Nevertheless, the agency acknowledges that the mere "presence of *Listeria monocytogenes* in food causes that food to be 'adulterated' under the FDCA." Def.'s Mot. at 26

pasteurization . . . effectively eliminates . . . numerous . . . harmful microorganisms," *id.* at 29,512, the agency acknowledged in its response to Plaintiffs' petition that contamination of pasteurized butter can sometimes occur, J.A. 1078. That rare possibility does not mean pasteurization is useless. Indeed, by Plaintiffs' own account, contamination of pasteurized milk products is "[u]sually" due to "germs introduced in the dairy *after* the pasteurization process." Pls.' Mot. at 17 (emphasis added) (quoting *Raw Milk Questions and Answers*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/foodsafety/rawmilk/raw-milk-questions-and-answers.html). At bottom, there is little doubt that pasteurization minimizes the "documented risks" posed by pathogens in dairy products like butter. *See* Pasteurization Rule, 52 Fed. Reg. at 29,513. The FDA thus reasonably concluded that requiring pasteurization would "result in some benefit to the public health." *See id.*

Second, Plaintiffs take issue with the FDA's list of outbreaks connected to butter. They point out that, for ten of the eleven outbreaks the agency identified, it was uncertain whether the contaminated butter was pasteurized. Pls.' Mot. at 18. As a result, Plaintiffs argue, the FDA cannot say that raw butter is any more dangerous than pasteurized butter and thus ban only the former product. *Id.* at 18–19.

This second argument is another nonstarter. As the FDA says, it compiled the list in response to Plaintiffs' assertion that "*all* butter, including that made from raw milk, poses a very low risk of foodborne illness." Defs.' Mot. at 27 (quoting J.A. 10). Furthermore, "[t]he mere fact that a 'dataset was less than perfect . . . does not amount to arbitrary decision-making.'" *Hisp. Affs. Project v. Acosta*, 901 F.3d 378, 392 (D.C. Cir. 2018) (quoting *District Hosp.*

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n.12 (citing 21 U.S.C. § 342(a)(1); *United States v. Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d 30, 48 (E.D.N.Y. 2001), *aff'd in relevant part*, 56 F. App'x 542 (2d Cir. 2003)).

Partners, L.P. v. Burwell, 786 F.3d 46, 61 (D.C. Cir. 2015)). It is enough that an "agency 'explain[s] the available evidence' and rationally connect[s] the facts to the choice made." *See id.* (quoting *New York v. EPA*, 413 F.3d 3, 31 (D.C. Cir. 2005)). That is what the FDA did. It explained that the early outbreaks listed in the table "were likely from raw cream butter because pasteurization of milk and cream only gradually increased from 1915 to the late 1940's in U.S. cities." J.A. 1076. That is a justifiable assumption given the history of pasteurization, so even if someone could reasonably disagree, it does not mean the agency acted arbitrarily. *See Bean Dredging, LLC v. United States*, 773 F. Supp. 2d 63, 85–86 (D.D.C. 2011) (explaining that, even though "reasonable minds could differ" about the meaning of certain evidence, the agency's position was not arbitrary because it "was considered and informed and had a rational basis" (citation omitted)). And in any case, the list was just one source of evidence the FDA drew on to deny Plaintiffs' petition. The agency also rested its denial on numerous studies that showed how raw butter could host pathogens in high enough levels to be dangerous or that linked outbreaks to other raw dairy products. *See, e.g.*, J.A. 1078 ("Literature (Lyytikiiinen et al. 2000 and Maijala et al. 2001) indicates that levels <100 cfu/g in butter have been implicated in outbreaks of human illness."); *id.* ("Verraes et al. . . . recognize that "for cream made from raw milk, the main microbiological hazards are estimated to be [*Listeria*], [*Staphylococcus*], and [*E. coli*] because [*Listeria*] and [*Staphylococcus*] have been detected in cream and [*E. coli*] was linked to a cream outbreak.").[5]

[5] Plaintiffs believe that the FDA acted arbitrarily because it never studied butter. *See* Pls.' Mot. at 15; Pls.' Reply at 12–13. But they cite no authority establishing that the FDA must conduct its own studies on every product it decides to regulate. In denying Plaintiffs' petition, the agency thoroughly examined data and third-party studies that shed light on the risks of raw butter. *See* J.A. 1076–86. It "'explained the available evidence' and rationally connected the facts to the choice made." *See Hisp. Affs. Project*, 901 F.3d at 392 (quoting *New York*, 413 F.3d at 31). And as the FDA points out, Plaintiffs did not offer evidence to challenge its assertion that

Ultimately, the FDA's decision to require the pasteurization of butter to prevent the spread of communicable diseases is "a scientific judgment within its area of expertise" that is entitled to "a high level of deference." *See Rempfer*, 583 F.3d at 867 (internal quotation marks and citation omitted); *see also* 42 U.S.C. § 264 (granting the FDA authority to "make and enforce such regulations as *in [its] judgment* are necessary to prevent the introduction, transmission, or spread of communicable diseases" (emphasis added)). Plaintiffs try to offer counterpoints, but the agency effectively addressed those points and put forth a great deal of scientific evidence in support of its judgment. Reweighing even a mixed bag of scientific evidence is inappropriate when there is plenty to support the agency's decision. *See Nat'l Ass'n of Mfrs. v. EPA*, 750 F.3d 921, 924 (D.C. Cir. 2014) ("Under the arbitrary and capricious standard, we exercise great deference when we evaluate claims about competing bodies of scientific research."). The Court declines Plaintiffs' invitation to do so here. The FDA is entitled to summary judgment on their second claim.

V. CONCLUSION

For the foregoing reasons, Plaintiffs' motion for summary judgment (ECF No. 15) is **DENIED** and Defendant's motion for summary judgment (ECF No. 17) is **GRANTED**. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: May 24, 2021

RUDOLPH CONTRERAS
United States District Judge

"'[t]he main ingredient in butter is cream' . . . and 'the manufacturing process for butter does not destroy pathogens that may be present in the cream.'" Def.'s Reply at 10 (quoting J.A. 1077).