



February 27, 2020

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Farm-to-Consumer Legal Defense Fund  
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7221 South Jameson Avenue  
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Re: Docket No. FDA-2016-P-1852

Dear Mr. Kennedy and Mr. McAfee:

This letter responds to your citizen petition, dated June 22, 2016, in which you request that the U.S. Food and Drug Administration (“FDA” or “we”) amend our regulations to allow the interstate distribution and sale of raw butter. Specifically, you request that we amend the definition of “milk products” in 21 CFR 1240.3(j) by deleting the term “butter” as one of the food products included in the definition and by adding the sentence “This definition shall not include butter meeting the standard established by 21 U.S.C. 321a” after the last sentence. Further, your citizen petition requests that we amend 21 CFR 1240.61(a), “Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption,” by adding the text “or except for butter meeting the standard established by 21 U.S.C. 321a” at the end to “allow unpasteurized butter to be legally transported across state lines.” *See* Citizen Petition from Pete Kennedy, Farm-to-Consumer Legal Defense Fund, and Mark McAfee, Organic Pastures Dairy Company submitted to the Division of Dockets Management, Food and Drug Administration (“Petition”) at page 3.

Your Petition does not contain facts demonstrating reasonable grounds for amending 21 CFR 1240.3(j) or 21 CFR 1240.61(a) as you requested, to allow the interstate delivery or sale or distribution of raw cream butter.<sup>1</sup> Further, your Petition does not substantially show that your proposal is in the public interest and will promote the public health objectives of FDA and the statutes we administer (*see* 21 CFR 10.40(a)(2)). Therefore, in accordance with 21 CFR 10.30(e)(3), and for the reasons stated below, we are denying your request.

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<sup>1</sup> In your Petition, you refer to raw butter, which is butter made from raw cream and commonly known as raw cream butter. Throughout our response, we use the term raw cream butter, except where we are referring to or quoting from the Petition.

## DISCUSSION

### *1. Argument claiming FDA erred in including raw butter and other manufactured dairy products in the ban of interstate transport of raw dairy products*

Section 1240.61(a) of title 21 of the Code of Federal Regulations states, in pertinent part:

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 . . . .

Pasteurization is a process that kills harmful bacteria by heating milk to a specific temperature for a set period of time. As reflected in the preamble of the final rule promulgating 21 CFR 1240.61, FDA concluded that the available record “demonstrate[d] an association between the consumption of raw milk and the outbreak of disease.” (52 FR 29509, 29511 (Aug. 10, 1987).) FDA also found that the record demonstrated “an association between the consumption of certified raw milk<sup>2</sup> and the outbreak of disease, particularly among consumers who are young, elderly, or infirm.” *Id.*

Based on these findings, FDA issued 21 CFR 1240.61 acting, in part, under section 361(a) of the Public Health Service Act (“PHS Act”), which authorizes us to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases. *See* 42 U.S.C. § 264(a).<sup>3</sup>

In 1992, FDA amended its regulations by defining “milk” and “milk products” in 21 CFR 1240.3 (57 FR 57343, Dec. 4, 1992). Under 21 CFR 1240.3(j), the term “milk product” is defined as “[f]ood products made exclusively or principally from the lacteal secretion obtained from one or more healthy milk-producing animals. . . , 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 . . . .” Thus, this definition includes butter. The purpose of the rulemaking defining “milk products” was to set out those dairy products that are covered under the pasteurization regulation in 21 CFR 1260.61. *See* 57 FR 1407, 1408 (Jan. 14, 1992).

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<sup>2</sup> “Certified raw milk” is raw milk produced in compliance with methods and standards developed by private organizations. 52 Fed. Reg. at 29510.

<sup>3</sup> In 1944, Congress passed the PHS Act, which vested certain authority in the Surgeon General. Pub. L. No. 111-25, 58 Stat. 703, 42 U.S.C. § 264(a). The Office of Surgeon General was abolished by section 3 of 1966 Reorg. Plan No. 3, eff. June 25, 1966, 31 FR 8855, 80 Stat. 1610, and all of its functions were transferred to the Secretary of Health, Education, and Welfare (now Secretary of Health and Human Services (“HHS”)) by section 1 of 1966 Reorg. Plan No. 3, set out under 42 U.S.C. § 202. The HHS Secretary’s authority has been delegated to FDA. *See* FDA Staff Manual Guide 1410.10.1.A.3 (*available at* <https://www.fda.gov/media/81983/download>).

In your Petition, you state that “Given the historical context of the case, butter (and other manufactured products) should not have been included in the ultimate ban. Instead, ‘all raw milk products’ should have been interpreted to cover only actual milk and cream items, not products manufactured from them, such as butter or cheese” (Petition at page 5). You argue that “In banning the interstate sale of raw butter, the agency acted beyond the scope of its statutory authority” (Petition at page 9).

Your argument relates to the basis for FDA’s pasteurization requirement in 21 CFR 1240.61. FDA promulgated the regulation after a court found that the agency’s previous denial of a request to ban all sales of raw milk and raw milk products was arbitrary and capricious. *Public Citizen v. Heckler*, 653 F.Supp. 1229 (D.D.C. 1986). The court concluded that the record presented “overwhelming evidence of the risks associated with the consumption of raw milk, both certified and non-certified” and was “replete with credible evidence of the danger of raw milk consumption.” *Id.* at 1238. Finding that the record “conclusively” demonstrated that raw milk is unsafe, *id.* at 1241, the court found that section 361(a) of the PHS Act provides sufficient authority to implement a complete ban on the interstate sale of raw milk and ordered that FDA promulgate “a rule banning the interstate sale of all raw milk **and all raw milk products**, both certified and non-certified.” *Id.* at 1242 (emphasis added).

Thus, far from suggesting that the “historical context” of FDA’s pasteurization requirement should not have applied to products manufactured from milk, the history demonstrates that a court specifically required FDA to ban the interstate sale of milk products in addition to milk itself. While the court in *Public Citizen* did not address what constitutes a “milk product,” there is no evidence that the court intended “milk product” to refer only to milk and cream, as you suggest, and, for the reasons discussed below, the scientific basis for the pasteurization requirement for milk and milk used to make milk products holds equally true for butter. Thus, it is proper to include butter among the articles covered by the definition of “milk products.”

## *2. Argument that FDA has established a de facto standard of identity for butter*

You argue that FDA “acted in contravention of its statutory authority by establishing a *de facto* standard of identity for butter” (italics in original) and assert that the act of including “butter” within the definition of “milk products” at 21 CFR 1240.3(j) creates a standard of identity for butter (Petition at page 7). This is incorrect.

As you note, butter is defined by statute. 21 U.S.C. 321a. FDA has not promulgated a regulation to further define butter, and the definition of milk products at 21 CFR 1240.3(j) does not constitute a standard of identity for butter or any other milk product included within the definition. FDA promulgates standards of identity under section 401 of the Federal Food, Drug, and Cosmetic Act (“FD&C Act”) (21 U.S.C. 341), which authorizes us to issue regulations fixing and establishing for any food a reasonable definition and standard of identity, quality, or fill of container whenever such action will promote honesty and fair dealing in the interest of consumers. Under section 701(e) of the FD&C Act, any action for the amendment or repeal of any definition and standard of identity under section 401 of the FD&C Act for any dairy product must be begun by a proposal made either by FDA or by petition, and be followed by an order about which interested parties may file objections that may operate to stay the effectiveness of the order. 21 U.S.C. 371(e). Standards of identity typically set forth permitted ingredients, both mandatory and optional, and sometimes specify the amount or proportion of each ingredient.

Although sometimes standards of identity may also designate the manner in which products are produced when the manufacturing process has a bearing on the identity of the finished food,<sup>4</sup> manufacturing controls intended to ensure safety may exist independent of any standards of identity. *See, e.g.*, 21 CFR part 117 (Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventative Controls for Human Food); 21 CFR 1240.60 (prohibiting transport in interstate commerce of any molluscan shellfish handled or stored in an insanitary manner that would render the molluscan shellfish to become agents in the spread of communicable disease). Standards of identity protect consumers against economic adulteration and reflect consumers' expectations about food. *Id.* They may also describe the basic nature and essential characteristics, including nutritional characteristics, of the food. *Id.* A food is misbranded if it purports to be or is represented as a food for which a standard of identity has been established but fails to conform to the standard. *See* section 403(g) of the FD&C Act (21 U.S.C. 343(g)). With regard to butter, section 401 of the FD&C Act further states that no definition and standard of identity shall be established for butter. FDA, cognizant of the limits of its legal authority to establish a standard of identity for butter, has never done so.

Indeed, far from relying on the authority and the specific procedures for promulgating standard of identity regulations when establishing the definition of milk products at 21 CFR 1240.3(j), FDA relied on the authority of the PHS Act and followed notice and comment procedures (informal rulemaking). Substantively, too, nothing about the 1240.3(j) rulemaking is akin to a standard of identity. That rule does not specify permitted ingredients, proportions of ingredients, methods of production, or characteristics of the covered milk products. It was not intended to reflect consumer expectations about the covered milk products or protect consumers from economic harm. Rather, it was simply intended to clarify those products that are covered by the safety-oriented pasteurization regulation in 21 CFR 1240.61. Notably, many milk products specifically included within 21 CFR 1240.3(j) are examples of milk products that have FDA standards of identity at 21 CFR 131 et seq. (e.g., the various types of creams, half-and-half, dry milk, nonfat dry milk, dry cream, condensed milk, concentrated milk, cultured milk, acidified milk, eggnog and yogurt or at 21 CFR 133 et seq (various cheeses) or at 21 CFR 135 et seq, e.g., ice cream). The 1240.3(j) rulemaking did not amend those standards in any way. Thus, not only did the 1240.3(j) rulemaking not purport to be a standard of identity rulemaking, it did not serve to operate as one in practice either. Your assertion that the rulemaking functioned as a *de facto* standard of identity for butter is erroneous and not supported by the record.

3. *Arguments claiming raw butter to be a low risk product that does not merit regulatory restrictions such as required pasteurization*

Your Petition advances several arguments with regard to risk in support of your request that raw cream butter be exempted from 21 CFR 1240.3(j) and thereby application of 21 CFR 1240.61. Specifically, in section C of your Petition, you claim that “raw butter is a low-risk product that does not merit these regulatory restrictions” (Petition at page 9). We address each subsection of section C below as it is presented in your Petition.

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<sup>4</sup> *See* 70 FR 29214, 29216 (May 20, 2005) (Proposed rule explaining that standards of identity “may describe the manufacturing process when that process has a bearing on the identity of the finished food”).

- a. Argument that “[b]ased on the actual occurrence of outbreaks, all butter, including butter made from raw milk, poses a very low risk of foodborne illness.”

In this subsection (*see* Petition at pages 10-11) you provide information (in your Table 1) that you indicate is derived from a search of CDC’s Foodborne Outbreak Online Database Tool and that the time frame covered by your search was 1998-2016. Your Petition asserts “there appear to have been no foodborne illness outbreaks linked to butter commercially prepared from raw milk” (Petition at page 10).

As an initial matter, we note that the interstate shipment (and the holding for sale after shipment in interstate commerce) of butter produced from raw milk has been legally prohibited by FDA regulation (21 CFR 1240.61) during the 1998-2016 timeframe you referenced. So, contrary to your inference that butter commercially prepared from raw milk is either low-risk or does not warrant pasteurization based on the absence of foodborne illness outbreaks, one also could infer that either the *prohibition* of interstate shipments of butter produced from raw milk contributed to the absence of foodborne illness outbreaks or that the *pasteurization requirement* resulted in a *safe* product which, in turn, did not result in foodborne illness outbreaks. One also could hypothesize that foodborne illness outbreaks occurred but were not reported or noticed. In short, absent more information to associate an outcome (absence of foodborne illness outbreaks) with a cause, we cannot conclude that the absence of reported foodborne illness outbreaks means that butter commercially prepared from raw milk must be low-risk or does not require pasteurization.

To the extent that you are asserting that there have not been outbreaks associated with raw cream butter, we disagree. Table 1, attached, is a compilation of foodborne illness outbreaks associated with butter. This evidence makes clear that butter can be, and has been, associated with foodborne illness. In some cases in Table 1, raw cream butter is specifically implicated. In other cases, the type of butter at issue was not reported. For the early cases, it is reasonable to assume that the illnesses 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.<sup>5</sup> For some of the outbreaks that occurred after pasteurization became widespread, it is not possible to determine whether the butter was made from raw or pasteurized cream. The existence of the outbreaks does show that, contrary to your assertions, butter is not a risk-free substance and pathogens in butter can and do cause illness. Critically, too, the data in Table 1 shows that unpasteurized butter has caused significant illnesses even in modern times. For example, an outbreak caused by butter made from unpasteurized cream caused more than 200 illnesses from 2001-2002.

You also state that “the lack of outbreaks linked to commercially prepared raw butter are similarly reflected in the Petitioner’s experience” and you specifically mention “McAfee’s dairy has sold over 2 million pounds of butter since 2001, without a single foodborne illness linked to such sales” (Petition at page 11). However, your Organic Pastures Dairy Company has been involved in recalls and quarantines that included raw cream butter.<sup>6</sup> Contrary to your claims, this establishes that there have been public health concerns associated with your raw cream butter. Although there were no specific findings of disease associated with the butter, the butter was

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<sup>5</sup> U.S.D.A Bulletin 342:1-27. Revised October 10, 1922. Ayers. The Present Status of the Pasteurization of Milk.

<sup>6</sup> [http://www.cdffa.ca.gov/egov/Press\\_Releases/Press\\_Release.asp?PRnum=06-055;](http://www.cdffa.ca.gov/egov/Press_Releases/Press_Release.asp?PRnum=06-055)  
[http://www.cdffa.ca.gov/egov/press\\_releases/Press\\_Release.asp?PRnum=12-018.](http://www.cdffa.ca.gov/egov/press_releases/Press_Release.asp?PRnum=12-018)

made from raw milk linked to pathogens. As explained below, the manufacturing process for raw cream butter does not destroy pathogens.

- b. Argument that “[t]he rarity of outbreaks connected to butter is consistent with the chemical and biological characteristics of this product”

This subsection (*see* Petition at pages 12-18) contains numerous claims about butter, the incidence of pathogens in butter, the potential for outgrowth of bacteria and pathogens in butter, microbial competition, the microbiota of butter and several other topics such as the Human Microbiome Project and colonization resistance.

We will address each of these claims as they arise in the text of this subsection to your Petition. At the outset, however, we believe it is important to identify important features about the manufacturing process for butter. The main ingredient in butter is cream. Raw cream may be contaminated with pathogens capable of causing disease. Pasteurization of the cream destroys such pathogens by treating the cream with heat for a period of time known to be adequate to kill pathogens. When butter is manufactured from raw cream, the manufacturing process itself will not cause a pasteurization effect. Consequently, the manufacturing process for butter does not destroy pathogens that may be present in the cream.

Your Petition does not directly address the inadequacy of the butter manufacturing process to destroy pathogens. Instead, you argue that “Properly prepared commercial butter is not sterile, but is rarely contaminated with pathogens at levels necessary to cause human disease” (Petition at page 12). As support for this argument, you cite a study by Lewis et al. from 2006 entitled “Prevalence of *Listeria monocytogenes* and other *Listeria* species in butter from United Kingdom production, retail and catering premises” (Lewis et al. 2006) and another by Verraes et al. from 2015 entitled “A review of the microbiological hazards of dairy products made from raw milk” (Verraes et al. 2015). The studies you cite do not suggest that pathogen levels in butter are too low to cause illness. Indeed, the facts demonstrate that butter can contain pathogens at levels that can cause illness in humans.

As an initial matter, your claim that “pathogen levels in naturally contaminated butter are too low to cause illnesses, as reflected in the very few outbreaks listed in the CDC database” (Petition at page 12), is belied by the existence of outbreaks attributed to butter. If pathogen levels in naturally contaminated butter were too low to cause illness, as you claim, there would not be any outbreaks attributed to butter. However, as discussed above, there have been such outbreaks.

Neither do the studies you cite establish that pathogen levels in naturally contaminated butter are too low to cause illnesses. With respect to the Lewis et al. 2006 study, the study found that a small percentage of all samples analyzed contained *Listeria monocytogenes* (“Lm”). The authors do not claim that their findings are definitive with respect to the incidence and levels of Lm in raw cream butter generally. Indeed, the authors discuss other literature on the incidence of Lm in butter. This includes a 2004 study by De Reu et al. on raw milk and farm-produced raw milk products, which found that 18.7% of all butter samples analyzed were positive for Lm. Lewis et al. 2006 also mention literature indicating that Lm can grow in butter, citing to Lanciotti et al. 1992 and Olsen et al. 1988. Thus, to reiterate, Lewis et al. 2006 does not show that pathogen levels are too low to cause illness.

Nor does the Verraes et al. 2015 paper support your position. The Verraes et al. paper is a review of the microbiological hazards in dairy products made from raw milk. For example, the Verraes et al. paper also cites to the De Reu et al. 2004 study discussed above among studies that report on the incidence of Lm in raw cream butter. Verraes et al. cited studies that detected Lm at a frequency of occurrence in raw milk butter between 3.6 to 29.9% and in raw cream between 0.7 to 8.3%. Additionally, Verraes et al. cited studies that detected *Staphylococcus aureus* (*S. aureus*) at a frequency of occurrence in butter between 1.6 to 20.3%. Interestingly, one study on butter cited by Verraes et al. reported that  $>2 \log$  of *L. monocytogenes*/g was found in 0.2% of samples analyzed.<sup>7</sup> Verraes et al. also mention a study on Lm in naturally contaminated butter that found contamination levels between 0.6 to 1.2 log/g (or approx. 4-16 colony forming units per gram (cfu/g)). Literature (Lyytikäinen et al. 2000 and Majjala et al. 2001) indicates that levels  $<100$  cfu/g in butter have been implicated in outbreaks of human illness.

Further, Verraes et al. themselves recognize that “For butter made from raw milk, the main microbiological hazards are Lm, [Verotoxigenic *Escherichia coli* (“VTEC”)] and *S. aureus* because these pathogens have been detected in butter” and “for cream made from raw milk, the main microbiological hazards are estimated to be Lm, *S. aureus* and VTEC because Lm and *S. aureus* have been detected in cream and VTEC was linked to a cream outbreak.”

The hazards identified by Verraes et al. for raw butter are consistent with those identified by the International Commission for Microbiological Standards for Foods (“ICMSF”) for butter, which lists *Salmonella* spp., *E. coli* O:157 H:7, Lm and *S. aureus* as pathogens to be controlled, citing pasteurization of cream prior to churning as a means of reducing the presence of said pathogens. ICMSF also indicates that *S. aureus* and *Salmonella* spp. are pathogens associated with cream (ICMSF6).

Thus, you have not established that pathogen levels in naturally contaminated butter are too low to cause illnesses.

Your Petition further argues that “contamination of commercial butter with pathogens is very rare in current practice, and when present, pathogen counts are low (less than 100 *L. monocytogenes*/g),” citing to Varga (2007), Lewis et al. (2006), and Verraes et al. (2015). While infrequent, contamination of commercial butter, (which is a term typically used in the literature to refer to butter made from pasteurized cream), with pathogens can and does occur. However, commercial butter made from pasteurized milk is not subject to 21 CFR 1240.61 and is not at issue here. Thus, the paper, which is a small Varga study on commercial Hungarian milk products, does not support your argument that raw cream butter should not be subject to 21 CFR 1240.61. Varga examined only 8 samples of butter, which were likely made from pasteurized cream, for the presence of *Salmonella* and Lm and did not find either to be present. Varga does not report his negative findings as “ $<100$  *L. monocytogenes*/g” but as zeros for both parameters. Varga does not claim that his findings can be extrapolated to butter generally or to raw cream butter in particular.

As discussed in more detail above, Verraes et al. (2015) does not support your claim that “when

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<sup>7</sup>  $>2 \log$  of Lm/g is equivalent to  $>200$  Lm cfu/g.

present, pathogen counts are low” since some literature reported on by Verraes determined that Lm was present in some samples analyzed at levels above 100 cfu/g, which you indicate is your threshold for “low.”<sup>8</sup>

In any case, levels of Lm at <100 cfu/g in butter have been associated with outbreaks of human illness. (Lyytikäinen et al. 2000). Thus, you have not established either that pathogen levels in commercial butter necessarily remain below your threshold for “low” levels, or that contamination at levels you deem “low” would be too low to cause human illness.

In this subsection, you also assert that the chemical and biological characteristics of butter do not support pathogen growth. For instance, you state that: “butter is not a good medium for growth of bacteria due to its nature as a water-in-oil emulsion;” “[g]rowth of bacteria is inhibited in the hardened butterfat;” “[t]he physical structure of commercially prepared butter is an influential factor limiting pathogen growth;” “the low temperatures at which it is kept (either refrigerated or frozen) reduce or eliminate bacterial growth;” “butter’s acidic pH limits or prevents pathogen growth;” “for salted butters, the dispersion of salt also inhibits bacterial growth;” and “[m]icrobial ecology – the competition and co-operation of microbes – plays a significant role in the safety of....raw butter” (Petition at pages 12-14).

The citations you offer in support of these various claims do not, in most instances, support the propositions for which they are being offered. For example, with respect to your claim that “pathogens do not grow in butter,” you cite to Michelin et al. (2016), Holliday et al. (2003) and Voysey et al. (2009). However, both Holliday et al. and Voysey et al. report growth of Lm occurring in butter in their studies. Voysey et al. studied the behavior of Lm in butter containing a wide range in salt levels – from 0.01% -2.4%. They reported that “growth was apparent at even the highest level of salt tested here.” Michelin et al. conducted their work on cultured butters, which have lower pH’s (*i.e.*, are more acidic) than sweet cream butters—thus making microbiological growth less likely. While Michelin et al. report no Lm growth, those findings are specific to cultured butters and should not be extrapolated to sweet cream butters.

In support of your claim that “properly produced butter simply does not support pathogen growth” (Petition at page 12) you cite to Holliday et al., Voysey et al., and Michelin et al. However, those studies neither make nor support this claim. Indeed, such a claim would contradict findings in the literature. Lanciotti et al. (1992) and Olsen et al. (1988) have found that Lm can grow in butter.

In support of your claim that “butter is not a good medium for the growth of bacteria” (Petition at page 12), you cite to Hammer and Long (1941), Wilbey (2002), Budhkar et al. (2014), Ghodussi and Ozer (2014), and Michelin et al. (2016). Hammer and Long is a discussion of the factors that limit bacterial growth in butter, but the authors concede that “bacterial spoilage of butter occurs rather frequently, even when protective measures are employed in the manufacture.” Butter can, in fact, support the growth of both spoilage microorganisms, such as some psychrotrophic, lipolytic, and proteolytic *Pseudomonads*, *Bacillus* species, and several types of yeasts and molds, as well as pathogens. Wilbey (2002) expressly recognizes that, “in well- made

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<sup>8</sup> FDA’s standard for Lm is negative by test. Bacteriological Analytical Manual. Chapter 10.  
<https://www.fda.gov/food/laboratory-methods-food/bam-detection-and-enumeration-listeria-monocytogenes>

salted butter the surviving microflora will be tolerant of low temperature and relatively high salt concentrations.” Budhkar et al. discuss the most common causes of spoilage in butter, many of which are microbial in nature, i.e., due to the outgrowth of spoilage organisms in butter. While Ghodussi and Ozer do state that “butter is not an ideal medium for the growth of microorganisms, especially for the pathogens”---which is certainly the case when one considers the composition of butter compared to many other foods, --- they devote an entire section of their chapter to a discussion of the research then available demonstrating the growth of Lm in butter, and another section to discussion of the research then available to the microbial spoilage of butter. Thus, the references you cite in support of your argument that bacteria do not grow in butter do not actually support your argument. The lone exception is the Michelin et al. study which did not find growth in the cultured butter studied but, given the differences between cultured butter and sweet cream butter (discussed above), that study is of limited applicability.

You also claim that “butter’s acidic pH limits or prevents pathogen growth” (Petition at page 13). However, your footnote and citation to Holliday et al. for this proposition<sup>9</sup> make clear that the product you are referencing is whipped butter containing preservatives. Whipped butter containing preservatives has very different properties from sweet cream butter. The whipped butter product with preservative had a more acidic pH (4.51) than is typical for a sweet cream butter. The pH of a sweet cream butter will approach neutrality (7.0) and is commonly cited as being between 6.1-6.4. (See Budhkar et al. 2014 and Ghoddusi and Ozer. 2014.) It is likely that the acidic nature of the whipped butter product and the fact that it contained preservatives inhibited microbial growth in that product. However, the same authors identify another butter product with a typical pH for butter that *did* demonstrate growth of pathogens Salmonella, E.coli O:157:H7, and Lm when stored at 21 degrees Celsius. The authors (Holliday et al.) conclude their paper by saying: “The behavior of enteric pathogens in other, similar products with higher pH values, lower concentrations of preservatives, or different emulsification characteristics may be different that that observed in products evaluated in this study. Challenge studies to determine survival and growth characteristics of pathogens in products presenting less hostile environments need to be done to accurately assess their level of microbiological safety.” Thus, the findings for one butter product are not extrapolatable to other butters, and the evidence for the other products studied by Holliday et al. contradicts your assertion that pathogens do not grow in butter.

With respect to your claim that “for salted butters, the dispersion of salt inhibits bacterial growth” (Petition at page 13), that is not accurate. While salt in the moisture phase of butter does help to control microbial growth, salting of butter does not prevent growth entirely. Indeed, Holliday et al. report growth of the pathogens, which they studied in a salted butter. Voysey et al. also report on growth of Lm in butter at varying salt concentrations.

With respect to your claim that “microbial ecology – the competition and co-operation of microbes – plays a significant role in the safety of....raw butter” (Petition at page 13), we note

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<sup>9</sup> No growth of inoculated *L. monocytogenes* was observed at an acidic pH (4.5) for sweet cream whipped unsalted butter over 21 days of incubation at 4.4 and 21 °C, while no growth or 0.5 log increase was observed for sweet cream whipped salted butter at a less acidic pH (6.4). Holliday et al., 2003. *supra* note 43.

that you cite to three references<sup>10</sup> that are concerned with cheese and do not discuss raw cream butter. Thus, these references do not support your claim that raw cream butter is safe.

Your Petition also refers to research about microbial economy and the Human Microbiome Project. However, you fail to connect this research to the issue of the safety of raw cream butter. With respect to your claim that microbes “provide active competition against growth of potentially pathogenic contaminants through a principle termed colonization resistance,” outgrowth of pathogens in butter, despite microbial competition, can occur---as is evidenced by the studies described above that documented pathogen growth in butter products.

You cite studies of butter produced in Algeria, Sudan and Egypt that reveal and characterize the presence of certain types of microorganisms in butter. You appear to intend for these studies to support your proposition that “active non-pathogenic bacteria more easily outcompete the pathogens under physicochemical conditions that limit all bacterial growth.” However, we note several inaccurate statements you make relative to these studies. Among these is your statement that “if one looks at the coliform counts - which more realistically reflect the potential for most pathogenic organisms – they are both low to start with and have little to no growth when the butter is refrigerated.” It appears that you are referring to the Ahmed et al. study, since that is the only one of the three that you cite that actually was a growth study. The coliform group of bacteria includes the genera *Citrobacter*, *Enterobacter*, *Hafnia*, *Klebsiella*, and *Escherichia*. Neither *Lm*, *S. aureus*, *Yersinia enterocolitica*, nor *Salmonellae* are coliforms, and it is not appropriate to assume that the growth rates in butter for members of the coliform family can be extrapolated to pathogens generally. In your very next paragraph, you claim that “Pathogens such as *L. monocytogenes* that are psychrotrophs grow at lower rates than the non-pathogenic microbiota” and cite to a reference on exposure assessment scenarios in meat as support for this claim. Thus, in two consecutive paragraphs, you make two different claims about growth rates of pathogens in butter, and neither of those claims is supported by citation to appropriate literature.

With respect to the Ahmed et al., Idoui et al., and Meshref butter studies that you cite, we point out Tables 2 and 3 in your Petition (Petition at 17) do not completely represent the data developed by these authors. Notably, you only provide data on a few quality parameters and the *S. aureus*, fecal coliform and *E.coli* data developed by Meshref are not reported in your tables.<sup>11</sup> Finally, Meshref did not conduct any growth studies nor did he make any statements relative to microbial competition and pathogens. Rather, he did say “The counts of microorganisms above the recommended criteria and the presence of pathogenic bacteria may pose a risk for public health” and “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.”

The Idoui et al. study is not relevant to your argument about microbial competition. Idoui et al. studied the fatty acid composition of traditional butter produced in East Algeria. Although Idoui

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<sup>10</sup> T.M. Cogan & T.P. Beresford, Microbiology of Hard Cheese, Chapter 11 in DAIRY MICROBIOLOGY HANDBOOK 515-560 (R.K. Robinson ed., 3rd ed. 2002); D.J. D’Amico, Microbiological Quality and Safety Issues in Cheesemaking, in CHEESE AND MICROBES 251-309 (Catherine W. Donnelly, Ed., 2014); American Academy of Microbiology, FAQ: Microbes Make the Cheese (2015), <https://www.asmscience.org/content/report/faq/faq.8>.

<sup>11</sup> Meshref did not report his data in decimal format, but as counts, and the decimal estimates that you report for the few Meshref parameters that you present do not accurately reflect Meshref’s data.

et al. does report the microbiological quality of the five samples of butter which were studied, it does not discuss microbial growth or competition.

Ahmed et al. report their findings relative to the impact of two different storage temperatures on several microbiological quality parameters for butter. The authors do not discuss microbial competition or the impact of the spoilage organisms they studied on the outgrowth of pathogens. Therefore, these studies do not support your arguments regarding microbial competition or that pathogens do not grow in butter.

Taken together, we 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.

- c. Argument that “[e]ven when butter is intentionally inoculated with pathogens, its natural properties limit or eliminate growth”

In this subsection (see Petition at pages 18-20), you assert that the natural properties of butter limit or eliminate pathogen growth in butter, even when butter is intentionally inoculated with pathogens. In the following paragraphs, we explain why your Petition does not support this argument. As we discuss earlier in this response, the manufacturing process for butter does not destroy pathogens that may be present in raw cream. Consequently, pathogens that are present in raw cream may end up in the finished butter product, regardless of whether the pathogens grow. Further, researchers have observed prolonged pathogen survival even in cultured butter products. Michelson et al. remarked that “these challenge tests show that MFPs (milk fat products) seem to hinder the growth of *Listeria* while promoting their survival. Thereby, if contamination occurs, *Listeria* can survive and outbreaks can still occur such as in the Finnish example. Nevertheless, these results highlight that MFPs allow the survival of *Listeria* in MFPs tested, meaning this risk remains especially to vulnerable populations.”

In this section of your Petition, you return to a discussion of Michelson et al., Voysey et al. and Holliday et al. We refer you to the discussion above relative to those references, microbial outgrowth in butter generally, and pathogen outgrowth in butter. For example, you point to findings of no or minimal pathogen growth in a study by Michelson et al. However, Michelson et al. conducted their work on cultured butters, which as we explained above, is of limited applicability. You also point to Voysey et al. for the proposition that fine butter and salt inhibited pathogen growth. However, we previously noted that Voysey et al. reported that “growth was apparent at even the highest level of salt tested here.” In addition, you point to Holliday et al. as finding that commercial butter samples did not support significant growth of the pathogens studied. However, Holliday et al. report growth of *Salmonella*, *E. coli* O157:H7, and *Lm* in their studies.

With respect to the new literature that you introduce in this subsection, we note that you refer to the Maijala et al. study, which observed different levels of growth in pooled butter samples from differing sized packages. Maijala et al. found different pathogen growth rates in butter samples contained in different package sizes, with the samples contained in small packages not supporting pathogen growth. You claim that “lack of growth in pooled butter samples from small packages may be due to absence of large water droplets removed with initial working of butter into the smaller packages and with further homogenization during pooling of 10 small

packages per sample after the outbreak” (Petition at page 20). You seem to suggest that this shows that “well-worked butter” shows lack of pathogen growth. However, Maijala et al. do not offer the same explanation for the different growth patterns observed in their samples. They state that, “The reason for the difference between the small and 500-g packages remained unclear. It could have been caused by different factors not studied such as contaminant flora, pH or water activity.” Water activity and water droplet size are not the same, so your conclusion does not align with the authors’ observation.

In addition, your Petition criticizes FDA’s reference to research by Olsen in a 2003 risk assessment that FDA and USDA/FSIS conducted on Lm in foods. You claim that FDA’s use of the Olsen research on Lm “biased the risk estimates and exaggerated potential risk for commercial butter.” Although you criticize the Olsen research as flawed, we note that Maijala et al. indicate that the Olsen research is consistent with their findings relative to commercially manufactured and naturally contaminated butter (as opposed to the artificially inoculated, laboratory batch-produced butter that was studied by Olsen), which was involved in an outbreak of listeriosis in Finland. Maijala et al. report that “the growth results in the naturally contaminated 500-g packages are in accordance with the results of Olsen et al. (1988) for the artificial contamination of butter by the *L. monocytogenes* serotype 4b.” Olsen et al. stated that, “*L. monocytogenes* increased several orders of magnitude during refrigerated storage of butter made from contaminated cream. Freezing the contaminated butter maintained the populations of *L. monocytogenes* at approximately their initial numbers. Therefore, to produce *Listeria*-free butter, cream must be properly pasteurized and post-pasteurization contamination must be avoided.” Olsen demonstrates growth of pathogens consistent with Maijala et al.<sup>12</sup>

Thus, you have not demonstrated that the natural properties of butter prevent the growth of pathogens.

- d. Argument that “[a] review of scientific literature supports the epidemiological data showing that butter is a low-risk product”

In this section of your Petition, you argue that butter is low-risk because of studies that did not find pathogens in specific butter products and because, you state, the presence of pathogens at “low levels” does not necessarily pose a significant risk. You return to a discussion of Varga, Verraes et al., and Lewis et al. We refer you to the discussion above on these references and microbial competition.

With respect to your argument that studies have not found pathogens in butter, you point to the Varga, Verraes et al., and Lewis et al. studies. However, as previously discussed, these studies do not demonstrate the safety of raw cream butter. For example, Varga examined only 8 samples of butter, which were likely made from pasteurized cream, and butter made from pasteurized cream is not subject to the restrictions in 21 CFR 1240.61 that you seek to modify. You also cite Verraes et al. for reporting on four studies conducted in the European Union that found some

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<sup>12</sup>We acknowledge that you criticize Olsen for various reasons. However, Olsen is a seminal piece of research in this field and widely cited by other authors, including, but not limited to, Holliday, Lewis, Ghoddusi, Voysey, Michelon, Lanciotti, Maijala, Ryser (1991), Fernandes (2008), The ACMSF (UK) in Publication ACM/667, SciCom (France) in Avis 09-2016 and Farber and Peterkin (1991).

pathogens in samples, but not other pathogens. However, Verraes et al. is a review of the microbiological hazards in dairy products made from raw milk; Verraes et al. does not support an assertion that pathogens have not been found in butter or that pathogen levels are too low to cause illness. You also cite Lewis et al. for the proposition that the risk of Lm appears to be lower in raw cream butter compared to pasteurized cream butter. However, Lewis et al. found that a small percentage of all samples analyzed contained Lm; the authors do not claim that their findings are or should be taken as definitive with respect to the incidence and levels of Lm in raw cream butter generally.

With respect to your argument that the presence of pathogens at “low levels” does not necessarily pose a significant risk, you claim that “Multiple risk assessment teams, including FDA teams, have determined that most listeriosis cases occur in foods contaminated with high levels of *Listeria monocytogenes*.” You then cite an FDA publication by Pouillot et al. as support for this claim. While Pouillot acknowledged that lower levels of contamination may not cause illness in all individuals, he stated that lower levels can cause illness in susceptible individuals. Pouillot et al. said: “most cases are expected to be caused by highly contaminated food items. Importantly, however, most of these cases attributable to low contamination doses are predicted to occur in the most highly susceptible population subgroups, including, for example, pregnant women.... [W]hile most of the cases are linked to medium to high exposure doses to *L. monocytogenes*, those at greatest risk of developing listeriosis are also at a measurable risk of illness when consuming food contaminated with relatively low doses of *L. monocytogenes*, especially if highly virulent bacterial strains are involved.” FDA’s regulations are intended to protect, not just healthy individuals, but also people who may be more susceptible. Thus, your argument does not provide a basis for modifying the existing regulations.

You also claim that FDA’s 2003 risk assessment contains “several implausible key assumptions,” including growth occurring in butter, consumption of a single cell leading to disease and a proportional increase in illness as dose increases. While the 2003 risk assessment was published *after* FDA’s pasteurization regulation, and therefore did not form the basis for the regulation, we nevertheless respond to your criticisms. With respect to growth in butter, the discussion above adequately demonstrates that growth of pathogens can occur in butter. With respect to the latter two criticisms, it must be said that all current dose response models for bacteria use a single hit model (Haas, C. N., J. B. Rose, and C. P. Gerba. 1999. Quantitative microbial risk assessment. Wiley, New York), which assumes that a single bacterial cell can cause illness. For Lm, the likelihood of a single cell causing illness is small. At low dose (small number of cells consumed) the dose-response model for Lm is linear, that is, the probability of illness when consuming two cells is twice the probability of illness when consuming one cell. This property is common to all currently accepted dose-response models for Lm and indeed, to many other dose-response models.

You also make arguments regarding gut microbiota. In the discussion that follows, we describe the flaws in your arguments. However, we stress that pathogens in butter can and have been found to cause illness. Your arguments regarding gut microbiota do not address these findings of illness. Regardless of how the gut microbiota functions, the fact is that pathogens in butter can be unsafe. The flaws in your argument regarding gut microbiota are as follows:

- You claim that “the gut microbiota of healthy humans provides colonization resistance against *L. monocytogenes* and other pathogens by multiple mechanisms that disrupt disease processes and maintain gut homeostasis and health.” This is not supported by the references which you cite, viz. Van der Waaij et al. and Gahan and Hill. The Van der Waaij et al. study is concerned with what those authors termed colonization resistance of the digestive tract in conventional and antibiotic-treated mice. While those authors demonstrate the role of intestinal flora in host resistance to orally introduced microbes, their research did not involve *Lm* or other pathogens. Other authors, including several discussed by Gahan and Hill, have conducted experiments on germ-free mice or rats, which Gahan and Hill consider indicates that the gastrointestinal flora does play an important role as a barrier to *Lm* infection. However, the Gahan and Hill paper is concerned with the survival and adaptation of *Lm* in the intestinal tract and how it makes the transition from an environmental saprophyte to a human pathogen. In other words, the paper discusses the mechanisms by which the microbe can adapt to and overcome the several factors which contribute to host resistance of infection.<sup>13</sup> Gahan and Hill do not claim that because of these various host defense mechanisms, infection with *Lm* cannot occur.
- Although you make arguments regarding the gut microbiota of “healthy humans,” FDA is concerned with the health and safety of all individuals and not merely “healthy humans.” Certain subsets of the population, including the aged, infirm, immunocompromised, and very young, possess a greater susceptibility to infection by pathogens.
- You claim that “a recent study provides experimental documentation that a related food microbiota (raw milk) protects isolated human tissue culture cells from a very high dose of *Lm* inoculum” and that study “demonstrated that even isolated human gut cells can successfully defend against *Lm* inoculated in raw milk, but not via pasteurized milk or buffer lacking the raw milk microbiota”(emphasis in original). These arguments are not supported by the reference you cite as support, i.e., Pricope-Ciolacu et al. Those authors examined the impact of milk components and storage conditions on the virulence of *Lm* as determined by a Caco-2 cell assay. They found that adhesion, invasion, and proliferation for the four strains of *Lm* did vary based on a number of factors, including growth medium. They did not, however, find that when *Lm* cultures are grown in raw milk “human gut cells can successfully defend against *Lm* inoculated in raw milk.” Rather, adhesion, invasion and proliferation did occur with cultures grown in raw milk, albeit at levels which were lower than the other two growth media studied. The authors, in speculating as to why there were differences observed for these pathogenicity parameters between *Lm* cultures grown in raw milk and pasteurized milk, speculated that the pasteurization and homogenization processes may have had an impact on milk chemically as well as with milk microflora, but they did not specifically determine causation of the differences observed to either of those possibilities. They conclude by saying “different milk environments and the storage conditions have an influence on the

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<sup>13</sup> These mechanisms include stress adaption in the gastrointestinal tract due to low pH conditions in the stomach and duodenum, bile acids, potential effects of food matrices, such as acid or salt adaptation during growth in foods, which may create a stress-hardening of the pathogen and the various mechanisms by which the intestinal microflora may protect against infection, including direct antagonism, immunomodulation, enhancement of the epithelial barrier function and bacterial signaling events.

in vitro virulence of Lm, but further studies are essential to investigate the factors involved in this process.”

For the reasons discussed above, you have not demonstrated that raw cream butter is a low-risk product or that FDA’s regulations should be changed to exempt raw cream butter from the pasteurization requirement.

*4. Arguments claiming regulatory agencies’ regulation of butter reflects the low risk*

In this section (see Petition at page 23), you argue that other federal regulations “reflect the relatively low risk from butter, both raw and pasteurized.” Your argument appears to be based on the fact that there are different quality standards for milk, depending on the intended use for that milk, e.g. bottling or cheese-making. However, you have not identified any evidence that the difference in quality standards is based on butter being low risk, much less raw cream butter being supposedly low risk.

The standards you identify are a measurement of quality and not safety. Milk of very good quality (possessing very low Standard Plate Counts (SPCs)) can and has been found to have relatively high levels of pathogens. Typical milk quality indicators, such as SPCs, coliform counts (CC), and somatic cell counts, are general indicators of animal health conditions and the level of sanitation that exists as milk is being produced and stored. These quality indicators do not provide any information as to the presence or absence of harmful bacteria. Raw milk with acceptable SPC and CC numbers may still contain pathogens. For example, in a study by van Kessel et al., (2008), raw milk samples taken from farm bulk tanks had SPCs which ranged from 197-3,248 cfu/milliliter (ml) and coliform counts which ranged from 3-164 cfu/ml, indicating very high quality; yet 11% of all samples were positive for the presence of Salmonella. Thus, the different standards that apply to milk intended for fluid consumption as opposed to milk intended for manufacturing represent quality parameters, not safety parameters. Moreover, the different standards do not represent any federal determination that raw cream butter is low risk or should be permitted in interstate commerce.

You argue “while raw cheeses are legal to sell in interstate commerce, raw butter is not” and that “the different treatment of these two manufactured dairy products is not based on any scientific evidence and is not rational” (Petition at page 23). It is true that some standards of identity (e.g., the standard of identity for soft-ripened cheese in 21 CFR 133.182) permit the manufacture of cheese from unpasteurized milk. These standards of identity specify that the process for cheese manufactured from unpasteurized milk include an aging period. A typical aging period is not less than 60 days at not less than 35 °F (see, e.g. § 133.182(a) in the standard of identity for soft-ripened cheese). When FDA established the standards of identity in 1950, the aging period for cheese manufactured from unpasteurized milk was presumed to act as a control measure to reduce the risk that pathogens would be present when the cheese was consumed. See 15 FR 5656, 5658 (August 24, 1950). FDA is unaware of, and you do not present, any literature that would indicate that there is a process associated with butter manufacturing that could serve as a control and reduce the risk that pathogens would be present in butter made from raw cream, as FDA determined to be the case in 1950 for certain raw milk cheeses.

You further argue that the Pasteurized Milk Ordinance (PMO) specifically excludes both butter and aged cheese from the definition of “milk and milk products. The differences in the definition of “milk products” between 21 CFR 1240.3(j) and the PMO reflect the different purposes of the two documents. The former defines “milk products” for purposes of application of 21 CFR 1240.61, which requires pasteurization of milk products of various grades, and the latter defines “milk products” for purposes of the PMO, which applies only to Grade A products, which butter is not. With respect to your argument that your “requested relief is also consistent with the way state laws address raw butter” (Petition at page 23), FDA notes that in many States where raw milk sales are legal, the State health departments 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. For example:

- The California Department of Public Health states, “[r]aw milk and raw dairy products are not as safe as pasteurized milk and dairy products made from pasteurized milk ... Raw milk and raw dairy products are inherently unsafe to consumers because they may contain one or more types of bacteria that can cause mild to severe illnesses.” (<https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/RawMilkandRawDairyProducts.aspx>)
- The Utah Department of Health states, “Consuming raw milk products can cause a variety of harmful illnesses, including *Salmonella*, *E. coli*, *Listeria*, and *Campylobacter*, among others. Children, the elderly, pregnant women, and people with weakened immune systems are especially at risk for contracting serious illness from consuming raw milk products.” ([http://health.utah.gov/epi/diseases/campylobacteriosis/raw\\_milk\\_FS.pdf](http://health.utah.gov/epi/diseases/campylobacteriosis/raw_milk_FS.pdf))
- The Washington State Department of Health states, “Raw milk and products such as cheeses and yogurts that are made with raw milk can be contaminated with harmful germs that can cause serious illness, hospitalization, or death.” (<https://www.doh.wa.gov/YouandYourFamily/FoodSafety/RawMilk>)
- The Pennsylvania Department of Health states “Avoid unpasteurized (raw) milk or foods made from unpasteurized milk.” (<https://www.health.pa.gov/topics/Documents/Diseases%20and%20Conditions/Listeriosis.pdf>)

Even if the States do not have regulations that are specific to butter, it is evident that State public health agencies have expressed safety concerns about products manufactured from raw milk. Butter is an example of a product manufactured from raw milk or raw cream.

## CONCLUSION

In sum, based on our analysis of the materials you provided in your Petition, along with other data and information, we have concluded that your Petition does not contain facts demonstrating any reasonable grounds for amending 21 CFR 1240.61. Further, your Petition does not substantially show that your proposal is in the public interest and will promote the objectives of FDA (see 21 CFR 10.40(a)(2)). Therefore, in accordance with 21 CFR 10.30(e)(3), we are denying your Petition.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark A. Moorman". The signature is fluid and cursive, with the first name "Mark" and last name "Moorman" clearly distinguishable.

Mark A. Moorman, Ph.D.  
Director  
Office of Food Safety  
Center for Food Safety  
and Applied Nutrition

Table 1. Illnesses and deaths associated with butter not known to be pasteurized (1908 to 2003)

| <u>Year</u> | <u>Pathogen</u>                          | <u>Food Vehicle Implicated</u> | <u>Pasteurization Status</u> <sup>14,15,</sup> | <u>Origin of Food Vehicle Implicated</u> | <u>Total Number of Illnesses</u> <sup>16</sup> | <u>Number Hospitalized</u> | <u>Death</u> | <u>References</u><br>(web links last accessed on 11/22/2019)                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-------------|------------------------------------------|--------------------------------|------------------------------------------------|------------------------------------------|------------------------------------------------|----------------------------|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1908 – 1927 | <i>Salmonella typhi</i><br>Typhoid Fever | Butter                         | Not Specified but commonly unpasteurized.      | U.S.                                     | 3 outbreaks (No. of illnesses not provided)    |                            |              | Bryan, Frank L. 1983. Epidemiology of Milk-Borne Diseases. J. Food Protection 40:7:637 -649<br><br>Armstrong, C, and T. Parran, Jr. 1927. Further studies on the importance of milk and milk products as a factor in the causation of outbreaks of disease in the United States. Public Health Rep. Supp. No. Title 17 U.S. Code: 62:1-81<br><br>Trask, I. W. 1908. Milk as a cause of epidemics of typhoid fever, Scarlet fever, and diphtheria. Hyg. Lab. Bull. No. 56. Title 17 U.S. Code:23-149. |

<sup>14</sup> Pasteurization of milk and cream only gradually increased from 1915 to late 1940's in U.S. cities. USDA Bulletin 342:1-27. Revised October 10, 1922. Ayers. The Present Status of the Pasteurization of Milk.

<sup>15</sup> Pasteurization was not common until late 1940's and early 1950's. Michigan was the first state to require statewide milk pasteurization in 1948. Steele. JAVMA. 2000. 217:2:175-178

<sup>16</sup> Three outbreaks reported for 1908 – 1927 were separate outbreaks that occurred sometime during those years and not for the duration. A specific year for each outbreak was not provided in the reference.

|                |                                                                                                                                                       |        |                                                |                 |         |                                               |    |                                                                                                                                                                                                                                                   |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|--------|------------------------------------------------|-----------------|---------|-----------------------------------------------|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1913           | <i>Salmonella typhi</i><br>Typhoid Fever                                                                                                              | Butter | Not Specified<br>but commonly<br>unpasteurized | Minnesota, U.S. | 35 – 40 | Not<br>Available<br>/ Not<br>Reported<br>(NA) | 6  | Budhkar, et al. Encyclopedia<br>of Food Microbiology,<br>2014. Microbiology of<br>Cream and Butter. 2:728-<br>737.<br><br>Singhal and Kulkarni.<br>Encyclopedia of Food<br>Microbiology. 1999.<br>Microbiology of Cream and<br>Butter. 1145-1455. |
| 1925 -<br>1927 | <i>Corynebacterium<br/>diphtheria</i><br>Diphtheria<br><br><i>Mycobacterium<br/>tuberculosis</i> or<br><i>Mycobacterium<br/>bovis</i><br>Tuberculosis | Butter | Not Specified<br>but commonly<br>unpasteurized | U.S. and Europe | NA      | NA                                            | NA | Budhkar, et al. Encyclopedia<br>of Food Microbiology,<br>2014. Microbiology of<br>Cream and Butter. 2:728-<br>737.<br><br>Singhal and Kulkarni.<br>Encyclopedia of Food<br>Microbiology. 1999.<br>Microbiology of Cream and<br>Butter. 1145-1455. |

|           |                                            |                |                                                |      |                                |    |    |                                                                                                                                                                                                                                                                                                                                                                 |
|-----------|--------------------------------------------|----------------|------------------------------------------------|------|--------------------------------|----|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1925-1927 | <i>Salmonella typhi</i><br>Typhoid fever   | Butter         | Not Specified<br>but commonly<br>unpasteurized | U.S. | NA                             | NA | NA | Budhkar, et al. Encyclopedia of Food Microbiology, 2014. Microbiology of Cream and Butter. 2:728-737.<br><br>Singhal and Kulkarni. Encyclopedia of Food Microbiology. 1999. Microbiology of Cream and Butter. 1145-1455.                                                                                                                                        |
| 1970      | <i>Staphylococcus aureus</i> enterotoxin A | Whipped Butter | Not Specified                                  | U.S. | 24                             | NA | NA | Minor and Marth. 1976. Staphylococci and Their Significance in Foods. Behavior of Staphylococci in Dairy Foods. Chapter 10:195-217.<br><br>Minor and Marth. 1972. J. Dairy Science. 55:10:1410-1414.<br><br><a href="http://www.sciencedirect.com/science/article/pii/S0022030272856856">http://www.sciencedirect.com/science/article/pii/S0022030272856856</a> |
| 1970      | <i>Staphylococcus aureus</i>               | Butter         | Not Specified                                  | U.S. | “reports of consumer injuries” |    |    | Rothchild, J. L., Editor. 1970. Food Chemical News 12:33.                                                                                                                                                                                                                                                                                                       |

|      |                                       |                                       |               |                                                       |     |    |    |                                                                                                                                                                                                                                                      |
|------|---------------------------------------|---------------------------------------|---------------|-------------------------------------------------------|-----|----|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1977 | <i>Staphylococcus aureus</i>          | Whipped Butter                        | Not Specified | Illinois, Indiana, Kentucky, Ohio, and Missouri, U.S. | 100 | NA | NA | Center for Disease Control, Morbidity and Mortality Report (MMWR) August 12, 1977. 26:32:268.                                                                                                                                                        |
| 1991 | <i>Staphylococcus intermedius</i>     | Blended butter and margarine products | Not Specified | California, Nevada, U.S.                              | 265 | NA | NA | Khambaty et al. 1994. Epidemiology Infections. 113:75-81.<br><a href="http://journals.cambridge.org/action/displayAbstract?fromPage=online&amp;aid=4710236">http://journals.cambridge.org/action/displayAbstract?fromPage=online&amp;aid=4710236</a> |
| 1995 | <i>Campylobacter jejuni</i> enteritis | Garlic Butter                         | Not Specified | Louisiana, U.S.                                       | 30  | 4  | NA | Subsequently, a study on the survival of <i>Campylobacter</i> in butter with and without garlic found that <i>C. jejuni</i> could survive in butter without garlic for 13 days at 5C.<br>Zhao et al. 2000. J. Food Protection. 63:120-122.           |

|           |                               |        |               |                      |     |    |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------|-------------------------------|--------|---------------|----------------------|-----|----|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2001-2002 | <i>E. coli</i> O157:H7        | Butter | Unpasteurized | North Carolina, U.S. | 202 | 1  | NA | <p>North Carolina Department of Health and Human Services Epi Notes. Dec.2001-Jan.2002. Vol. 2001-04. p 7. <a href="http://epi.publichealth.nc.gov/pdf/en2001-4.pdf">http://epi.publichealth.nc.gov/pdf/en2001-4.pdf</a></p> <p>Marler. 2001. <a href="http://www.marlerclark.com/case_news/view/roberson-schools-e-coli-outbreak-north-carolina">http://www.marlerclark.com/case_news/view/roberson-schools-e-coli-outbreak-north-carolina</a></p> |
| 2003      | <i>Listeria monocytogenes</i> | Butter | Not Specified | England              | 17  | NA | NA | <p>Health Protection Agency (London). 2004. Department of Gastrointestinal Infections annual report 2003. Service delivery, incidents and outbreaks. 2.3 p.18 <a href="http://webarchive.nationalarchives.gov.uk/20140714084352/http://www.hpa.org.uk/hpa/publications/DGI_ann_rep_03/dgi_ann_rep_03.htm">http://webarchive.nationalarchives.gov.uk/20140714084352/http://www.hpa.org.uk/hpa/publications/DGI_ann_rep_03/dgi_ann_rep_03.htm</a></p> |