

**CITIZEN PETITION BEFORE THE
UNITED STATES FOOD AND DRUG ADMINISTRATION**

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Docket Number _____

**CITIZEN PETITION SEEKING LEGALIZATION OF
INTERSTATE TRANSPORT OF UNPASTUERIZED BUTTER**

Date: June 22, 2016

The undersigned submits this Citizen Petition under the statutory and regulatory provisions discussed herein, to request the Commissioner of the Food and Drug Administration (FDA) amend the regulations to legalize interstate sales of unpasteurized butter.

Unpasteurized, or raw, butter is currently legal to sell in several states. Nonetheless, the FDA has a categorical ban on the interstate transport of unpasteurized butter for sale. As discussed in this amended petition, the agency erred in adopting this overly broad and unnecessary ban.

Pursuant to the right to Petition Government Clause contained in the First Amendment of the United States Constitution,¹ the Administrative Procedures Act,² and the FDA's implementing regulations,³ petitioners respectfully request that FDA reverse its ban on the interstate transport of raw butter. The requested actions are necessary to prevent economic harm to producers and to allow consumers the ability to purchase the foods of their choice.

In banning the interstate sale of raw butter, the agency acted beyond the scope of its statutory authority, an issue of law rather than fact.⁴ In addition, the FDA "entirely failed to consider an important aspect of the problem" and "offered an explanation for its decision that runs counter to the evidence before the agency."⁵ Accordingly, based on the evidence and justifications in this petition, failure by FDA to take the requested actions would be arbitrary, capricious, and contrary to law.⁶

¹ U.S. Const., amend. I. The right to "petition for redress of grievances is among the most precious of the liberties safeguarded by the Bill of Rights." *United Mine Workers of Am., Dist. 12 v. Ill. State Bar Ass'n*, 389 U.S. 217, 222 (1967). It shares the "preferred place" according to our system of government to the First Amendment freedoms, and has "sanctity and a sanction not permitting dubious intrusions." *Thomas v. Collins*, 323 U.S. 516, 530 (1945). "[A]ny attempt to restrict those First Amendment liberties must be justified by clear public interest, threatened not doubtful or remotely, but by clear and present danger." *Id.* The Supreme Court has recognized that the right to petition is logically implicit in, and fundamental to, the very idea of a republican form of government. *United States v. Cruikshank*, 92 U.S. 542, 552 (1875).

² 5 U.S.C. § 553(e) (2015).

³ 21 C.F.R. §§ 10.20, 10.30 (2015).

⁴ *Trimmer v. United States Dep't of Labor*, 174 F.3d 1098, 1102 (10th Cir.1999).

⁵ *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

⁶ *Id.*; 5 U.S.C. § 706(2)(A) (2015).

ACTION REQUESTED

Petitioners seek the following:

1. Amend the definition in 21 C.F.R. §1240.3(j) as follows (proposed new regulatory language indicated in bold underlined and/or strikethrough text):

§1240.3: (j) Milk products. Food products made exclusively or principally from the lacteal secretion obtained from one or more healthy milk-producing animals, e.g., cows, goats, sheep, and water buffalo, including, but not limited to, the following: lowfat milk, skim milk, cream, half and half, dry milk, nonfat dry milk, dry cream, condensed or concentrated milk products, cultured or acidified milk or milk products, kefir, eggnog, yogurt, ~~butter~~, cheese (where not specifically exempted by regulation), whey, condensed or dry whey or whey products, ice cream, ice milk, other frozen dairy desserts and products obtained by modifying the chemical or physical characteristics of milk, cream, or whey by using enzymes, solvents, heat, pressure, cooling, vacuum, genetic engineering, fractionation, or other similar processes, and any such product made by the addition or subtraction of milkfat or the addition of safe and suitable optional ingredients for the protein, vitamin, or mineral fortification of the product. **This definition shall not include butter meeting the standard established by 21 USC 321a**

2. Amend 21 C.F.R. §1240.61 to allow unpasteurized butter to be legally transported across state lines, as follows (proposed new regulatory language indicated in underlined and/or strikethrough text):

§1240.61 (a) No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package form for direct human consumption unless the product has been pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized, except where alternative procedures to pasteurization are provided for by regulation, such as in part 133 of this chapter for curing of certain cheese varieties **or except for butter meeting the standard established by 21 USC 321a.**

PETITIONERS

Petitioner Mark McAfee is the founder of Organic Pastures Dairy Company (OPDC). OPDC is a Grade A licensed raw dairy in California that sells butter intrastate. There have been no reported foodborne illnesses from OPDC's butter.

Petitioner Farm-to-Consumer Legal Defense Fund (FTCLDF) is a nonprofit organization based in Virginia. Founded in 2006, the FTCLDF protects the rights of farmers and consumers to engage in direct commerce. The organization works to protect both the rights of farmers to sell the products of the farm and the rights of consumers to access the foods of their choice from the source of their choice.

STATEMENT OF GROUNDS

I. INTRODUCTION

Butter is generally considered a low-risk product, with a long history of safe use in the United States and around the world.

Butter has been traded internationally since the 14th century, and global consumption was more than 5,250,000 tons in 2009.⁷ In the U.S. alone, butter production was reportedly 800,000 tons in 2011.⁸ Despite this vast, widespread consumption, outbreaks of foodborne illness are very rarely linked to butter.⁹

II. APPLICABLE STATUTES AND REGULATIONS

Administrative Procedures Act, 5 U.S.C. § 551 *et seq.*
Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 *et seq.*
Public Health Service Act, 42 U.S.C. §201 *et seq.*
Food and Drug Administration, 21 C.F.R. part 101 *et seq.*

III. PROCEDURAL HISTORY

⁷ Y.A. Budhkar et al., *Milk and milk products: microbiology of cream and butter*, in *ENCYCLOPEDIA OF FOOD MICROBIOLOGY VOL. 2*, 728-737 (C.A. Batt and M.L. Tortorello, Eds., 2nd ed. 2014).

⁸ H. Ghoddusi & B. Ozer, *Microbiology of cream, butter, ice cream, and related products*. Chapter 10 in *DAIRY MICROBIOLOGY AND BIOCHEMISTRY* 245-270 (2014).

⁹ R.A. Wilbey, *Microbiology of cream and butter*, Chapter 4 in *DAIRY MICROBIOLOGY HANDBOOK* 123-174 (R.K. Robinson, Ed., 3rd ed. 2002); H.C. Lewis et al., *Prevalence of Listeria monocytogenes and other Listeria species in butter from United Kingdom production, retail, and catering premises*, *J. FOOD PROT.* 69(7):1518-1526 (2006); P.A. Voysey et al., *The effects of butter characteristics on the growth of Listeria monocytogenes*, *INT'L J. DAIRY TECH.* 62(3):326-330 (2009); Ghoddusi & Ozer, *supra* note 8; Table 1, *infra*.

On March 27, 2015, Petitioner McAfee filed a citizen petition requesting that the FDA narrowly amend CFR 1240.61 to permit the interstate commerce of retail approved, state inspected unpasteurized butter. The agency has acknowledged receipt of the petition but has not provided a substantive response as of this time, over a year later. Petitioners file this new petition seeking broader relief and providing the following information and arguments in support.¹⁰

IV. ARGUMENT

A. In banning the interstate transport of raw dairy products, the FDA erred in including raw butter and other manufactured dairy products.

In 1973, the FDA issued a regulation that required pasteurization as part of the standard of identity for raw milk and specific raw milk products being transported interstate.¹¹ Shortly thereafter, in 1974, the agency stayed the effect of the order with respect to certified raw milk; the agency state that it would hold a public hearing to resolve the factual dispute over the safety of certified raw milk.¹²

The agency took no further action on this issue until it was sued in 1985 in the case of *Public Citizen v. Heckler*.¹³ In that case, the district court ordered FDA to take action in issuing a regulation addressing certified raw milk, without specifying what the substance of the action had to be. Two years later, in 1987, the court extended the scope to order the FDA to “approve a rule banning the interstate sale of all raw milk and all raw milk products, both certified and non-certified, based on the now completed rulemaking proceedings and consistent with the opinion herein.”¹⁴

The *Heckler* court did not address butter or any other manufactured dairy product specifically in its decision. Moreover, the FDA does not appear to have discussed butter either during the court proceedings or in the regulations that preceded them. Without any precedent, and without providing any explanation for the inclusion of butter in the new regulations, the FDA’s regulation implementing the 1987 decision included butter (and other manufactured dairy products).

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.

¹⁰ See 21 CFR § 10.30 (d) (“A request for alternative or different administrative action must be submitted as a separate petition.”).

¹¹ 38 Fed. Reg. 27,924 (Oct. 10, 1973).

¹² 39 Fed. Reg. 42,351 (Dec. 5, 1974).

¹³ *Public Citizen v. Heckler*, 602 F. Supp. 611 (D.C. Dist.1985) (hereinafter “Heckler I”).

¹⁴ *Public Citizen v. Heckler*, 653 F. Supp. 1229 (D.C. Dist. 1987) (hereinafter “Heckler II”).

The limited scope of the term “raw milk products” can be seen in the FDA regulations that were discussed in both *Heckler* decisions. The facts and arguments presented to the court focused on the issue of certified raw milk, which was the contested portion of the 1973 and 1974 agency actions. For example, the court reviewed the agency’s justification for not banning the sale of raw milk in terms of the resources and authority of the agency to regulate certified raw milk as compared to all raw milk.¹⁵ The court’s review did not address the agency’s authority or actions with respect to manufactured raw milk products such as butter.

Indeed, at no time was butter or any other manufactured dairy product discussed. While the court included the phrase “all raw milk and raw milk products” in the opening and final sections, all of the analysis looked solely at certified raw milk.

In addition, the court’s reasoning in *Heckler* does not support the inclusion of raw butter and other manufactured products within the scope of the case. The basis for the *Heckler* court’s decision was FDA’s slowness and delay in acting on what had been presented as a temporary stay more than a decade before.¹⁶

Yet FDA does not appear to have **ever** considered the issue of raw butter. The original 1973 regulations that triggered the discussion on pasteurization of “dairy products” covered raw milk and cream products, not butter or similar manufactured products. Factually, there was no “delay” in concluding the analysis on manufactured products, and the court’s reasoning would not apply to whether or not butter should be required to be pasteurized.

At no time prior to 1987 does FDA appear to have identified butter as a “milk product.” The FDA’s Pasteurized Milk Ordinance (PMO) in 1978 specifically **excludes** butter from the definition of “milk and milk products.”¹⁷ That exclusion has been consistent for the last four decades.¹⁸

Neither the FDA nor the courts have ever addressed the specific question of whether manufactured raw dairy products in general should be banned in interstate commerce. As discussed next, the agency’s decision to require pasteurization for butter in particular was in error because Congress has spoken to the specific issue of butter in interstate commerce.

In addition, as discussed in section C below, the physical, chemical, and biological characteristics of butter make it a very low-risk product, whether produced from pasteurized or raw milk. The agency erred in banning all raw dairy products as a group, including butter, without considering the differences among the types of products that influence risk of foodborne illness.

¹⁵ See *Heckler II*, 653 F. Supp. at 1239.

¹⁶ *Heckler I*, 602 F. Supp. at 613.

¹⁷ See Food and Drug Administration (FDA), U.S. Department of Health, Education and Welfare, Part I in GRADE A PASTEURIZED MILK ORDINANCE 1978 RECOMMENDATIONS, 20-21 (Rev. 1978).

¹⁸ See Food and Drug Administration (FDA), U.S. Department of Health and Human Services, *Section I: Definitions*, GRADE “A” PASTEURIZED MILK ORDINANCE (PMO), 6-7 (Rev. 2011).

B. The agency acted in contravention of its statutory authority by establishing a *de facto* standard of identity for butter.

FDA lacks authority to require pasteurization of butter. Congress explicitly defined butter by statute:

For the purposes of the Food and Drug Act of June 30, 1906 (Thirty-fourth Statutes at Large, page 768) “butter” shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for.¹⁹

Moreover, Congress specifically **prohibited** FDA from issuing a standard of identity for butter: “Definitions and standards for food. No definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter....”²⁰ In doing so, Congress re-affirmed its intention that the statutory standard of identity was the exclusive provision; in the introduction of the 1938 Act before the Senate it provides that “the Act of March 4, 1923 (USC, title 21, sec. 6; 42 Stat. 1500 ch. 268), defining butter and providing a standard therefor...shall remain in force and effect and be applicable to the provisions of this Act.”²¹

Currently, the FDA’s requirement that butter be pasteurized is based on the statutory provisions on the transmission of communicable diseases.²² However, a well-established canon of statutory interpretation provides that “the specific governs the general.”²³ This is true even when the provisions are found in two separate statutes: “There the canon avoids not contradiction but the superfluity of a specific provision that is swallowed by the general one, ‘violat[ing] the cardinal rule that, if possible, effect shall be given to every clause and part of a statute.’ The terms of the specific authorization must be complied with.”²⁴

Thus, whether FDA is acting under the statutory provisions governing standard of identity or those governing communicable diseases, the agency cannot contradict Congress’ clear, specific prohibition on establishing a standard of identity for butter. The fact that the statutory standard of identity for butter pre-dates the later statutory provisions does not alter this result:

¹⁹ 21 U.S.C.A. § 321a (adopted in 42 Stat. 1500 (1923)).

²⁰ 21 U.S.C.A. § 341.

²¹ Vincent A. Kleinfeld & Charles Welsey Dunn, *Part VI, Senate 5-74th Congress, 1ST and 2D Sessions, in FEDERAL FOOD, DRUG AND COSMETIC ACT. A STATEMENT OF ITS LEGISLATIVE RECORD 1938-1949*, 189, 209 (1938).

²² 21 C.F.R. Part 1240.

²³ *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384, (1992).

²⁴ *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 132 S. Ct. 2065, 2070-71, 182 L. Ed. 2d 967 (2012) (quoting *D. Ginsberg & Sons, Inc. v. Popkin*, 285 U.S. 204, 208, (1932)).

While a later enacted statute can sometimes operate to amend or even repeal an earlier statutory provision, “repeals by implication are not favored” and will not be presumed unless the “intention of the legislature to repeal [is] clear and manifest.” The courts will not infer a statutory repeal “unless the later statute ‘expressly contradict[s] the original act’ ” or unless such a construction “is absolutely necessary ... in order that [the] words [of the later statute] shall have any meaning at all.” Outside these limited circumstances, “a statute dealing with a narrow, precise, and specific subject is not submerged by a later enacted statute covering a more generalized spectrum.”²⁵

In authorizing FDA to address communicable diseases, Congress gave **no** indication whatsoever, and there is no reasonable basis to infer, that it intended to repeal its earlier specific statutes, 21 U.S.C. §321 and §341, governing butter.

FDA’s own actions in establishing pasteurization requirements make it clear that these act as standards of identity. When initially adopted, the pasteurization requirement was explicitly part of the standard of identity for milk. The FDA’s 1973 regulation states as follows:

§18.2. Milk; identity

- (a) Description. Milk is the lacteal secretion ... of one of more healthy cows. Milk that is in final package form for beverage use shall have been pasteurized or ultrapasteurized, and shall contain not less than 8 ¼ percent milk solids not fat and not less than 3 ¼ percent milkfat. ...²⁶

The provision for pasteurization is also found in the 1973 regulatory standards of identity for lowfat milk, skim milk, half-and-half, light cream, light whipping cream, concentrated milk, sweetened condensed milk, and nonfat dry milk.²⁷ **In each case, the pasteurization requirement is treated no differently than standards for the amount of milk fat, vitamins, or other elements of the standard of identity.**

This inclusion of bacterial concerns in the standard of identity is not unique to dairy. For example, the standards for liquid egg products require these products to be pasteurized or otherwise treated to destroy all viable *Salmonella* bacteria.²⁸

The FDA explicitly addressed the question of requiring pasteurization as part of a standard of identity in its 1974 partial stay of the requirement. The agency stated that such health-based requirements were properly addressed as standards of identity: “The Commissioner

²⁵ Nat'l Ass'n of Home Builders v. Defs. of Wildlife, 551 U.S. 644, 662-63, (2007) (internal citations omitted).

²⁶ 38 Fed. Reg. 27,921 (Oct. 10, 1973) (emphasis added).

²⁷ 38 Fed. Reg. 27,921 (Oct. 10, 1973).

²⁸ 21 C.F.R. §160.115.

rejects the contention that section 401 of the act does not permit provisions of a standard of identity to be promulgated for health reasons.”²⁹

While the agency may be correct that in most cases it can promulgate health-related requirements such as pasteurization as part of a standard of identity, it is clearly wrong in the case of butter – because the agency has no legal authority to require **any** standard of identity for butter beyond the one established by Congress. By requiring that all butter be pasteurized under 21 C.F.R. §1240.61, FDA acted in contravention of the statute by effectively establishing a standard of identity for butter that differed from the one established by Congress.

The U.S. Supreme Court has repeatedly held that “an administrative agency’s power to promulgate legislative regulations is limited to the authority delegated by Congress.”³⁰ The FDA’s or the *Heckler* court’s unfounded belief that raw dairy products posed a serious risk cannot expand the agency’s authority.³¹ In banning the interstate sale of raw butter, the agency acted beyond the scope of its statutory authority and its decision is not entitled to deference.³²

C. Raw butter is a low-risk product that does not merit these regulatory restrictions.

Even if it were within FDA’s authority to address the question of pasteurizing butter, there is no sound scientific basis for requiring pasteurization of butter. As discussed below and in the original petition, butter is a low-risk product whether it is produced from pasteurized or raw milk.

Petitioners reiterate that FDA did not have statutory authority to create a *de facto* standard of identity for butter through the pasteurization requirement. Without waiving that argument, Petitioners urge FDA to reconsider whether the Public Health Service Act and Food, Drug, and Cosmetic Act’s provisions for the control of communicable diseases and adulterated foods support a ban on the interstate transport of commercially prepared raw butter.³³ An agency may change its interpretation of a statute as long as it provides a “reasoned analysis” explaining its altered stance.³⁴

²⁹ 39 Fed. Reg. 42,351 (Dec. 5, 1974).

³⁰ *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208, (1988).

³¹ “Regardless of how serious the problem an administrative agency seeks to address, [] it may not exercise its authority ‘in a manner that is inconsistent with the administrative structure that Congress enacted into law.’” *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000) (quoting *ETSI Pipeline Project v. Missouri*, 484 U.S. 495, 517 (1988)).

³² *Trimmer*, 174 F.3d 1102.

³³ *Cf. Heckler I*, 602 F. Supp. at 613 (directing the FDA to issue a regulation addressing the transport of certified raw milk under these statutory provisions).

³⁴ *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) (“An agency must be given ample latitude to adapt their rules and policies to the demands of changing circumstances.”) (quoting *Permian Basin Area Rate Case*, 390 U.S. 747, 784 (1968)).

1. Based on the actual occurrence of outbreaks, all butter, including that made from raw milk, poses a very low risk of foodborne illness.

Petitioners conducted a search of the CDC's Foodborne Outbreak Online Database (FOOD Tool). The FOOD Tool provides information on foodborne outbreaks reported to the CDC over the last 18 years, since 1998. As explained in detail below, not even one outbreak has been connected to commercially prepared raw butter during that time period.

As set out in Table 1, below, the database lists 10 outbreaks in which butter was one of the listed "food vehicles" for the outbreak. In most of these outbreaks, other food vehicles were also listed that were much higher risk and more likely to have been the source of the outbreak, such as seafood or pork. Thus, the data shown in Table 1 almost certainly overstates the risk of illness from butter. Even considering the worst-case scenario, however – that butter was responsible for all of these outbreak cases – that still reflects only 242 illnesses in a period of 18 years, or an average of fewer than 14 illnesses per year.

Moreover, these numbers include butter prepared from both pasteurized and raw milk, and both homemade and commercially prepared. The CDC database lists only **one** outbreak in which the butter appears to have been produced from raw milk: a 2007 outbreak in Utah. The Utah Health Department's description of the outbreak makes no mention of butter or cheese,³⁵ although these are listed in the CDC's FOOD Tool. Since Utah regulations outlaw the sale of raw milk products such as butter and cheese,³⁶ these products must have been made at home from the milk, not commercially prepared and sold. Moreover, while extremely few illnesses have ever been linked to butter, there have been several connected to soft homemade raw cheese,³⁷ making it probable that the illnesses came either from the milk or the homemade cheese, not the butter.

In summary, there appear to have been no foodborne illness outbreaks linked to butter commercially prepared from raw milk. Only a small number of outbreaks have been linked to **any** butter, prepared from pasteurized or raw milk. Particularly in light of the hundreds of millions of pounds of butter that Americans consume annually, this reflects a remarkably low risk of foodborne illness from this food.

³⁵ Utah Department of Agriculture and Food and the Utah Department of Health, *Unpasteurized Milk-Associated Diseases in Utah*, 2013 Report to the Natural Resources, Agriculture & Environment Interim Committee and the Health & Human Services Interim Committees 5, <http://health.utah.gov/legislativereports/2013UnpasteurizedMilkReport.pdf>; see also, W. Marler (aka Food Poisoning Lawyer), *Unpasteurized milk sold at Utah dairy traced as source of Campylobacter outbreak*, FOOD POISON JOURNAL (Mar. 22, 2007), http://www.foodpoisonjournal.com/foodborne-illness-outbreaks/unpasteurized-milk-sold-at-utah-dairy-traced-as-source-of-campylobacter-outbreak/#.VvWUI_q2Ib4

³⁶ Utah Admin. Code R70-330-5 (2016).

³⁷ E. Burkett, *Queso Fresco: Cheese with a Reputation*, FOOD SAFETY NEWS (May 16, 2010), <http://www.foodsafetynews.com/2010/05/queso-fresco-cheese-with-a-reputation/>

**Table 1: Outbreaks listing butter as a possible food vehicle,
CDC Foodborne Outbreak Online Database³⁸**

Year	State	Genus specis	Illnes- ses	Hospital- izations	Deaths	Food vehicle	Contaminated Ingredient
1998	PA		21	0	0	Salad; butter; water	
1998	PA		20	0	0	Seafood soup/stew; butter; soda	
1998	PA		11	0	0	Soda; butter; seafood	
2002	FL		2	0	0	Hollandaise sauce	Butter
2002	WA	<i>Bacillus cereus</i>	8	0	0	Butter; bread; pork	
2002	TN	<i>Staphylococcus aureus</i>	9	0	0	Butter; vegetable dip; bread	
2005	GA	<i>Salmonella</i>	34	7	0	Hollandaise sauce	Butter; egg
2007	UT	<i>Campylobacter jejuni</i>	62	4	0	Unpasteurized whole cow milk, goat milk, butter, and goat cheese/chevre	Milk; milk; butter; cheese
2009	CO	<i>Staphylococcus aureus</i>	4	0	0	Fish, ono; bok choy; sweet potato	Fish; leafy green; butter; cream; sweet potato
2012	MI		71	0	0	Butter; soda	Butter; n/a

The lack of outbreaks linked to commercially prepared raw butter are similarly reflected in the Petitioner’s experience. Petitioner McAfee’s dairy has sold over 2 million pounds of butter since 2001, without a single foodborne illness being linked to such sales.³⁹

³⁸ The search was conducted on March 11, 2016, using the search term “butter.” Table 1 reflects the exact language downloaded from the FOOD database, with the following exceptions: Outbreaks linked to peanut or other nut butters were deleted. Outbreaks in which the causative agent was norovirus were also deleted, since the illnesses were likely the result of human transmission, either directly or when an infected food handler touched ready-to-eat foods. See Centers for Disease Control and Prevention, Norovirus Transmission, <http://www.cdc.gov/norovirus/about/transmission.html>. Outbreaks due to “paralytic shellfish poison” or “other chemical/ toxin” and that involved shellfish were deleted, as these clearly stemmed from food vehicles other than butter. Last, an outbreak which listed butter as one of multiple food vehicles, but specifically identified only egg as the contaminated ingredient, was deleted.

³⁹ Specifically, Organic Pastures Dairy Company produced 69,941 lbs in 2002; 77,713 lbs in 2003; 86,347 lbs in 2004; 95,942 lbs in 2005; 106,602 lbs in 2006; 118,446 lbs in 2007; 131,607 lbs in 2008; 146,230 lbs in 2009; 162,478 lbs in 2010; 180,531 lbs in 2011; 200,590 lbs in 2012; 227,202 lbs in 2013; 227,343 lbs in 2014; 233,664 lbs in 2015; and 88,434 lbs as of April of 2016. The total estimated butter production from 2002 to the present is 2,153,070 lbs.

2. The rarity of outbreaks connected to butter is consistent with the chemical and biological characteristics of this product.

Properly prepared commercial butter is not sterile, but is rarely contaminated with pathogens at levels necessary to cause human disease.⁴⁰ While butter has the potential to become contaminated with pathogens in multiple ways (including the cream, the water used for washing, or poor sanitation at any point), contamination of commercial butter with pathogens is very rare in current practice, and when present, pathogen counts are low (<100 *L. monocytogenes*/g).⁴¹ In addition, contrary to FDA's assumptions,⁴² pathogens do not grow in butter.⁴³ Thus, pathogen levels in naturally contaminated butter are too low to cause illnesses,⁴⁴ as reflected in the very few outbreaks listed in the CDC database.

Even if butter is contaminated with pathogens, intrinsic and extrinsic factors limit or prevent pathogen growth in butter. Microbiological data on growth potential for pathogens are summarized below and illustrated in Figure 2, *infra*. Properly produced butter simply does not support pathogen growth.⁴⁵

Butter is not a good medium for growth of bacteria due to its nature as a water-in-oil emulsion. As Congress specified, butter must be constituted of at least 80% fat by weight; fat forms the continuous phase, with a small amount of water in the form of droplets dispersed in the fat.⁴⁶ In contrast, both milk and cream are better media for bacterial growth because water forms a continuous phase that is more conducive to bacterial growth, as illustrated in Figures 2 and 3, *infra*.

⁴⁰ Lewis et al. *supra* note 9; C. Verraes et al., *A review of the microbiological hazards of dairy products made from raw milk*, INT'L DAIRY J. 50:32-44 (2015).

⁴¹ L. Varga, *Microbiological quality of commercial dairy products*, in COMMUNICATING CURRENT RESEARCH AND EDUCATIONAL TOPICS AND TRENDS IN APPLIED MICROBIOLOGY, 487-494 (2007), <http://real.mtak.hu/id/eprint/6206>; Lewis et al, *supra* note 9; Verraes et al, *supra* note 40.

⁴² Food and Drug Administration (FDA) and Food Safety Inspection Service (FSIS), *Quantitative Assessment of Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods* (2003), <http://www.fda.gov/downloads/food/foodscienceresearch/ucm197330.pdf>; Food and Drug Administration (FDA), Draft Compliance Policy Guide Sec. 555.320 *Listeria monocytogenes*, Fed. Reg. 73(26):7299-7300 (Feb. 7, 2008).

⁴³ S.L. Holliday et al., *Viability of Salmonella, Escherichia coli O157:H7, and Listeria monocytogenes in butter, yellow fat spreads, and margarine as affected by temperature and physical abuse*, FOOD MICROBIOLOGY 20:159-168 (2003); D. Michelon et al., *Growth Potential Assessment of Listeria in Milk Fat Products by Challenge Testing*, J. FOOD SAFETY 36(1):1-11 (2016); Voysey et al., *supra* note 9.

⁴⁴ Lewis et al., *supra* note 9; Verraes et al., *supra* note 40.

⁴⁵ Holliday et al., *supra* note 43; Voysey et al., *supra* note 9; Michelon et al., *supra* note 43.

⁴⁶ B.W. Hammer, & H.F. Long, *Factors influencing bacterial growth in butter*. MICROBIOL MOL. BIOL. REV. 5(4):337-374 (1941), <http://mmlbr.asm.org>; Wilbey, *supra* note 9; Budhkar et al., *supra* note 7, Ghoddsi & Ozer, *supra* note 8; Michelon et al., *supra* note 43.

Growth of bacteria is inhibited in the hardened butterfat, the fatty continuous phase of the butter emulsion.⁴⁷ Bacterial growth in butter is thought to be restricted to the water droplets originally colonized during manufacture because migration of bacteria between water droplets is restricted by fat.⁴⁸ Steric and compositional limitations to growth arise from various processes for producing butters.⁴⁹ When “well-worked,” butter has very low water activity, due to the dispersion of the water phase as fine droplets. In contrast, handmade butter, which is worked less, may have larger water droplets and water channels that support bacterial growth.⁵⁰ The physical structure of commercially prepared butter is an influential factor limiting pathogen growth. For example, two independent research groups demonstrated some bacterial growth in ‘coarse’-grained butter with large water droplets produced with laboratory scale (not commercial) equipment, but not in ‘fine’-grained butter typical of commercial processes, with small, well-dispersed water droplets.⁵¹

Butter has several other physiochemical factors that limit or prevent pathogen growth. First, the low temperatures at which it is kept (either refrigerated or frozen) reduce or eliminate bacterial growth.⁵² Second, butter’s acidic pH limits or prevents pathogen growth.⁵³ Third, for salted butters, the dispersion of salt also inhibits bacterial growth.⁵⁴

In addition to the physical and chemical properties, the biological properties of butter also prevent pathogen growth. The major sources of microbes in butter are the ingredients: cream and the water used to wash butter grains in batch processes. Butter produced from fresh unpasteurized cream is likely dominated by non-pathogens, as documented below for raw milk. Non-pathogenic bacteria colonize water droplets making up the aqueous phase of the emulsion in butter and are typically dominated by micrococci that may grow under certain conditions.⁵⁵

Microbial ecology -- the competition and cooperation of microbes -- plays a significant role in the safety of raw milk and products prepared from it, including raw butter.⁵⁶ Tremendous advances were made in the past decade to interconnect and extend the fields of microbial ecology and the Human Microbiome Project (HMP) into a new field of research, termed

⁴⁷ Budhkar et al., *supra* note 7; Ghoddusi & Ozer, *supra* note 8.

⁴⁸ Hammer & Long, *supra* note 46.

⁴⁹ Hammer & Long, *supra* note 46; Wilbey, *supra* note 9; Budhkar et al., *supra* note 7; Ghoddusi & Ozer, *supra* note 8; Voysey et al., *supra* note 9; Michelon et al., *supra* note 43.

⁵⁰ Voysey et al., *supra* note 9; Ghoddusi & Ozer, *supra* note 8.

⁵¹ Voysey et al., *supra* note 9; Michelon et al., *supra* note 43.

⁵² Ghoddusi & Ozer, *supra* note 8.

⁵³ 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., *supra* note 43.

⁵⁴ Ghoddusi & Ozer, *supra* note 8.

⁵⁵ Wilbey, *supra* note 9.

⁵⁶ 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), <http://academy.asm.org/images/stories/documents/FAQ--cheese.pdf>.

metagenomics⁵⁷. Recent advances in DNA sequencing technologies (independent of culturing) have greatly expanded our knowledge of the dense and diverse microbial communities in and on the human body making up the healthy microbiota.

For example, scientists prior to the initiation of the HMP in 2007 assumed that human breast tissue and aseptically collected human milk were sterile based on now recognized technological limitations of traditional culturing methods. Yet recent metagenomic studies have found a high diversity of bacteria in human breast tissue and in aseptically collected human milk, including up to 700 bacterial species in breast milk of healthy mothers.⁵⁸ Research funded through the HMP continues to expand knowledge of beneficial human-associated bacterial communities and challenge simplistic assumptions incompatible with the complexity of the microbiota of healthy humans and the foods they consume.

Similarly, knowledge of the complexity of the microbial ecology of raw dairy milk and milk products have also been advancing in recent years.⁵⁹ Raw milk is now known to have dense and diverse communities of commensal or beneficial microorganisms, its natural microbiota. Information is available on the density, diversity, and functions of commensal and beneficial bacteria (non-pathogens) dominating the microbiota of raw milk of dairy animals raised in Italy. This raw milk microbiota is dominated by non-pathogens: five genera represented 91% of the raw milk microbiota (*Lactococcus*, *Acinetobacter*, *Streptococcus*, *Chryseobacterium*, and *Lactobacillus*), three genera represented 8% (*Yersinia*, *Pseudomonas*, and *Hafnia*), and 21 subdominant genera represented the remainder, as illustrated in Figure 1 below. The study did not report identification of any pathogenic species. Diversity of the raw milk microbiota was high as estimated by a Chao1 richness index of 50.2 and a Shannon diversity index of 2.15. Other studies have also documented the significant diversity and dominance of non-pathogenic bacteria in raw milk, with only infrequent and low-level contamination with pathogens.⁶⁰

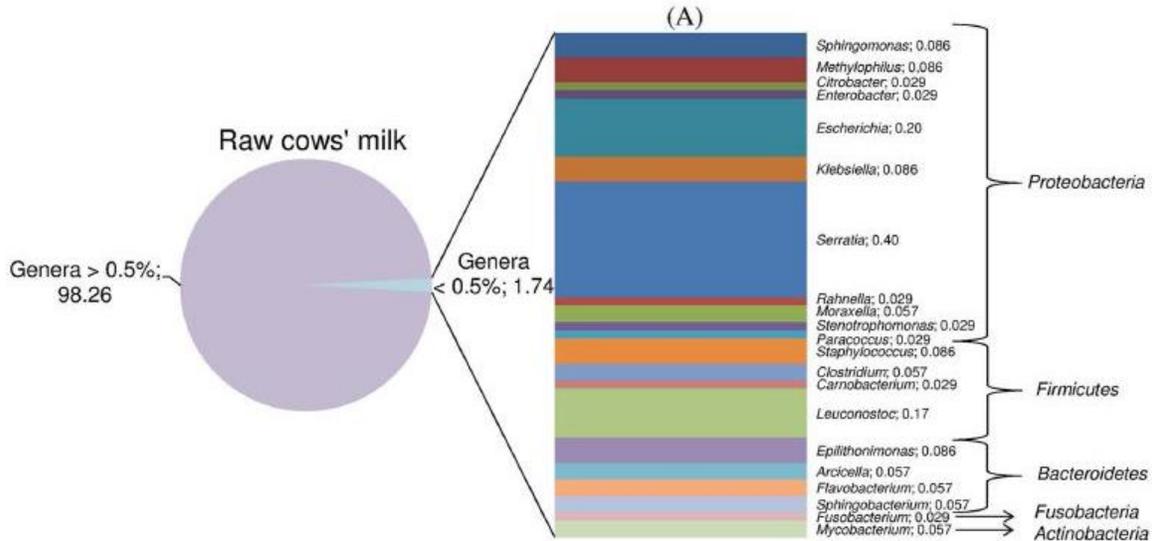
⁵⁷ Human Microbiome Project, <https://commonfund.nih.gov/hmp/overview>.

⁵⁸ K.M. Hunt et al., *Characterization of the Diversity and Temporal Stability of Bacterial Communities in Human Milk*, PLoS ONE 6(6):e21313 (2011); R. Cabrera-Rubio et al., *The human milk microbiome changes over lactation and is shaped by maternal weight and mode of delivery*, AM. J. CLIN. NUTR. 96:544–51 (2012); T. Jost et al. *Vertical mother–neonate transfer of maternal gut bacteria via breastfeeding*, ENVTL. MICROBIOLOGY 16:2891–2904 (2014); C. Urbaniak et al., *Microbiota of Human Breast Tissue*, APPLIED ENVTL. MICROBIOLOGY 80(10):3007–3014 (2014).

⁵⁹ L. Quigley et al., *Molecular approaches to analysing the microbial composition of raw milk and raw milk cheese*, INT’L J. FOOD MICROBIOLOGY 150:81–94 (2011); L. Quigley et al., *High-throughput sequencing for detection of subpopulations of bacteria not previously associated with artisanal cheeses*, APPLIED ENVTL. MICROBIOLOGY 78(16):5717–5723 (2012); L. Quigley et al., *The complex microbiota of raw milk*, FEMS MICROBIOLOGY REV. 37:664–698 (2013); I. De Pasquale et al., *Microbial ecology dynamics reveal a succession in the core microbiota involved in the ripening of pasta filata caciocavallo pugliese cheese*, APPLIED ENVTL MICROBIOLOGY 80(19):6243–55 (2014), <http://www.ncbi.nlm.nih.gov/pubmed/25085486>.

⁶⁰ D.J. D’Amico et al., *Low incidence of foodborne pathogens of concern in raw milk utilized for farmstead cheese production*, J. FOOD PROT. 71(8):1580-9 (2008); E.E. Jackson et al., *Detection and enumeration of four foodborne pathogens in raw commingled silo milk in the United States*, J. FOOD PROT. 75(8):1382-93 (2012).

Figure 1. Microbiota of raw cow milk generated by culture-independent methods (Figure 4A from De Pasquale et al., 2014)



The diverse and dense populations of non-pathogens in raw milk outcompete low densities of potentially contaminating bacteria including pathogens under controlled conditions of modern dairy production.

The natural microbiota provide active competition and other protections against growth of potentially pathogenic contaminants through a principle termed colonization resistance.⁶¹ The World Health Organization/Food and Agricultural Organization of the United Nations (WHO/FAO) has determined that competition by the food microbiota can cause profoundly lower risk estimates for listeriosis as compared to simulations based on assumptions of optimal growth of pathogens representative of pure cultures in media including heat-treated foods.⁶²

In a 2001 FDA report, the food microbiota is described as an intrinsic factor of foods limiting the growth of pathogens.⁶³ Yet the agency then ignores this fact in later documents, failing to acknowledge the influence of the butter microbiota in limiting or preventing pathogen growth, particularly at the low levels of contamination that would occur in real-world conditions.

⁶¹ D. Van der Waaij et al., *Colonization resistance of the digestive tract in conventional and antibiotic-treated mice*, J. HYGIENE 69:405–411 (1971); L. Pricope-Ciolacu et al., *The effect of milk components and storage conditions on the virulence of Listeria monocytogenes as determined by a Caco-2 cell assay*, INT’L J. FOOD MICROBIOLOGY 166:59-64 (2013).

⁶² World Health Organization/Food and Agricultural Organization (WHO/FAO), Example Risk Assessments, Part 4 in RISK ASSESSMENT OF LISTERIA MONOCYTOGENES IN READY-TO-EAT FOODS 132, (2004), <http://www.fao.org/docrep/010/y5394e/y5394e00.htm>

⁶³ Food and Drug Administration, *Factors that Influence Microbial Growth*, Chapter 3 in Evaluation and Definition of Potentially Hazardous Foods (2001), <http://www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/ucm094141.htm>.

In its 2003 risk assessment, the FDA cited a study⁶⁴ that used a laboratory batch-produced butter, which is not one of the modern commercial processes used for butter production. This study also inoculated artificially high levels of the pathogen (100,000/g) to pasteurized cream, which lacks the protective microbiota of raw butter that would limit pathogen growth. As a result, the study produced experimental butter lacking both a protective microbiota and also the fine droplet structure of commercial butters that would limit bacterial growth at natural levels of contamination. FDA's use of this study in risk assessment biased the risk estimates and exaggerated potential risk for commercial raw butter.

When researchers inoculated pasteurized cream with a pathogen, and then used the cream to make butter, the pathogen was found almost entirely in the aqueous-phase buttermilk, with only 5% of the inoculated pathogen distributed into butter. While the precise composition and abundance of the microbiota of commercial butter produced in the U.S. is unknown, the physicochemical nature and structure of butter as a water-in-oil emulsion is a critical factor limiting bacterial contamination and survival.⁶⁵

Petitioners identified a few studies describing aspects of the microbiota of butter produced outside the U.S. Although commercial butter production practices differ globally, it is relevant to consider the information available on the microbiota of butter produced in Algeria, Egypt, and Sudan, set out in Tables 2 and 3, below.

Butter produced in Sudan (both commercially produced and produced on-farm) was analyzed for initial counts of **non-pathogenic** indicator bacteria including total (viable) bacteria, total psychrotrophs, and coliforms, as well as growth potential. Sudanese butter supported significant growth of total viable bacteria at 5°C over 60 days. Growth of coliforms at 5°C was <0.5 log cfu (non significant) over the storage period.⁶⁶

⁶⁴ FDA/FSIS 2003, *supra* note 42, at 263,509 citing J.A. Olsen et al., *Growth and survival of Listeria monocytogenes during making and storage of butter*, MILCHWISSENSCHAFT 43:487-489 (1988).

⁶⁵ Ryser & Marth, *Incidence and behavior of Listeria monocytogenes in unfermented dairy products*, in *Listeria, Listeriosis, and Food Safety* 323-325, 329 (1991)) citing J.A. Olsen et al., *Growth and survival of Listeria monocytogenes during making and storage of butter*, MILCHWISSENSCHAFT 43:487-489 (1988).

⁶⁶ S.S.J. Ahmed et al., *Microbiological quality of cow's milk butter processed in Khartoum State, Sudan*, BRITISH MICROBIOLOGY RESEARCH J. 11(1):1-10 (2016).

Table 2. Range of counts or mean counts in butter produced in Algeria, Egypt, and Sudan

Bacterial Groups	Counts in butter (log ₁₀ colony forming units per gram)		
	Produced in Algeria ⁶⁷	Produced in Egypt ⁶⁸	Produced in Sudan ⁶⁹
Total bacteria	5.2 to 6.8	Not analyzed	2.7 to 3.5
Total psychrotrophs	4.1 to 4.7	4.5	Not analyzed
Coliforms	Nondetectable to 3.3	2.9	0.7 to 0.9

Table 3. Growth of bacterial groups in commercial and traditional farm butter produced in Sudan⁷⁰

Bacterial Groups	Counts in Sudanese butter stored at 5°C (log cfu/g) ⁷¹	
	Range of initial counts	Range of final counts after 60 days
Total Viable Bacteria	2.7 to 3.5	4.0 to 4.4
Coliforms	0.7 to 0.9	0.8 to 0.9

As can be seen in these two tables, the microorganisms in the butter studied in these countries consisted mostly of psychrotrophs, which are bacteria that thrive at colder temperatures typical of modern refrigeration. Despite the physicochemical characteristics of the butter, some growth of the **non-pathogenic** butter microbiota was observed. But 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. Specific growth studies for inoculated pathogens are presented in the following section.

In other words, the indigenous **non-pathogenic** microbiota in butter grow at refrigerated temperatures, but coliforms and most potential pathogens do not. Pathogens such as *L. monocytogenes* that are psychrotrophs grow at lower rates than the non-pathogenic microbiota.⁷² This biological dynamic provides another layer of protection against foodborne illness, because

⁶⁷ T. Idoui et al., *Microbial quality, physicochemical characteristics and fatty acid composition of a traditional butter produced from cows' milk in East Algeria*, GRASAS Y ACEITES 61(3):232-236 (2010). Fresh unprocessed milk samples from 5 farms were incubated at ambient temperature in a laboratory in Algeria and used in traditional butter manufacture.

⁶⁸ A.M.S. Meshref, *Microbiological quality and safety of cooking butter in Beni-Suef governorate-Egypt*, AFRICAN HEALTH SCIENCES 10(2):193-198 (2010). Cooking butter from 60 home refrigerators on farms in Egypt was analyzed for microbial populations.

⁶⁹ Ahmed et al., *supra* note 66.

⁷⁰ Ahmed et al., *supra* note 66.

⁷¹ log cfu/g = log₁₀ colony forming units per gram

⁷² M.E. Coleman et al., *Impact of microbial ecology of meat and poultry products on predictions from exposure assessment scenarios for refrigerated storage*, RISK ANALYSIS 23(1):215-28 (2003).

the active non-pathogenic bacteria more easily outcompete the pathogens under physiochemical conditions that limit **all** bacterial growth.

3. *Even when butter is intentionally inoculated with pathogens, its natural properties limit or eliminate growth.*

Multiple challenge-test studies demonstrate non-significant growth of *L. monocytogenes* and other pathogens in commercially produced butter. Some of these studies examined only levels of pathogens much higher than would ever naturally occur in commercially produced butter; such studies are likely to be biased (predicting exaggerated growth potential or extended survival periods) because doses of pathogens are so unrealistically high that the protective effect of the natural butter microbiota is reduced or eliminated.

In a 2015 study,⁷³ butter prepared with starter cultures was inoculated with *L. monocytogenes* or *L. innocua* and incubated at 8°C for 42 days; since most regulations require that butter be kept at 4 or 5 degrees Celsius, this experiment reflects warmer temperatures and thus better conditions for pathogen growth than would be legally allowed in butter for sale in the U.S. The butter was monitored over its shelf life for the pathogen or its surrogate, total mesophilic microbiota (TMM, including lactic acid bacteria, LAB), and pH. No growth of *L. monocytogenes* or TMM was observed in commercial butter. No growth of *L. innocua* or LAB was observed in laboratory butters with large or small droplet sizes, and TMM only increased up to 1.5 log cfu/g for coarse laboratory butter with large droplet sizes. The growth potential for *L. monocytogenes* remained below the limit value of 0.5 log cfu/g (decision point for ready-to-eat food classification as non-significant growth in the EU) during the whole shelf life of inoculated butter.

In an earlier study,⁷⁴ butters of different water droplet size and salt concentrations were prepared using a bench-top butter churn, inoculated with *L. monocytogenes* at various salt concentrations, incubated at 8°C or 21°C, and monitored for 30 days. Again, the temperatures were higher than what would be allowed under U.S. regulations. While coarse butter permitted growth, fine butter inhibited pathogen growth. Salt also inhibited growth.

Another study inoculated separate butter samples with *Listeria*, *Escherichia coli* O157:H7, or *Salmonella* species.⁷⁵ The commercial butter samples did not support significant growth of **any** of these pathogens inoculated at moderate levels (~100 bacteria/g or 2.0 to 2.5 on the log₁₀ scale reported in the study and illustrated in Figure 2) when incubated at 4.4°C for up to 21 days. In every case, the pathogen populations actually decreased over time. These pathogens inoculated into commercial butter at high levels (~100,000 bacteria/g or 5.0 on the log₁₀ scale, data not shown) also did not grow significantly at refrigeration temperatures. Additional data for incubation of inoculated butter at 21°C were consistent with the patterns of decline for refrigeration temperature (data not shown). In contrast, as reflected in another study and Figure

⁷³ Michelon et al., *supra* note 43.

⁷⁴ Voysey et al., *supra* note 9.

⁷⁵ Holliday et al., *supra* note 43.

3, ultra high temperature (UHT) cream treated then inoculated with *L. monocytogenes* showed significant growth, even at a lower refrigeration temperature.⁷⁶

Figure 2. Pathogen inhibition following inoculation of sweet cream unsalted butter at 4.4 ° (data reported in Holliday et al., 2003).

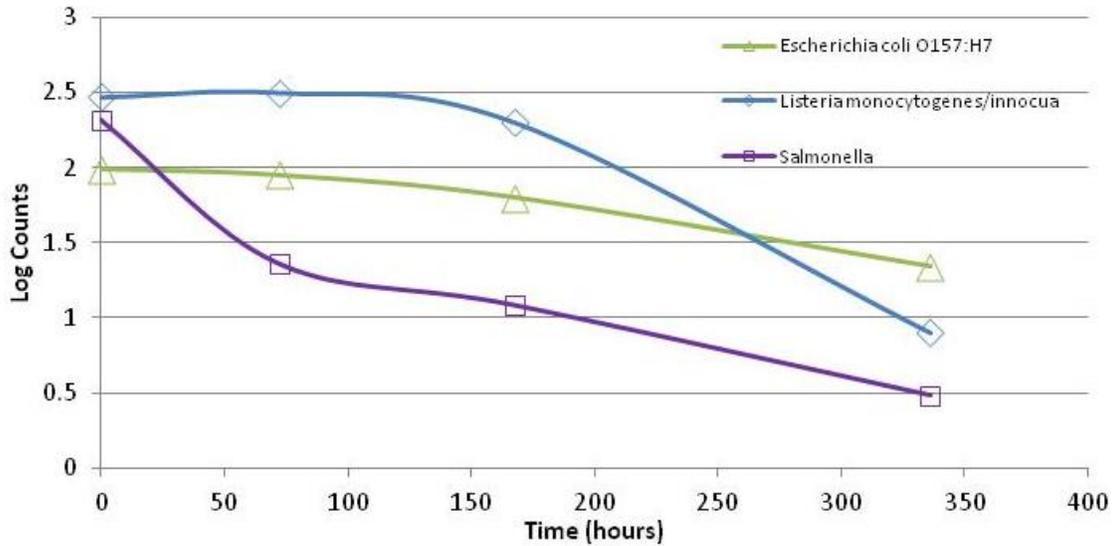
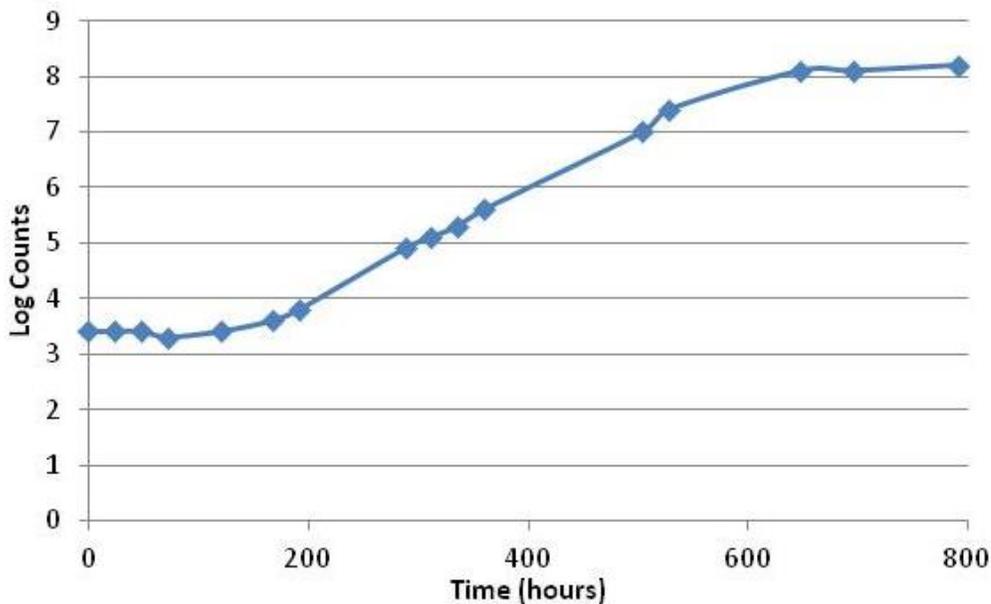


Figure 3. Pathogen growth following inoculation of UHT cream at 3 ° (data reported in ComBase).



⁷⁶ Data downloaded from ComBase, <http://www.combase.cc>. ComBase is a systematically formatted database of quantified microbial responses to the food environment with more than 50,000 records. Individuals can search microbial growth and survival curves that have been collated in research establishments and from publications.

Growth potential was assessed in butter naturally contaminated with *L. monocytogenes* after an outbreak in hospitalized immunocompromised patients in Finland. Researchers assessed natural contamination levels in butter samples from the implicated dairy's wholesale store and incubated samples at 6.5 to 7.2°C to assess growth potential over 50 to 120 days.⁷⁷ Samples of the smaller size butter packages (7-gram and 10-gram) did not support growth of the pathogen. Some growth was observed in pooled samples of the largest butter packages (500-g). 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. (The largest sample packages were not pooled.) Lack of pathogen growth in well-worked butter samples is consistent with studies by two independent research groups discussed previously in this section.⁷⁸

In its 2003 analysis, FDA cited a much older, flawed study⁷⁹ to support the claim that butter would support *Listeria* growth. That now almost-30-year-old study used butter prepared in the laboratory, rather than commercially prepared butter, in addition to using artificially high inoculation levels. As more recent research has established, such laboratory-produced butters likely had larger moisture droplets than commercially-produced butter and thus permitted growth of inoculated *L. monocytogenes*.⁸⁰

4. A review of the scientific literature supports the epidemiological data showing that butter is a low-risk product.

Petitioners also conducted a literature search for scientific studies on the data required to assess the risk of illness for butter consumers (pathogen presence, levels and growth in butter and pathogen doses causing foodborne illness).

The FDA risk assessment cited two small studies, one unpublished, that reported no detectable *L. monocytogenes* in 53 samples of U.S. butter.⁸¹ While there were no other published studies that characterized the prevalence and level of pathogens in commercial butter produced in the United States, studies from the European Union also indicate that commercially prepared butter, prepared under modern sanitary conditions, rarely contains pathogens. For example, butter produced in Turkey tested negative for *Listeria monocytogenes*, *Salmonella* species, and *Staphylococcus aureus*, as well as coliforms, an indicator of proper sanitation; overall yeast and bacterial counts were very low.⁸² Similarly, while a report on four studies conducted in the

⁷⁷ R. Maijala et al., *Exposure of Listeria monocytogenes within an epidemic caused by butter in Finland*, INT'L J. FOOD MICROBIOLOGY 70:97-109 (2001).

⁷⁸ Voysey et al., *supra* note 9; Michelon et al., *supra* note 43.

⁷⁹ FDA/FSIS 2003, *supra* note 64; Ryser & Marth, *supra* note 65.

⁸⁰ Ryser & Marth, *supra* note 65 at 324.

⁸¹ FDA/FSIS 2003, *supra* note 42, at 240, 487 citing C.P. Frye, *Milk product pathogen sampling (2000*, unpublished) and citing J. Kozak et al., *Prevalence of Listeria monocytogenes in foods: Incidence in dairy products*, FOOD CONTROL 7(4/5):215-221 (1996).

⁸² Varga, *supra* note 41.

European Union found unspecified levels of *Listeria* in anywhere from 4% to 30% of the samples, no positive samples were detected – out of hundreds tested -- for *Salmonella* species, pathogenic *E. coli*, or enterotoxins from *Staphylococcus aureus* (although 2% to 20% tested positive for the *S. aureus* bacteria at unspecified densities).⁸³

While the European Union study found positive samples for *Listeria*, the risk appears to be **lower** for unpasteurized butter than for pasteurized. Another study from the United Kingdom did not detect any *Listeria* species in butter produced from 61 samples of unpasteurized cream; however, butter produced from pasteurized cream had 60 positive samples out of 2,748 tested.⁸⁴ The detection of *Listeria* in pasteurized but not raw butter may reflect the lack of a protective microbiota and enhanced growth rates of *Listeria* species in heat treated milks,⁸⁵ as illustrated in Figure 3, *supra*.

Moreover, particularly with respect to *Listeria*, the simple presence of the pathogen at low levels does not necessarily pose a significant risk. Multiple risk assessment teams, including FDA teams, have determined that most listeriosis cases occur in foods contaminated with high levels of *Listeria monocytogenes*. One study found that food servings with high *Listeria monocytogenes* doses, between 31 hundred and 31 million bacteria, are associated with illness.⁸⁶ Under FDA's 2008 study, less than one annual case of listeriosis was predicted from all servings of the food groups considered, including butter in the high fat and other dairy products group, at levels between 100,000 and 3 million *Listeria monocytogenes* counts per serving. FDA predicted **no** cases of listeriosis for doses of less than 31,600 *Listeria monocytogenes* counts per serving. Further, FDA predicted comparable risks of listeriosis for consumers of pasteurized and unpasteurized milk and butter.⁸⁷

The World Health Organization has stated that “Nearly all cases of listeriosis (are predicted to) result from consumption of high numbers of the pathogen.”⁸⁸ The WHO considered four commodities; for pasteurized milk, which unlike butter permits the growth of *L. monocytogenes*, only 9 cases out of every 10 million consumers per year were predicted.

Multiple studies support the position that the risk of listeriosis to consumers of butter is overestimated because models of dose-response relationships are biased. As FDA and others have acknowledged, risk of illness in consumers of butter and other foods is likely overestimated due to inappropriate assumptions about human dose-response relationships for listeriosis.⁸⁹ The FDA's risk assessment includes several implausible key assumptions: (1) growth occurs in

⁸³ Verraes et al., *supra* note 40.

⁸⁴ Lewis et al., *supra* note 9.

⁸⁵ Ryser & Marth, *supra* note 65; M.J. Stasiewicz et al., *Responding to bioterror concerns by increasing milk pasteurization temperature would increase estimated annual deaths from listeriosis*, *J. Food Prot.* 77(5):696-705 (2014).

⁸⁶ R. Pouillot et al., *Listeria monocytogenes dose response revisited—incorporating adjustments for variability in strain virulence and host susceptibility*, *RISK ANALYSIS* 35(1):90–108 (2015).

⁸⁷ FDA/FSIS 2003, *supra* note 42.

⁸⁸ WHO/FAO, *supra* note 62, *Key Findings and Conclusions*, Part 6 at 149.

⁸⁹ FDA/FSIS 2003, *supra* note 42; WHO/FAO, *supra* note 62; Y. Chen et al., *Listeria monocytogenes: low levels equal low risk*, *J. FOOD PROT.* 66(4):570-577 (2003); FDA 2008, *supra* note 42; Pouillot et al., *supra* note 86.

commercial butter; (2) a single bacterial cell causes disease (no threshold); and (3) illness increases proportionately as doses increases from one to thousands of bacteria (low-dose linearity).

In contrast to these erroneous assumptions, scientific studies demonstrate 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.⁹⁰ Mechanisms of protection afforded by the gut microbiota include direct antagonism of *L. monocytogenes* and other pathogens, competition for micronutrients and binding sites on host cells, and enhancement of immunity and epithelial barrier function in the healthy gut.⁹¹ The low attack rates observed for listeriosis⁹² and frequent exposures to the pathogen in many ready-to-eat foods⁹³ reflect the need for foods to be highly contaminated (such as exposures above 3 million *L. monocytogenes* as estimated by FDA in 2008) to overcome the innate defenses of healthy humans.

A recent study⁹⁴ provides experimental documentation that a related food microbiota (raw milk) protects isolated human tissue culture cells from a very high dose of *L. monocytogenes* inoculum. Isolated human intestinal epithelial cells were incubated with 100,000,000 *L. monocytogenes* (10^8 bacteria) administered in: (1) raw milk; (2) pasteurized milk; or (3) a buffer solution. These simple tissue culture experiments, lacking the full arsenal of human gut defenses, demonstrated that even isolated human gut cells can successfully defend against *L. monocytogenes* inoculated in raw milk, but **not** via pasteurized milk or buffer lacking the raw milk microbiota. The raw milk microbiota significantly reduced adhesion, invasion, and growth in the human intestinal epithelial cell assay relative to responses to the same dose administered in pasteurized milk and buffer. The low doses of *L. monocytogenes* and other pathogens rarely detected in raw milk and butter⁹⁵ are expected to be more strongly inhibited or eliminated by the microbiota acting in concert with the full immune defenses than the artificially high dose administered in these tissue culture experiments. Thus, this study and other evidence from epidemiology, risk assessment, and microbial ecology studies⁹⁶ are consistent with the likelihood of full protection for healthy humans against low doses of *L. monocytogenes* contamination in foods, with natural food microbiota acting in concert with the intact human gut's full arsenal of immune defenses.

⁹⁰ Van der Waaij et al., *supra* note 61; C.G.M. Gahan & C. Hill, *Listeria monocytogenes: survival and adaptation in the gastrointestinal tract*, FRONTIERS IN CELLULAR & INFECTION MICROBIOLOGY 4(9):1-7 (2014), <http://doi.org/10.3389/fcimb.2014.00009>

⁹¹ Gahan & Hill, *supra* note 90.

⁹² J. McLauchlin et al., *Listeria monocytogenes and listeriosis: a review of hazard characterisation for use in microbiological risk assessment of foods*, INT'L J. FOOD MICROBIOLOGY 92(1):15-33 (2004).

⁹³ D.E. Gombas et al., *Survey of Listeria monocytogenes in ready-to-eat foods*, J. FOOD PROT. 66(4):559-569 (2003).

⁹⁴ Pricope-Ciolacu et al., *supra* note 61.

⁹⁵ Quigley et al. 2013, *supra* note 59; D'Amico et al. 2008, *supra* note 60; Jackson et al., *supra* note 60; Lewis et al., *supra* note 9; Varga et al., *supra* note 41; Verraes et al., *supra* note 40.

⁹⁶ Chen et al., *supra* note 89; FDA 2008, *supra* note 42; Pouillot et al., *supra* note 86; Gahan & Hill, *supra* note 90; Coleman et al., *supra* note 72.

Modern commercially produced butter that is properly manufactured and stored is infrequently contaminated with *L. monocytogenes* and other pathogens, and even if contaminated, it is at levels too low to cause illness.

D. Regulatory agencies' regulation of butter reflects the low risk.

Other federal regulations reflect the relatively low risk from butter, both raw and pasteurized. While the United States Department of Agriculture's recommended requirements for milk for manufacturing purposes include both quality standards for the milk itself and standards for the farms on which it is produced, they reflect a lower standard than that required for milk intended for fluid consumption.⁹⁷ For example, while the Pasteurized Milk Ordinance sets a limit of 300,000 bacteria per ml for fluid milk,⁹⁸ the requirements for milk for manufacturing purposes allows up to 500,000 bacteria per ml.⁹⁹

The same standards apply whether the milk is to be used for manufacturing butter or other products such as cheese. Raw milk cheeses that have been aged for at least 60 days are a low-risk product that have resulted in only a small handful of outbreaks over the last two decades.¹⁰⁰ As discussed above, raw butter has been linked to – at most – one outbreak in that same time period. Yet while raw cheeses are legal to sell in interstate commerce, raw butter is not. The different treatment of these two manufactured dairy products is not based on any scientific evidence and is not rational.

The FDA's PMO specifically excludes **both** butter and aged cheese from the definition of "milk and milk products."¹⁰¹ The FDA similarly excludes aged cheese from the pasteurization requirements in 21 C.F.R. 1240.61, yet includes butter without any stated rationale or scientific support. Petitioners simply seek to have FDA treat butter and raw cheeses the same in interstate commerce, an approach which is consistent with the low risk levels of both products.

The requested relief is also consistent with the way state laws address raw butter. To Petitioners' knowledge, no state imposes specific regulations on raw butter; in states where it is legal to sell, it is either unregulated or regulated the same way as "raw dairy products" in general.¹⁰²

⁹⁷ Agricultural Marketing Service (AMS), United States Department of Agriculture, Milk for Manufacturing Purposes and its Production and Processing: Recommended Requirements (2011).

⁹⁸ FDA 1978, *supra* note 17, at 29.

⁹⁹ AMS, *supra* note 97, at 6.

¹⁰⁰ Weston A. Price Foundation (WAPF), *Comments on Understanding Potential Intervention Measures To Reduce the Risk of Foodborne Illness From Consumption of Cheese Manufactured From Unpasteurized Milk* (analyzing the available CDC and publicly available data), submitted to the FDA on Nov. 2, 2015, https://www.regulations.gov/?utm_campaign=comment%20publication%20notification%20email&utm_source=federalregister.gov&utm_medium=email#!documentDetail;D=FDA-2015-N-2596-0024

¹⁰¹ FDA 1978, *supra* note 17, at 6-7.

¹⁰² *See, e.g.*, CAL. CODE REGS., 17 CCR § 11380 (2015) (defining "raw milk product" as "any food which contains raw milk, and shall include, but not be limited to, ... butter."); IDAHO ADMIN. CODE, ID ADC § 02.04.13.007 ("Raw milk products include any milk product processed from raw milk that has not been pasteurized and is intended for human consumption..."); ARIZ. REV. STAT. §3-606 (exempting "cottage cheese, buttermilk, butter, kefir, and other cheeses made from grade A raw or certified raw milk" from the requirement for pasteurization before sale).

E. Conclusion

The agency's ban on the interstate transport of raw butter is arbitrary, capricious, not in accordance with applicable law, and contrary to the agency's statutory authority. Petitioners urge the agency to amend the definition in 21 C.F.R. §1240.3(j) and adopt a new regulation to allow for the interstate transport of raw butter.

ENVIRONMENTAL IMPACT

The specific actions requested by petitioners are categorically excluded under 21 C.F.R. §§ 25.30(h) and 25.32(a) and therefore do not require the preparation of an environmental assessment.

CERTIFICATION

The undersigned certify that, to the best knowledge and beliefs of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

CONCLUSION

In accordance with FDA's governing regulations and the APA, Petitioners request that FDA provide an answer to this petition in accordance with 21 C.F.R. 10.30(e)(2) and within a reasonable time.¹⁰³

Respectfully submitted,



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¹⁰³ 21 C.F.R. §10.30(e)(2) ("Except as provided in paragraph (e)(4) of this section, the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition."); 5 U.S.C. §555(b) ("[W]ithin a reasonable time, each agency shall proceed to conclude a matter presented to it."); *id.* §706(1) ("The reviewing court shall ... compel agency action unlawfully withheld or unreasonably delayed."); *id.* §555(e) ("Prompt notice shall be given of the denial in whole or in part of a written application, petition, or other request of an interested person").