



NOV 25 2014

Mr. Mark McAfee  
Organic Pastures Dairy  
7221 South Jameson Avenue  
Fresno, California 93706

Via UPS Overnight Mail

Re: Docket No. FDA-2013-P-0701

Dear Mr. McAfee:

This letter is in response to your citizen petition, dated May 31, 2013, and received June 5, 2013, filed under Docket No. FDA-2013-P-0701 (the “2013 Citizen Petition”). In your 2013 Citizen Petition, you request that the U.S. Food and Drug Administration (“FDA” or “the agency”) modify its denial of a citizen petition you submitted in 2008 (the “2008 Citizen Petition”), which the agency denied on February 26, 2013. In your 2008 Citizen Petition, you requested that FDA amend 21 CFR 1240.61 to include an exception that would read as follows:

Raw milk that is tested, state inspected, state regulated, carries a “government warning statement” and labeled for retail sale in one state may be transported to another state if that other state allows the sale of raw un-pasteurized milk and or [sic] dairy products.<sup>1</sup>

In your 2013 Citizen Petition, you ask that FDA “review the information in support of the 2008 petition and the additional information in support of [the 2013 Citizen Petition] and take additional administrative action in the form of a modification to the February 26<sup>th</sup> 2013 denial.” You further state that this “modification would allow the interstate delivery or sale or distribution of raw milk<sup>2</sup> and raw dairy products from the seller’s state to the destination state.” Thus, your 2013 Citizen Petition asks that FDA modify its decision, made in response to your 2008 Citizen Petition, to not amend 21 CFR 1240.61 to include an exception that would allow for the interstate distribution of

<sup>1</sup> Specifically, the 2008 Citizen Petition proposed adding an asterisk to 21 CFR 1240.61(a), with your proposed exception appearing at a corresponding asterisk. The full text of 21 CFR 1240.61(a) is presented here, with the location of your proposed asterisk shown in brackets: “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.”

<sup>2</sup> You state that “[f]or purposes of [the 2013 Citizen Petition], references to raw milk include references to raw dairy products.”

raw milk between states where raw milk is legal, provided the raw milk is “tested, state inspected, state regulated, carries a ‘government warning statement,’ and [is] labeled for retail sale.” Your 2013 Citizen Petition also appears to ask that FDA more generally “allow the interstate delivery or sale or distribution” of raw milk and raw milk products.

Your 2013 Citizen Petition does not contain facts demonstrating any reasonable grounds for (1) modifying FDA’s denial of your 2008 Citizen Petition, or (2) amending or rescinding 21 CFR 1240.61 to “allow the interstate delivery or sale or distribution” of raw milk and raw milk products. Further, your 2013 Citizen Petition does not show that your proposal is in the public interest or that it will promote the public health objectives of FDA. See 21 CFR 10.40(a)(2). Therefore, in accordance with 21 CFR 10.30(e)(3), and for the reasons stated below, as well as the reasons set forth in the agency’s February 26, 2013 response to your previous petition, FDA is denying your 2013 Citizen Petition.

## **DISCUSSION**

21 CFR 1240.61(a) was promulgated in 1987 and states, in pertinent part, as follows:

No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product 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.” Requirements Affecting Raw Milk for Human Consumption in Interstate Commerce, 52 Fed. Reg. 29509, 29511 (Aug. 10, 1987). FDA also found that the record demonstrated “an association between the consumption of certified raw milk<sup>3</sup> and the outbreak of disease, particularly among consumers who are young, elderly, or infirm.” *Id.* As FDA noted at the time, its findings paralleled the conclusions of a study published in the *Journal of the American Medical Association (JAMA)* that “the role of unpasteurized dairy products, including raw and certified raw milk, in the transmission of disease has been established repeatedly.” *Id.* Particularly persuasive to FDA were statistics collected by the California Department of Health Services (“CDHS”) on the incidence of *Salmonella dublin* (“*S. dublin*”) infections. *Id.* at 29511-12. FDA summarized these statistics as follows:

[CDHS] has reported that 50 percent of all the *S. dublin* infection cases reported in California in 1984 involved the use of certified raw milk. According to CDHS, no other risk factor has been prevalent among cases. For example, even though *S. dublin* is host adapted to cattle,

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<sup>3</sup> “Certified raw milk” is raw milk produced in compliance with methods and standards developed by private organizations. 52 Fed. Reg. at 29510.

only a small percent (15 percent or less) of cases report use of either lightly cooked or uncooked beef or beef products. CDHS concluded that the relative risk of contracting *S. dublin* is 158 times greater for those Californians who consume certified raw milk than for those who do not drink any form of raw milk. CDHS considered this relative risk extremely large and among the largest obtained in any epidemiologic investigation.

*Id.*

Based on these findings, FDA issued 21 CFR 1240.61 acting in part under the broad grant of authority conferred by section 361(a) of the Public Health Service Act (“PHSA”), which states:

The Surgeon General, with the approval of the Secretary, *is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases* from foreign countries into the States or possessions, or from one State or possession into any other State or possession.

42 U.S.C. § 264(a) (emphasis added). This broad authority has been delegated to FDA.<sup>4</sup>

As discussed below, FDA remains of the view that there is a demonstrated association between the consumption of raw milk and the outbreak of disease, and that raw milk can contain a wide variety of harmful bacteria, including *E.coli* O157:H7 and other Shiga toxin-producing *E. coli*, *Salmonella*, *Yersinia enterocolitica*, *Campylobacter jejuni*, *Staphylococcus aureus*, *Listeria monocytogenes*, and *Coxiella burnetii*.<sup>5,6</sup> See Table 1.

Furthermore, there is no reliable method available to determine that raw milk, even from a state-regulated farm or raw milk manufacturer, is or will be free of pathogens, or that raw milk from any such farm or manufacturer will not cause disease. In the preamble to the final rule promulgating 21 CFR 1240.61, FDA concluded that “raw milk, no matter how carefully produced, may be unsafe.” 52 Fed. Reg. at 29512. FDA is unaware of any information published since the promulgation of 21 CFR 1240.61 that would cause it to change its conclusions on this matter. Although your 2013 Citizen Petition suggests that there are standards for raw milk that are sufficient to adequately ensure the safety of such milk, FDA is not aware of any standards that are sufficient to call into question, much less to overcome, the findings that the agency made in promulgating 21 CFR 1240.61.

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<sup>4</sup> In 1944, Congress passed the PHSA, 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 <http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm080711.htm>).

<sup>5</sup> Hayes and Boor, 2001. *Applied Dairy Microbiology*, 2 ed. Marcel Decker, Inc., New York. pp 59-76.

<sup>6</sup> Oliver et al. 2005. *Foodborne Pathogens and Disease*. 2:115-119.

The “Statement of Grounds” in your 2013 Citizen Petition contains five sections, each of which contains a number of assertions. Beyond the general propositions discussed above, FDA addresses the assertions you make in each of these five sections below.

### Section B.1 of your 2013 Citizen Petition

#### A. “Healthy diversity of gut bacteria”

You assert that “[a]ccess to raw milk is in the public’s interest because it promotes a healthy diversity of gut bacteria that is essential for human health.” However, you provide no basis upon which to conclude that raw milk in fact “promotes healthy diversity of gut bacteria that is essential for human health.” Bacteria found in raw milk can be pathogenic and, therefore, not healthy. The human pathogens found in raw milk include *E. coli* O157:H7, *Salmonella*, *Streptococcus spp.* *Yersinia enterocolitica*, *Campylobacter jejuni*, *Staphylococcus aureus*, *Listeria monocytogenes*, *Mycobacterium tuberculosis*, and *Coxiella burnetti*.<sup>5</sup>

In support of your assertion, you provide: (1) printouts of the website of the Human Microbiome Project;<sup>7</sup> (2) a description of demonstration projects funded by the Human Microbiome Project;<sup>8</sup> (3) an article published in the journal *Nature* authored by the Human Microbiome Project;<sup>9</sup> (4) the transcript of a Technology, Entertainment, and Design (“TED”) talk concerning the role of bacteria;<sup>10</sup> (5) an article published in YaleNews about bacteria;<sup>11</sup> (6) an abstract of an article published in *JAMA* about *Campylobacter jejuni* infection and raw milk;<sup>12</sup> and (7) articles published in nine editions of the “Splash” newsletter.<sup>13</sup> We do not agree that this information demonstrates that raw milk “promotes healthy diversity of gut bacteria that is essential to human health” and/or demonstrates that FDA should amend or rescind 21 CFR 1240.61.

Most of the information you provide, including the Human Microbiome Project’s homepage, the description of the Human Microbiome Project’s demonstration projects, the article published in *Nature*, the TED talk transcript, and the article published in YaleNews about bacteria, makes no mention of any purported effects raw milk has on “promot[ing] healthy diversity of gut bacteria.” Although these materials discuss the issue of bacteria generally, they do not address raw milk, much less raw milk’s purported role in “promot[ing] healthy diversity of gut bacteria.” Moreover, even your 2013 Citizen Petition concedes that “gut bacteria ‘remains largely unstudied, leaving their influence . . . almost entirely unknown’” and that “‘future study’ is needed.”

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<sup>7</sup> Human Microbiome Project Homepage. National Institutes of Health.

<sup>8</sup> Hmpdacc.org. 2014. Human Microbiome Project DACC – Impacts on Health. National Institutes of Health. Last accessed 30 Oct 2014. [http://www.hmpdacc.org/impacts\\_health/impact\\_health.php](http://www.hmpdacc.org/impacts_health/impact_health.php).

<sup>9</sup> Human Microbiome Project Consortium. 14 June 2012. Structure, function and diversity of the healthy human microbiome. *Nature*. 486:207-214.

<sup>10</sup> Transcript of Bassler, B. “How Bacteria ‘talk.’” TED Conferences, Long Beach, Feb 2009.

[http://www.ted.com/talks/bonnie\\_bassler\\_on\\_how\\_bacteria\\_communicate/transcript?language=en#t-12901](http://www.ted.com/talks/bonnie_bassler_on_how_bacteria_communicate/transcript?language=en#t-12901).

<sup>11</sup> Yale News. ‘Friendly’ Bacteria Protect Against Type 1 Diabetes, Yale Researchers Find. 21 Sept 2008),

<http://news.yale.edu/2008/09/21/friendly-bacteria-protect-against-type-1-diabetes-yale-researchers-find>. CP Exhibit 5.

<sup>12</sup> Although you only submitted the abstract for the *JAMA* article, FDA reviewed the full article. Blaser et al. 1987. The Influence of Immunity on Raw Milk— Associated Campylobacter Infection. *JAMA*. 257:1:43-46.

<sup>13</sup> Splash newsletters. April 2012, June 2012, Sept 2012, Oct 2012, Nov 2012, Dec 2012, Feb 2013, March 2013, April 2013.

The *JAMA* article about *Campylobacter jejuni* infection and raw milk similarly does not address raw milk's purported role in "promot[ing] healthy diversity of gut bacteria" but , instead, addresses *Campylobacter jejuni* infections that occurred during an Oregon farm retreat for college students.<sup>14</sup> Similarly, contrary to your characterizations, none of the articles from the "Splash" newsletter addresses whether raw milk "promotes healthy diversity of gut bacteria that is essential for human health." In many cases, you appear to be referring to discussions in the Splash newsletter of human breast milk, as some of those discussions address issues related to the gut. However, because neither your 2008 Citizen Petition nor your 2013 Citizen Petition requests action with respect to the regulation of human breast milk, these Splash newsletter articles are not relevant to your requested action.<sup>15</sup> In other cases, the Splash newsletter articles to which you refer appear to discuss studies related to milk generally, not raw milk. Accordingly, these materials do not support your argument that raw milk, specifically, promotes healthy gut bacteria.

B. "Build[ing] immunity to bad bacteria"

The *JAMA* article about *Campylobacter jejuni* infection and raw milk<sup>12</sup> is the only support you provide for your argument that raw milk has been found to "help the body build immunity to certain bad bacteria." This article describes what happened after a retreat to an Oregon farm caused 19 of 31 college students to develop an acute gastrointestinal illness caused by *Campylobacter jejuni* infection. Eighty-eight percent of the students who consumed raw milk for the first time became infected, compared with none of the ten students who chronically consumed raw milk. The authors of the study concluded that chronic raw milk consumption is associated with elevated levels of *Campylobacter jejuni*-specific serum antibodies and with immunity to symptomatic infection.

By relying on this article, you seem to be arguing that raw milk should be consumed in order to build up immunity to *Campylobacter jejuni*. This study, however, does not provide any support for the notion that raw milk is safe and/or that FDA should amend or rescind 21 CFR 1240.61 in order to help individuals "build immunity to bad bacteria." Raw milk contaminated with *Campylobacter jejuni* is dangerous. *Campylobacteriosis* can lead to diarrhea, abdominal pain, vomiting, and, in more serious cases, to dehydration requiring hospitalization, and chronic illness.<sup>16</sup> *Campylobacteriosis* can also lead to health conditions and disorders such as Guillain-Barre syndrome ("GBS"), a cause of paralysis, occurring at a rate of between 1 in 1,000 to 1 in 3,300 cases.<sup>17, 18, 19, 20</sup> For infections with the O:19 strains of *Campylobacter*, the risk of GBS may be as

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<sup>14</sup> We also discuss this article in section B.1.B below addressing your arguments related to raw milk and immunity to bad bacteria.

<sup>15</sup> Your cite to a study on human breast milk in support of your assertion that "raw milk is a food that assists in the repair of a leaky gut" is similarly irrelevant to the action you request in your 2013 Citizen Petition. Maciej Chichlowski et al. *Annual Review of Food Science and Technology*. 2011. 2:331-351. Although this study includes a brief section recommending future research on bovine milk (for the purpose of improving infant formula so it provides the same benefits as human breast milk), the study does not address raw milk.

<sup>16</sup> Havelaar et al. 2009. *Critical Reviews in Microbiology*. 35:1:1-22.

<sup>17</sup> Nachamkin et al. 1998. *Clinical Microbiology Reviews*. 11:3:555-567.

<sup>18</sup> Nachamkin et al. 2002. *Microbes and Infection*. 4:4:399-403.

<sup>19</sup> McCarthy and Glesecke. (2001). *American Journal of Epidemiology*. 153(6):610-614.

<sup>20</sup> Tam et al. 2006. *Journal of Infectious Diseases*. 194:1:95-97.

high as 1 in 160.<sup>17</sup> For patients infected with the Penner type HS:19 strain of *Campylobacter*, the risk of contracting GBS is estimated to be 1 in 200.<sup>18</sup> In addition, any immunity to *Campylobacter jejuni* is not necessarily permanent and can be overcome by larger doses.<sup>16</sup>

Moreover, the authors of the *JAMA* article do not make any claim that raw milk should be consumed to build up immunity to *Campylobacter jejuni*, and FDA is not aware of any research that recommends consuming raw milk as a means of providing immunity to *Campylobacter* infection. Instead, research notes the role of pasteurization in preventing *Campylobacter* infection. For example, Humphrey et al. (2007)<sup>21</sup> state that: “The presence of campylobacters in the intestinal tract of dairy animals will mean that milk will frequently be contaminated at milking as a consequence of fecal contamination. Although proper hygiene at milking can reduce both the incidence and level of contamination, and udders should be washed and dried prior to milking, this is not a completely effective control measure. The only way to ensure that people are protected from infection by this route is for milk to be pasteurized, as this process, if applied properly, will kill campylobacters. In discussing two outbreaks of campylobacteriosis associated with the consumption of raw milk, Heuvelink et al. (2009)<sup>22</sup> state: “To ensure drinking milk is safe, raw milk needs to be heat-treated” and “[a]s long as legislation allows the sale and distribution of untreated milk, the risk of milk-borne outbreaks of illness remains.”

Importantly, FDA promulgated 21 CFR 1240.61 based on evidence that raw milk is associated with the outbreak of numerous diseases, not just campylobacteriosis. In recent years, for instance, there have been raw milk outbreaks in states where raw milk sale is permitted involving a variety of pathogens, including *Campylobacter*. Table 2 illustrates some examples of raw milk outbreaks in recent years (2010 – September 2014) in states where raw milk sales are legal. Information about the legality of raw milk sales was obtained from the 2011 survey conducted by the National Association of State Departments of Agriculture (NASDA).<sup>23</sup>

### C. Nutritive Value of Milk

You also state that FDA incorrectly concluded that pasteurization has little or no effect on the nutritive value of milk. As noted in response to your 2008 Citizen Petition, FDA expressly found during the process of promulgating 21 CFR 1240.61 that “pasteurization does not significantly change the nutritive or immunologic value of milk.” 52 Fed. Reg. at 29513. FDA’s response to your 2008 Citizen Petition noted that the agency was unaware of any scientific data published since the promulgation of 21 CFR 1240.61 that would cause the agency to change its opinion on this matter. This continues to be true. Moreover, with a single exception, the Splash newsletters you cite in Section B.1 in support of your position do not address the purported effect of pasteurization on milk’s nutritive value,<sup>24</sup> much less provide evidence consistent with your position.<sup>25</sup>

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<sup>21</sup> Humphrey et al. 2007. *International Journal of Food Microbiology*. 117:3:237-257.

<sup>22</sup> Heuvelink et al. 2009. *International Journal of Food Microbiology*. 134:70-74.

<sup>23</sup> NASDA News Release, July 19, 2011. NASDA Releases Raw Milk Survey.

<sup>24</sup> One of the articles contained in the Splash newsletter relates to the supposed benefits of raw milk in relationship to the purported effect of pasteurization on milk’s nutritive value, but it contains serious mischaracterizations. Anna Petherick, *The evidence around raw milk*, SPLASH! Milk Science Update (Oct. 2012). This article discusses the GABRIELA and PASTURE studies, which we address in Section B.2 of this letter. We note here, however, that the author of the Splash article mischaracterizes the GABRIELA study and what it shows about the impact of pasteurization on milk. The

## Section B.2 of Your 2013 Citizen Petition

### A. Allergies and Asthma

You assert that “FDA lists pasteurized milk as the most allergenic food in all of America,” that “[a]ccess to raw milk is in the public’s interest as an alternative to a known allergen,” and that “raw fresh milk is associated with reduction of allergies and prevention of asthma.” FDA acknowledges that milk allergy is an important food allergy of concern in the United States, especially in children. We also acknowledge that there have been studies examining infants and young children mostly from rural areas and finding that those infants or children with reduced incidence or manifestations of allergic disorders or asthma were more likely to be raw milk consumers rather than non-raw milk consumers. In some studies, the association between raw milk consumption and reduced incidence of allergic disorders/asthma was found to be independent of other farm-related factors or living on a farm,<sup>26,27</sup> and individuals reported to consume raw milk were found to have evidence of certain protective immune markers as a possible explanation for this association.<sup>28</sup>

Notably, however, these studies do not always distinguish between raw milk and pasteurized milk. In fact, non-raw milk does not always mean pasteurized milk in these studies.<sup>26,27</sup> Some studies refer to consumed milk as farm milk or shop milk which could be heated, cooked, or pasteurized.<sup>26,27</sup> Moreover, the information in these studies regarding milk consumption is from questionnaires that may be subject to recall bias.<sup>26,27</sup> Furthermore, from these questionnaires, it is not always clear that raw milk or non-raw, pasteurized milk consumption is mutually exclusive.<sup>26,27</sup> Because of these study limitations, it cannot be concluded that raw milk was consumed alone and contributed to the stated associations.

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GABRIELA authors never stated, nor did their research indicate, that “most whey proteins . . . don’t survive pasteurization,” as the Splash newsletter article claims. The authors of the GABRIELA study analyzed the whey protein fraction of milk, especially bovine serum albumin (BSA),  $\alpha$ -lactalbumin ( $\alpha$ -la), and  $\beta$ -lactoglobulin ( $\beta$ -lg). These whey protein fractions were detected in all samples of pasteurized store milk and the levels of  $\alpha$ -la and  $\beta$ -lg found in pasteurized milk samples (1.11 mg/ml and 3.7 mg/ml, respectively) were similar to those found in raw farm milk samples (1.12 mg/ml and 4.0 mg/ml, respectively). BSA was found by the GABRIELA authors to be only slightly lower in pasteurized milk than in raw milk; specifically, they found about 0.085 mg/ml for raw milk and about 0.055 mg/ml for pasteurized milk. The author of the Splash newsletter also incorrectly claims that “the study’s implication of specific whey proteins suggests raw milk is actively priming the immune system in some helpful way.” Not only do the GABRIELA authors not make such a claim, the data from that study demonstrate that “pasteurized shop milk” had about the same levels of the whey proteins (*i.e.*, the main whey protein species) as raw milk.

<sup>25</sup> You also criticize FDA’s conclusion that pasteurization does not significantly change the nutritive or immunologic value of milk and cite these same Splash newsletters in Section B.5 of your 2013 Citizen Petition. In Section B.5, you quote one Splash newsletter article out of context as saying: “will store bought milk provide the desired benefits? The answer to that question is unfortunately NO.” However, the quoted article is not about raw milk, nor does it compare raw milk to store-bought pasteurized milk. Instead, the article is entitled “Buttermilk as a source of protective glycolipids,” and the quoted text is an observation that buttermilk is a more concentrated source of glycolipids than the milk used to make the butter from which the buttermilk was derived.

<sup>26</sup> Loss et al. 2011. *Journal of Allergy and Clinical Immunology*. 128:4: 766-773.

<sup>27</sup> Waser et al. 2007. *Clinical and Experimental Allergy*. 37:661-670.

<sup>28</sup> Although you only submitted the abstract for the PASTURE article, FDA reviewed the full article. Loss et al. 2012. *Journal of Allergy and Clinical Immunology*. 130:523-530.

Further, the associations found in these studies do not support your statements that consuming raw milk (at the expense of pasteurized milk) reduces risk for or prevents these individuals from developing allergic disease. None of the epidemiological studies you cite directly examined whether raw milk consumption significantly alters the allergic disease course compared to pasteurized milk consumption. Indeed, we are not aware of any intervention trials comparing raw milk versus non raw milk that establish a causal association with allergic disease or asthma. There is also absolutely no evidence to support your statement that raw milk would be an “alternative to a known allergen” (*i.e.*, pasteurized milk), as raw milk contains all the allergenic proteins of milk and would not be recommended as a substitute for pasteurized milk in individuals with milk allergy.<sup>29, 30</sup> Further, your statement that “FDA lists pasteurized milk as the most allergenic food in all of America” is not accurate.<sup>31</sup> Milk allergy is indeed one of the most prevalent food allergies in the United States, especially in children.<sup>32</sup> Since milk is one of the earliest foods encountered in the infant’s diet, it is therefore not surprising that infants and children at increased genetic risk for allergic disease would develop and manifest allergies to milk.<sup>33, 34</sup>

It should also be noted that most epidemiological studies showing an inverse association between raw milk consumption and development of allergies and asthma have predominantly involved children and infants from rural European communities.<sup>26, 27, 28</sup> Although you draw attention to a study that showed a possible effect of raw milk consumption in U.S. children,<sup>35</sup> that study was too small to draw meaningful conclusions. The subjects of the larger studies, children and infants from rural European communities, may have a different genetic make-up and more diverse environmental exposures compared to children growing up in non-rural areas outside Europe.<sup>36</sup> Also, the true mechanism(s) for the development of allergies/asthma is unknown, but is likely to be multifactorial and likely to involve both genetic and environmental factors.<sup>32</sup> Evidence from prevalence studies conducted in mostly urban populations suggests that family history of allergic conditions, socioeconomic factors, tobacco smoke, number of siblings, length of breastfeeding, and pet exposure

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<sup>29</sup> Host and Samuelsson. 1988. *Allergy*. 43:113-118

<sup>30</sup> Poulsen et al. 1987. *Clinical Allergy*. 17:449-458; McLaughlan et al. 1981. *Arch. Dis. Child.* 56:165-171.

<sup>31</sup> The exhibit you provide in support of this assertion is a printout from FDA’s website explaining that the Food Allergen Labeling and Consumer Protection Act of 2004 requires that labels must clearly identify the food source names of all ingredients that are the eight most common food allergens. The website then lists the eight foods identified by the statute: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans. That list refers to “milk” only, not “pasteurized milk,” as you contend.

<sup>32</sup> Boyce et al. 2010. *Journal of Allergy Clinical Immunology*. 126:S1-S58.

<sup>33</sup> Lack. 2008. *Journal of Allergy Clinical Immunology*. 121:6::1331-6; Eder et al. 2006. *New England Journal of Medicine*. 355:21:2226-35.

<sup>34</sup> Greer et al. 2008. American Academy of Pediatrics (AAP) Committee on Nutrition; AAP Section on Allergy and Immunology. *Pediatrics*. 121:1:183-91.

<sup>35</sup> Holbreich et al. 2012. Letter to the editor. *Journal of Allergy and Clinical Immunology*. 129:6:1671-1673. You describe this as the “Amish study.”

<sup>36</sup> Ege et al. 2011. *Journal of Allergy Clinical Immunology*. 127:1:138-44; Radon et al. 2004. *Clinical Exp Allergy*. 34:8:1178-83; Ege et al. 2007. *Journal of Allergy Clinical Immunology*. 119:5:1140-7.

all seem to be factors that may be associated with the development of allergic conditions.<sup>32, 34, 37</sup> Although certain studies<sup>26, 27</sup> that you cite control for other farm-related factors that could affect allergies, these studies do not control for the multitude of genetic or environmental factors that have been associated with the development of allergies in urban populations.<sup>32</sup> Thus, it is not clear that results from these farm studies are applicable to the general population, nor is it clear whether those studies truly support the notion that raw milk consumption would curb the incidence of allergic disease in children in urban populations.

FDA also does not find evidence that validates your assertions that raw milk can be safely recommended as an alternative milk source to individuals with milk allergy. Research has shown that raw milk and pasteurized milk do not differ in their capacity to cause allergy or severe allergic reactions (*i.e.*, anaphylaxis) when tested in both animal models<sup>30</sup> and human clinical trials.<sup>29</sup> Although there may be some evidence to suggest that raw milk has a slightly different protein fraction profile from either a boiled or a pasteurized milk, pasteurization conditions have little impact on the amounts or allergenic potential of known major milk allergens from whey proteins and caseins found in milk. Therefore, it is not surprising that pasteurization does not change the allergenicity of milk proteins. For example, Host and Samuelsson (1988)<sup>29</sup> compared the allergic responses caused by raw, pasteurized, and homogenized/pasteurized milk in five children who are allergic to cow milk (aged 12 to 40 months). All children developed significant and similar allergic reactions from the consumption of the above three types of milk. The authors concluded that children with proven milk allergy cannot tolerate milk, raw or pasteurized. Because the proteins in milk may induce an allergic response in allergic individuals, regardless of whether the milk is raw or pasteurized, raw milk is not “an alternative to a known allergen,” as you contend.

As a final point, the argument you raise above about raw milk and allergic disease do not negate the fact that pathogenic microorganisms may be present in raw milk. In fact, the authors of many of the epidemiologic studies you cite specifically state that consumption of raw milk by the general population cannot be recommended because of these pathogen concerns. Accordingly, the information you provide does not call into question FDA’s findings during the rulemaking for 21 CFR 1240.61, which focused primarily on the safety of raw milk.

FDA has reviewed the four studies you cite that relate to raw milk and allergies/asthma. FDA does not concur that these studies support any amendments to 21 CFR 1240.61.<sup>38</sup>

- **The GABRIELA study:** The GABRIELA study<sup>26</sup> involved a questionnaire about farm milk consumption and other farm-related exposures in rural regions of Germany, Austria, and Switzerland, as well as analysis of serum samples and cow’s milk samples. The authors state that they found that raw milk consumption was inversely associated to asthma independent of other farm exposures. However, the study did not control for other factors (*e.g.*, family history of allergies, breastfeeding history) that may be relevant for allergic disease development.

<sup>37</sup> Gupta et al. 2011. *Pediatrics*. 128:1:e9-17.

<sup>38</sup> In this section, you also refer to three reports attached as Exhibits 39, 40 and 41. However, these reports do not relate to your argument that raw milk is an alternative to a known allergen. Rather, these reports relate to risks associated with raw milk. Accordingly, we address these reports in our response to Section B.3 of your 2013 Citizen Petition.

Importantly, the authors also found an association between pasteurized shop milk and reduced risk of asthma. The extent of that association was very similar to the association they identified for raw milk and asthma, although the risk reduction findings for pasteurized milk were not statistically significant. The authors also indicated that total viable bacterial counts and total fat content of milk were not significantly related to asthma. Although the authors speculated that “the protective effect of raw milk consumption on asthma might be associated with the whey protein fraction of milk,” they qualified this by noting that “whey protein fractions were detected in all samples of pasteurized store milk.” The levels of whey proteins,  $\alpha$ -la and  $\beta$ -lg, found in pasteurized milk samples (1.11 mg/ml and 3.7 mg/ml, respectively) were similar to those found in raw farm milk samples (1.12 mg/ml and 4.0 mg/ml, respectively). BSA was found by the authors to be only slightly lower in pasteurized milk than in raw milk. Specifically, they found about 0.085 mg/ml for raw milk and about 0.055 mg/ml for pasteurized milk. Furthermore, the authors state that “on the basis of current knowledge, raw milk consumption cannot be recommended because it might contain pathogens.” Thus, the GABRIELA study authors do not believe that their research supports recommending consumption of raw milk in light of the current state of scientific knowledge.

- **The PASTURE study:** The PASTURE cohort study,<sup>28</sup> which focused on rural areas in five European countries, had as its objective a determination of “environmental and nutritional exposures associated with gene expression of innate immunity receptors during pregnancy and the first year of a child’s life.” The authors found that farming-related exposures, such as raw farm milk consumption, that were previously reported to decrease the risk for allergic outcomes were associated with a change in gene expression of innate immunity receptors in early life. The authors also found that increased gene expression for certain gene receptors at year 1 was most strongly associated with a child’s consumption of raw farm milk during the first year of life. The authors of this study conclude that “[t]he present study does not allow us to answer whether the upregulation of innate immune receptors directly modulates the development of allergic disease or whether it is a marker for the effect of genes and the environment on allergic disease.” Thus, the authors of the study do not conclude that the observed upregulation of innate immune receptors directly modulates the development of allergic disease. It would therefore be inaccurate to interpret the study as demonstrating a causal relationship between raw milk consumption and decreased allergic disease.
- **The PARSIFAL study:** The PARSIFAL study,<sup>27</sup> which involved questionnaires sent to parents in five European countries, found an inverse association of farm milk consumption, not raw milk consumption, with asthma and allergy. The authors stated in the paper that the “present study does not allow evaluating the effect of pasteurized vs. raw milk consumption because no objective confirmation of the raw milk status of the farm milk samples was available.” In fact (as you noted), in the study, about half of the farm milk was boiled, a heat treatment much harsher than pasteurization. The authors also concluded that “raw milk may contain pathogens such as salmonella or EHEC, and its consumption may therefore imply serious health risks . . . At this stage, consumption of raw farm milk cannot be recommended as a preventive measure.” Thus, the authors of this study, like the authors of the GABRIELA study, do not believe that their research supports recommending the consumption of raw milk in light of the current state of scientific knowledge.

- **The “Amish study”:** The letter to the editor of the *Journal of Allergy and Clinical Immunology* that you refer to as the “Amish Study”<sup>35</sup> describes the authors’ comparison of the prevalence of allergic sensitization in a population of Amish children aged 6 to 12 years with both children living on farms in Switzerland and nonfarm Swiss children. The letter notes that the authors’ research supports “the effect of early farm exposures and their impact in significantly reducing the prevalence of asthma and allergic sensitization.” It notes, however, that “we have not determined specific mechanisms” that explain the impact. Raw milk is merely one of the exposures investigated by the authors. The authors further state that “[b]ecause of the small number of children in the study, we were not able to determine specific differences in lifestyle, diet, exposures or family history between those Amish children who were sensitized and those who were not sensitized” (emphasis added). Thus, this research does not demonstrate that raw milk reduces or prevents allergies or asthma.

#### B. Public Support

You also state that “the public has displayed huge support” for raw milk and that “[a]t least 3% of the United States population, or more than 9 million people, consume raw milk regularly.” The exhibit you provide in support of your estimate is a population survey of exposures. This survey was conducted in the 10 states that participate in the Foodborne Active Surveillance Network (FoodNET) Population Survey Atlas of Exposures,<sup>39</sup> and the question asked of participants was whether they consumed any unpasteurized milk in the 7 days prior to their participation in the survey. The results of that survey may not be taken to mean that the survey respondents usually or regularly drink raw milk. Langer et al. (2012) reported that less than 1% of the population usually or regularly consumes raw milk, and FDA considers that estimate to more accurately reflect usual or regular raw milk consumption.<sup>40</sup> Moreover, even if 3 percent of the U.S. population consumed raw milk regularly, FDA would still find that 21 CFR 1240.61 continues to be justified. That is, the level of consumption of raw milk does not call into question FDA’s concern that raw milk may contain dangerous pathogens. You also state that “[i]ncreasing access to raw milk is also being espoused by farming organizations, and state that the National Farmers Union (NFU) supports such access and that “[l]obbyists in Washington” will “use the NFU policy manual to determine the basis of farm policy.” The fact that the NFU has adopted a policy position in favor of raw milk (or that lobbyists may make use of the policy position) similarly does not change our conclusion that 21 CFR 1240.61 continues to be justified, because the policy position of any particular organization does not change the fact that raw milk may contain pathogens.

#### Section B.3 of Your 2013 Citizen Petition

##### A. Safety

You assert that “[a] comprehensive look at the data shows that responsibly produced raw milk is safe and should not be treated differently from other foods in interstate commerce.” As we noted in response to your 2008 Citizen Petition, the preamble to the final rule promulgating 21 CFR 1240.61 concluded that “raw milk, no matter how carefully produced, may be unsafe.” 52 Fed. Reg. at

<sup>39</sup> Centers for Disease Control and Prevention (CDC). *Foodborne Active Surveillance Network (FoodNet) Population Survey Atlas of Exposures*. Atlanta, Georgia: U.S. Department of Health and Human Services, CDC. 2006-2007.

[http://www.cdc.gov/foodnet/surveys/foodnetexposureatlas0607\\_508.pdf](http://www.cdc.gov/foodnet/surveys/foodnetexposureatlas0607_508.pdf)

<sup>40</sup> Langer et al. 2012. *Emerging Infectious Diseases*. 18:385-391.

29512. FDA is unaware of any information published since the promulgation of 21 CFR 1240.61 that would cause the agency to change its conclusions on this matter.

The quantitative risk assessment reports you attached as Exhibits 39, 40, and 41 do not support your position. You state that these risk assessments “found that raw milk presents either a ‘very low’ or a ‘low risk’ food against *Campylobacter*, *Listeria*, and *Staphylococcus aureus*,” and “found a ‘low risk’ of Hemolytic uremic syndrome (HUS) from *E. coli* O157 and that *Listeria* is not associated with the consumption of raw milk or miscarriages.” These risk assessments do not call into question the basis for FDA’s restrictions on raw milk but rather highlight the risks associated with raw milk.

The assessment performed by Giacometti et al., for instance, finds that raw milk should be stored at cold temperatures and boiled to reduce pathogen levels and contamination, while also finding that “the risk of illness linked to raw milk consumption should not be ignored.”<sup>41</sup> The assessment performed by Latorre et al.<sup>42</sup> provides that “consumption of raw milk from any source is not recommended.” Although that assessment identifies the probability of *Listeria* infection to be low, it underscores the severity of the risk posed by *Listeria*. The authors note, for instance, that “[d]espite the low probability of acquiring listeriosis from a single raw milk serving, the serious consequences of the disease such as miscarriages, stillbirths, meningitis, or even death, and the high hospitalization rates attributed to listeriosis, should not be disregarded by raw milk consumers.” The authors also note that “if raw milk is purchased from a retail store, the estimated risks of listeriosis for the intermediate, perinatal, and elderly populations correspond to 14, 5.8, and 29 cases per year, respectively.” Further, the authors state that pasteurization of milk “effectively eliminates” *Listeria* and other pathogenic microorganisms.<sup>43</sup>

In the third report,<sup>44</sup> the authors examine *Staphylococcus aureus*, which they describe as a major cause of foodborne illness because of its ability to persist and grow under various conditions. They find that refrigeration reduces the probability of outgrowth to the levels at which Enterotoxin A (a chemical that can cause severe diarrhea, nausea, vomiting, and abdominal pain) may be found in a food. Despite this, the authors still caution that “[t]he three growth modules predicted that *S. aureus* levels could surpass the 10(5) CFU/ml level of concern (*i.e.* the level at which Enterotoxin may occur) at the 99.9<sup>th</sup> or 99.99<sup>th</sup> percentile of servings and therefore may represent a potential consumer risk.” These findings do not call into question FDA’s concerns about the safety of raw milk. FDA agrees that enterotoxin outbreaks from raw milk are likely to be rare. But, as the authors point out, such outbreaks may occur. Moreover, the most serious risks posed by raw milk are primarily attributable to other pathogens such as *Campylobacter jejuni*, *E. coli* O157:H7, *Salmonella* and *Listeria monocytogenes*.<sup>45</sup>

<sup>41</sup> Giacometti et al, (2012). *Journal of Food Protection*. 75(11): 2031-2038.

<sup>42</sup> Latorre et al. 2011. *Journal of Food Protection*. 74:8.

<sup>43</sup> We note that this finding expressly acknowledges the risks posed by *Listeria* in raw milk and, thus, undercuts your contention that problems with *Listeria* are limited to products such as cheeses, and not raw milk.

<sup>44</sup> Joelle et al. 2009. *Journal of Food Protection*. 72:8.

<sup>45</sup> Also in Section B.3, you make certain arguments regarding “illnesses and deaths caused by human consumption of pasteurized milk and other foods” (emphasis in original), which are similar to arguments you make in Section B.4 of your petition. FDA addresses this line of argument in Section B.4 of this letter.

B. Outbreaks of Salmonellosis in California

You take issue with FDA's citation of pre-1987 data from the California Department of Health Services in the agency's response to your 2008 Citizen Petition. You state that the "number of outbreaks associated with *Salmonella* in raw milk has all but disappeared" since 1987, and that "at no time in the last 15 years has the California Department of Health Services or any other branch of California government collected any data showing a single instance of *Salmonella* illness in California associated with the consumption of Grade A raw milk." You state that neither your raw milk dairy nor the Claravale raw milk dairy "has ever produced any milk for human consumption that has had *Salmonella* in it."

*Salmonella* is only one of numerous pathogens that may be present in raw milk, and FDA promulgated 21 CFR 1240.61 due to safety concerns with all such pathogens, not just *Salmonella*. Although FDA is not aware of any recent *Salmonella* outbreaks associated with raw milk in California, FDA is aware of a number of outbreaks in California involving other pathogens in raw milk, including outbreaks associated with Claravale Farm and your raw milk dairy, Organic Pastures Dairy Company (OPDC). As recently as 2012, raw milk and raw milk products produced by OPDC and Claravale Farm were associated with a campylobacteriosis outbreak with 33 illnesses.<sup>46</sup> In California, there have been nine quarantines (recalls) involving raw milk or raw milk products since 2006. See Table 3. Seven of them have involved OPDC. See Table 4 for a listing of all outbreaks of foodborne illness associated with raw milk and raw milk products that FDA knows to have occurred in California since 1971. Also see Table 2 for a list of examples of raw milk-associated outbreaks, including outbreaks of salmonellosis, in recent years (2010 – September 2014) in all states where raw milk sales are legal.

**Section B.4 of Your 2013 Citizen Petition**

A. FDA's Treatment of Other Foods

You provide examples of foodborne illness outbreaks which have been attributed to foods other than raw milk. In addition, you assert that FDA requires a "guarantee" of safety from raw milk and raw dairy products when not requiring the same from other foods," and that this requirement is arbitrary and capricious.

This is not a new argument. In the preamble to 21 CFR 1240.61, FDA responded to a comment that FDA was singling out raw milk and that other ready-to-consume foods are, naturally or by virtue of cross-contamination, sources of disease. FDA responded to that comment as follows:

Other ready to consume foods of domestic animal origin are subjected to processing procedures designed to render them safe for consumption and are microbiologically monitored for adequacy of processing. Raw foods of animal origin, such as chicken, may also be contaminated with microorganisms such as *Salmonella* and *Campylobacter*, but are normally cooked before consumption . . . . For

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<sup>46</sup> CDPH. 2013. CA EPI 12-02.

[http://www.outbreakdatabase.com/reports/2012\\_Organic\\_Pastures\\_Campy\\_Outbreak\\_final\\_report.pdf](http://www.outbreakdatabase.com/reports/2012_Organic_Pastures_Campy_Outbreak_final_report.pdf), last accessed 11/21/14.

other foods, like oysters, that are often consumed raw . . . practical measures to eliminate the contamination are not available. A practical measure – pasteurization – is available for milk. Under these circumstances, the agency finds no merit in any argument that raw milk in interstate commerce is wrongly being singled out for regulation.

52 Fed. Reg. at 29512.

As the preamble language indicates, whether FDA takes regulatory action depends on the risk presented and the tools available to the agency. When assessing risk and considering risk management options for products within FDA's jurisdiction, the agency considers and balances a number of factors, including the nature and likelihood of the hazard; routes of contamination; the individuals or groups at risk and whether some people are more likely than others to be at risk; the severity of the anticipated adverse impacts or effects of the hazard; the scientific evidence that supports the conclusions about the risk; scope of the problem (*e.g.*, the number of firms involved); history of effectiveness of prior risk mitigation efforts; the tools available to FDA and its regulatory partners and the agency's resources. As discussed above, FDA concluded in 1987 that prohibiting raw milk in final package form from interstate commerce was a necessary and appropriate means of protecting the public health. FDA still finds no merit in any argument that raw milk in interstate commerce is wrongly being singled out for regulation and you have not provided any information or data which would cause us to change our position on this matter.

We also disagree with any suggestion that FDA does not take regulatory action with respect to other foods. FDA's approach to preventing foodborne illness is wide-ranging and complex. FDA has been able to take measures to reduce the risk of foodborne illness through a variety of measures. For example, FDA has developed targeted regulations to address the risks associated with low acid canned food, seafood, infant formula, and juice. *See* 21 CFR Parts 113, 120, 106, and 123. Moreover, the Federal Food, Drug, and Cosmetic Act ("FDCA") prohibits the distribution of adulterated food in interstate commerce, which includes food that (1) bears or contains any added poisonous or deleterious substance which may render it injurious to health, (2) consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, or (3) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. *See generally* sections 301(a), 301(b), 301(c), and 301(k) of the FDCA (21 U.S.C. §§ 331(a), (b), (c) & (k)); section 402(a) of the FDCA (21 U.S.C. § 342(a)). FDA actively regulates the food industry to prevent the distribution of adulterated food products.

Furthermore, there are methods in place to control pathogens in many foods. Many prepared foods incorporate a pathogen "kill" step in the manufacturing process. *See, e.g.*, 21 CFR Part 113 (thermally processed low-acid foods packaged in hermetically sealed containers); 21 CFR Part 106 (requiring manufacturers of liquid infant formula to comply, as appropriate, with the procedures specified in 21 CFR Part 113 for thermally processed low-acid foods). Additionally, FDA has approved other methods to render food negative for bacteria. *See, e.g.*, 21 CFR Part 179. Accordingly, raw milk is not the only food that FDA has found necessary to regulate through a pathogen-control method (in the case of raw milk, pasteurization). We also note that you refer to instances where outbreaks have been associated with pasteurized milk products. Although

historically there have been some outbreaks linked to pasteurized milk, such outbreaks are rare and do not call into question the role that pasteurization plays in the safety of the country's milk supply. Raw milk and raw milk products have been found to be 150 times more likely to cause foodborne illness than pasteurized milk products.<sup>40</sup>

B. State Regulation of Raw Milk

You also repeat an argument made in your 2008 Citizen Petition: that state regulation of raw milk provides evidence that raw milk is safe. FDA addressed this argument in response to your 2008 Citizen Petition, and you have not provided any new evidence to warrant a change in our position. As in response to your 2008 Citizen Petition, we note that in many states where raw milk sales are legal the state health departments warn of the danger of raw milk consumption and emphasize that state regulation does not ensure that raw milk is safe and free of pathogens. This is true for states that you mentioned in your 2008 Citizen Petition, as well as for additional states that you mention in your 2013 Citizen Petition. 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.”<sup>47</sup>
- The Utah Department of Health states, “[w]hile dairies permitted to sell raw milk do follow strict standards designed to help limit disease-causing bacteria commonly found in milk, this still does not guarantee that the raw milk will be free of disease-causing bacteria.”<sup>48</sup>
- The Washington State Department of Health states, “[c]onsumers should be aware that while licensure to sell raw milk represents a basic level of sanitation, it doesn't assure that raw milk is free of illness-producing bacteria.”<sup>49</sup>
- The Pennsylvania Department of Health states that it “advise[s] those who wish to reduce their risk of food borne infections to avoid the consumption of raw (unpasteurized) milk, products that are derived from raw milk, and raw-milk cheeses that are not aged for at least 60 days,” noting that “[w]hile the Pennsylvania Department of Agriculture permitting process can enhance the safety of raw milk, there are no measures that can render raw milk as safe as milk that has been heat sterilized (pasteurized).”<sup>50</sup>
- The Arizona Department of Health Services states: “[R]aw, unpasteurized milk can carry dangerous bacteria such as *Salmonella*, *E. coli*, *Listeria*, *M. bovis*, *Brucella*, and *Campylobacter*. These harmful bacteria can seriously affect the health of anyone who drinks raw milk, or eats foods made from raw milk. The bacteria can be especially dangerous to pregnant women, children, the elderly, and people with weakened immune systems.”<sup>51</sup>

<sup>47</sup> <http://www.cdph.ca.gov/HealthInfo/discond/Documents/RawMilkFactsheet.pdf>

<sup>48</sup> [http://health.utah.gov/epi/diseases/campylobacteriosis/raw-milk\\_flyer.pdf](http://health.utah.gov/epi/diseases/campylobacteriosis/raw-milk_flyer.pdf)

<sup>49</sup> <http://www.doh.wa.gov/Portals/1/Documents/1500/NewsReleases/2010/10-087RawMilk.pdf>

<sup>50</sup> [http://www.dsf.health.state.pa.us/health/lib/health/epidemiology/Raw\\_Milk\\_Update.pdf](http://www.dsf.health.state.pa.us/health/lib/health/epidemiology/Raw_Milk_Update.pdf)

<sup>51</sup> <http://www.azdhs.gov/phs/oids/vector/brucella/pdf/DangersOfRawMilk.pdf>

- The Connecticut Department of Agriculture provides the following warning to consumers: “Warning: Retail Raw Milk has not been pasteurized and may contain harmful bacteria. Pregnant women, children, the elderly and persons with lowered resistance to disease have the highest risk of harm from use of unpasteurized milk. Unpasteurized milk may contain several human pathogens including: *Listeria monocytogenes*, *Salmonella spp.*, *E. Coli O157:H7*, *Yersinia enterocolita*, *Campylobacter jejuni* and *Staphylococcus aureus* which in high enough quantities produces a toxin that results in food poisoning. Pregnant women, children, the elderly and immune compromised individuals are most susceptible to contracting an illness through the consumption of unpasteurized milk. The Connecticut Department of Agriculture, Connecticut Department of Public Health, Federal Food and Drug Administration, and other public health authorities such as the American Medical Association, the American Academy of Pediatrics, the National Conference on Interstate Milk Shipments, the National Association of State Departments of Agriculture, the Association of Food and Drug Officials, and National Association of State Public Health Veterinarians advise consumers not to consume unpasteurized milk because of the health risks.”<sup>52</sup>
- The New Hampshire Department of Health and Human Services states: “Avoid unpasteurized (raw) milk or foods made from unpasteurized milk such as cheese.”<sup>53</sup>
- The Maine Center for Disease Control and Prevention states: “Raw milk or foods made from raw milk should be avoided.”<sup>54</sup>

For other examples of regulatory, public health, educational, and scientific organizations that share these states’ and FDA’s concerns about raw milk, see Table 5.<sup>55</sup> FDA further notes that most of the raw milk outbreaks since the promulgation of 21 CFR 1240.61 have occurred in states where raw milk sales are lawful. Indeed, in a 2012 publication,<sup>40</sup> the Centers for Disease Control and Prevention (“CDC”) found that in states where it was lawful to sell raw milk products, the rate of outbreaks caused by raw fluid milk was more than twice as high as in states where the sale of raw dairy products is illegal.<sup>56</sup> CDC noted: “the large number of outbreaks caused by unpasteurized dairy products is consistent with findings that more outbreaks occur in states that permit the sale of unpasteurized dairy products.”

#### C. Voluntary Standards

You also assert that voluntary standards ensure that raw milk is a low-risk food, pointing to an organization called the Raw Milk Institute that has “published voluntary food safety standards, voluntary food safety plans and voluntary testing protocols that address the concerns of the FDA.” However, these standards do not address the concerns that led FDA to promulgate 21 CFR 1240.61, nor do they address the agency’s continuing concerns because, based on our review, these standards will not ensure that raw milk is safe.

<sup>52</sup> <http://www.ct.gov/doag/cwp/view.asp?a=3260&q=414944>

<sup>53</sup> <http://www.dhss.nh.gov/dphs/cdcs/documents/listeriosis.pdf>

<sup>54</sup> <http://www.maine.gov/dhhs/mecdc/infectious-disease/epi/disease/summary/listeriosis.shtml>

<sup>55</sup> Table 5 is an updated version of Table 8 that appeared in our response to your 2008 Citizen Petition.

<sup>56</sup> CDC. 2013. MMWR 62:3:41-47. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6203a1.htm>.

The test requirements that you describe in these standards are minimal. For example, one of the principal requirements is that raw milk producers analyze raw milk for coliform counts (CC) and standard plate count (SPC).<sup>57</sup> This requirement, however, cannot ensure raw milk safety. That is because, as explained in response to your 2008 Citizen Petition, these milk quality indicators, (i., SPC, CC, and somatic cell counts (SCC)) 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 deadly pathogens. For example, in a study by van Kessel, et al. (2008),<sup>58</sup> raw milk samples taken from farm bulk tanks had SPC's ranging from 197-3,248 colony-forming units (CFU)/ml and coliform counts ranging from 3-164 CFU/ml, indicating very high quality; yet 11% of all samples were positive for the presence of *Salmonella*.<sup>58,59</sup>

FDA also addressed arguments regarding quality standards during the rulemaking process for 21 CFR 1240.61. In the preamble to 21 CFR 1240.61, FDA stated that “supporters of certified raw milk pointed to standards such as total bacterial counts as proof of safety, but the high incidence of disease associated with certified raw milk is strong evidence that these standards are unreliable indexes of safety.” 52 FR at 29512. FDA concluded that “the certification process alone provides no assurance that raw milk is free of *Salmonella* and other harmful organisms.” *Id.* FDA is unaware of any information published since the promulgation of 21 CFR 1240.61 that would cause the agency to change its conclusions on this matter. Thus, we do not agree with your suggestion that the Raw Milk Institute’s standards, or any other standards, are sufficient to challenge, much less to overcome, the findings that were made in promulgating 21 CFR 1240.61.

## Section B.5 of Your 2013 Citizen Petition

### A. Technology and Testing

You assert that “[a]dvances in technology and testing make raw milk safe and it should not be treated the same as raw milk intended for pasteurization.” In support, you discuss a study conducted by Pitt et al. (2000),<sup>60</sup> which you say “concludes that raw milk kills all *Listeria monocytogenes* after 56 hours of inoculation.” The study does not support your assertion. In fact, the authors do not claim that “raw milk kills all *Listeria monocytogenes* after 56 hours of inoculation,” and the study does not discuss advances in technology and testing. Rather, the study merely describes the effects of the study conditions, which involved observing the milk samples over 72 hours at 37°C (or 98.6°F). In those conditions, milk (both raw and pasteurized) will experience relatively rapid acidity

<sup>57</sup> Although the Raw Milk Institute standards document also provides that “[r]aw milk shall not contain zoonotic pathogens including *Salmonella* spp., E.coli O157:H7, *Campylobacter* spp., and *Listeria monocytogenes*,” it does not describe how raw milk producers can prevent raw milk from containing those pathogens. Furthermore, the document does not appear to require post-collection testing for pathogens; instead, such testing is optional. See “Procedures, protocols, documentation” section, referring to “[t]esting procedures (*if utilized . . .*)” (emphasis added).

<sup>58</sup> van Kessel et al. 2008. *Journal of Food Protection*. 71:1967-1973.

<sup>59</sup> Furthermore, the Raw Milk Institute’s standards are inadequate even by your own criteria (with which we do not agree) that “when coliforms rarely reach above 5 and conditions are correct pathogens are simply not present or do not contain enough concentration to be detected or cause illness.” The coliform standard for the Raw Milk Institute is “a rolling three month average of less than 25 cfu’s/ml,” which is nearly 5 times higher than the level you cite.

<sup>60</sup> Pitt et al. 2000. *Milchwissenschaft*. 55:5.

development, with the consequence that milk (again, both raw and pasteurized) will become an inhospitable medium for the continued growth and survival of pathogens. The fact that microbes have specific growth ranges and that certain parameters, such as acidity (pH), temperature, water activity and redox potential, affect growth, has been understood by microbiologists for decades. Moreover, raw milk is neither processed nor consumed under conditions that mirror the study conditions, i.e., raw milk is neither processed nor consumed after being stored at 37°C (or 98.6°F) for 72 hours. Such conditions cause milk to sour. For all these reasons, the study does not demonstrate that raw milk that is intended for human consumption kills all *Listeria monocytogenes*, as you suggest.

What the Pitt et al. study does demonstrate is that, as milk is left to sour at essentially human body temperature (i.e., 37°C or 98.6°F), the pathogen *Staphylococcus aureus*, if present initially at the levels to which the milk was inoculated by the study authors, can grow to levels where it will produce toxins, thus making the milk unsafe to consume.

Therefore, this study does not demonstrate that raw milk is safe. It merely corroborates long-standing and basic knowledge in the field of microbiology (i.e., that high temperature storage can lead to outgrowth of pathogens to high numbers and that those numbers will decrease as the organisms face increasingly hostile growth conditions (increased acidity, in this case)). The authors in conclusion speculate that their work “may present future applications for both cheesemakers and the dairy industry alike,” possibly because of the fact that their work involved acidification, which is, of course, a step in cheesemaking and the manufacture of fermented milks, but the authors nowhere claim that raw milk is safe.<sup>61</sup>

You also refer to milk filter tests, stating they “are 3 to 10 times more pathogen-sensitive than previously used milk sample tests.” You further state that “detection rates of pathogens have recently been enhanced, allowing mitigation of any perceived risk associated with production of raw dairy products.” However, you provide no references in support of these assertions. Most importantly, you do not provide any data or information demonstrating that these milk filter tests or other enhanced tests are being used to improve the safety of raw milk, much less to make it safe.

### **Supplement to Your 2013 Citizen Petition**

We acknowledge your November 18, 2013 letter supplementing your 2013 Citizen Petition with seven attachments. FDA considered each attachment provided, but none of the attachments changes FDA’s decision to deny your 2013 Citizen Petition. We address each of the attachments in turn:

- The first attachment is a report by the Michigan Fresh Unprocessed Whole Milk Workgroup. This report acknowledges that “it is important for farmers and consumers to understand that following the guidelines [in the document] will not guarantee that the produced and consumed milk will never be a vehicle for milkborne illnesses.” The workgroup does not imply that production, handling, and consumption of milk following the guidelines will result in fewer illnesses, nor does it imply the standards will be an assurance that the milk will always be safe. Thus, the document does not address FDA’s safety concerns regarding raw milk.
- The second attachment is a review article authored by Ton Baars. FDA must be able to review the critical elements of any study to determine whether any scientific conclusions can be drawn from it. The review article you provided does not provide sufficient information about the

individual studies reviewed to allow FDA to determine whether the studies are valid. Moreover, we note that some of the article's conclusions are flawed for reasons discussed above (see Section B.2 of this letter discussing lack of evidence concerning raw milk and asthma and allergies), and that the article only concludes that hygienic standards for raw milk are "helpful," not that they will ensure safety. In addition, the article incorrectly characterizes a number of factual matters. For instance, the article incorrectly states that "[t]he available lysine in milk, which is seen as a parameter for the protein quality in human milk, was also lost after pasteurization." This is not true, as made clear by Claeys et al. 2013.<sup>61</sup> Further, the citation the author offers in support of that assertion relates to human milk, not bovine milk. The article is also misleading in its description of the PARSIFAL study, as the article does not address the fact that the milk examined in the PARSIFAL study was farm milk, much of which was boiled—a heat treatment much harsher than pasteurization, as discussed in Section B.2 of this letter.

- The third attachment is a description of the "German system" (presumably, the "German system" for raw milk certification), although it is not possible to determine who authored this document or whether it was published. We assume you included this document as an example of a certification system for raw milk. As described in the document, a key requirement for certified raw milk under the "German system" is that it meets certain microbiological standards. Most of those standards are quality standards, however, not safety standards, and the only specific standard for the presence of pathogens is for *Salmonella*. As discussed in Section B.4.C of this letter, there is no existing certification process that provides assurance that raw milk is free of pathogens. Accordingly, this document does not call into question FDA's findings.
- The fourth attachment consists of testing results from farms listed with the Raw Milk Institute. The results reflect quality indicators such as SPCs and CCs which, as discussed in Section B.4.C of this letter, **do not** provide any information as to the presence or absence of harmful bacteria. Therefore, this attachment does not change FDA's conclusion that raw milk may be unsafe, and that 21 CFR 1240.61 should not be amended or rescinded.
- The fifth attachment appears to consist of testing results from your farm's raw milk for "COLI," "SPC," and *E. coli* O157:H7, as well as other testing results. The testing results do not alleviate FDA's concerns as to the safety of raw milk. Again, as discussed in Section B.4.C of this letter, quality indicators such as SPC and CC **do not** provide any information as to the presence or absence of harmful bacteria. With respect to the pathogen test results you provide, negative pathogen results for any particular pathogen in any particular sample of raw milk do not call into question FDA's findings that raw milk may contain pathogens and that raw milk has been linked to numerous outbreaks.
- The sixth attachment is a news article concerning an outbreak of listeriosis linked to a Wisconsin cheese operation, which states that three pasteurized soft cheeses were recalled. To the extent you include this article to support your contention that pasteurized milk products are not safe, we do not agree that this particular outbreak incident calls into question FDA's basis for 21 CFR

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<sup>61</sup> Claeys et al. 2013. *Food Control*. 31:1251-262.

1240.61. As stated in Section B.4.A of this letter, raw milk and raw milk products have been found to be 150 times more likely to cause foodborne illness than pasteurized milk products.<sup>40</sup>

- The seventh attachment is a portion of a magazine article about the role of microbes. Because this article does not address raw milk, it does not support your arguments about raw milk.

## **CONCLUSION**

In sum, based on FDA's analysis of the materials you provided in your 2008 Citizen Petition and your 2013 Citizen Petition, along with other data and information available to the agency and the information you submitted in your supplement to the 2013 Citizen Petition, FDA has concluded that your 2013 Citizen Petition does not contain facts demonstrating any reasonable grounds for rescinding or otherwise amending 21 CFR 1240.61. Furthermore, your petition does not show that your proposal is in the public interest or will promote the objectives of FDA. See 21 CFR 10.40(a)(2). Therefore, in accordance with 21 CFR 10.30(e)(3), FDA denies your petition.

Sincerely,



Michael M. Landa  
Director  
Center for Food Safety  
and Applied Nutrition

Enclosure

**List of Tables**

- Table 1. Incidence of microbial pathogens in bulk raw milk
- Table 2. Examples of recent raw milk-associated outbreaks in states where raw milk sales are permitted (2010 – September, 2014)
- Table 3. California quarantines (recalls) associated with raw milk and raw milk products, 2006 to September, 2014
- Table 4. Outbreaks associated with raw milk and raw milk products in California, 1971 to September, 2014
- Table 5. Raw milk position statements from various organizations, including FDA

Table 1. Incidence of microbial pathogens in bulk raw milk

Pathogen	Incidence in Bulk Milk - Percent (No. of samples)	Comments	Reference
<i>Campylobacter jejuni</i>	9.2 (12/131)	Bulk milk samples from eastern South Dakota and western Minnesota	Jayarao B.M. and Henning D.R 2001. Prevalence of Foodborne Pathogens in Bulk Tank Milk. J. Dairy Sci. 84:2157-2162.
<i>Campylobacter jejuni</i>	2 (5/248)	Bulk milk samples from 16 counties in Pennsylvania	Jayarao B.M. et al, 2006. A Survey of Foodborne Pathogens in Bulk Tank Milk and Raw Milk Consumption among Farm Families in Pennsylvania. J. Dairy Sci. 89:2451-2458.
Shiga-toxin <i>E. coli</i> (STEC)  <i>E. coli</i> O157:H7	3.8 (5/131)  0	Bulk milk samples from eastern South Dakota and western Minnesota	Jayarao B.M. and Henning D.R. 2001. Prevalence of Foodborne Pathogens in Bulk Tank Milk. J. Dairy Sci. 84:2157-2162.
<i>E. coli</i> O157:H7	0.75 (2/268)	Bulk milk samples from east Tennessee (2000-2001)	Murinda S.E. et al., 2002. Prevalence and Molecular Characterization of <i>Escherichia coli</i> O157:H7 in Bulk Tank Milk and Fecal Samples from Cull Cows: A 12-Month Survey of Dairy Farms in East Tennessee. J. Food Prot. 65(5):752-759.

Pathogen	Incidence in Bulk Milk - Percent (No. of samples)	Comments	Reference
Shiga-toxin <i>E. coli</i> (STEC)	2.4 (6/248)	Bulk milk samples from 16 counties in Pennsylvania	Jayarao B.M. <i>et al</i> , 2006. A Survey of Foodborne Pathogens in Bulk Tank Milk and Raw Milk Consumption among Farm Families in Pennsylvania. <i>J. Dairy Sci.</i> 89:2451-2458.
<i>E. coli</i> O157:H7	23 (199/859) [detected eaeA gene encoding intimin, a virulence factor associated with EPEC and EHEC; 4.2 (36/859) [positive for eaeA, the gamma allele of the translocated initmin receptor found in EHEC of O157:H7] 0.2 percent likely positive for O157:H7]	U.S.; bulk milk from 21 States; National Animal Health Monitoring System Dairy 2002 survey (NAHMSD, 2002)	Karns J.S. <i>et al</i> , 2007. Incidence of <i>Escherichia coli</i> O157:H7 and <i>E. coli</i> Virulence Factors in US Bulk Tank Milk as Determined by Polymerase Chain Reaction. <i>J. Dairy Sci.</i> 90:3212-3219.
<i>Listeria monocytogenes</i>	6.5 (56/861)	NAHMSD, 2002	Van Kessel J.S. <i>et al.</i> , 2004. Prevalence of Salmonellae, <i>Listeria monocytogenes</i> , and Fecal Coliforms in Bulk Tank Milk on US Dairies. <i>J. Dairy Sci.</i> 87:2822-2830.

Pathogen	Incidence in Bulk Milk - Percent (No. of samples)	Comments	Reference
<i>Listeria monocytogenes</i>	4.6 (6/131)	Bulk milk samples from eastern South Dakota and western Minnesota	Jayarao B.M. and Henning D.R. 2001. Prevalence of Foodborne Pathogens in Bulk Tank Milk. J. Dairy Sci. 84:2157-2162.
<i>Listeria monocytogenes</i>	2.8 (7/248)	Bulk milk samples from 16 counties in Pennsylvania	Jayarao B.M. et al, 2006. A Survey of Foodborne Pathogens in Bulk Tank Milk and Raw Milk Consumption among Farm Families in Pennsylvania. J. Dairy Sci. 89:2451-2458.
<i>Salmonella</i> spp.	6.1 (8/131)	Bulk milk samples from eastern South Dakota and western Minnesota	Jayarao B.M. and Henning D.R. 2001. Prevalence of Foodborne Pathogens in Bulk Tank Milk. J. Dairy Sci. 84:2157-2162.
<i>Salmonella</i> spp.	2.6 (22/861) [9 serotypes identified]	NAHMSD, 2002	Van Kessel J.S. et al., 2004. Prevalence of <i>Salmonellae</i> , <i>Listeria monocytogenes</i> , and Fecal Coliforms in Bulk Tank Milk on US Dairies. J. Dairy Sci. 87:2822-2830.
<i>Salmonella enterica</i>	11.8 (101/854)	NAHMSD, 2002	Karns J.S. et al., 2005. Prevalence of <i>Salmonella enterica</i> in Bulk Tank Milk from US Dairies as Determined by Polymerase Chain Reaction. J.Dairy Sci. 88:3475-3479.

Pathogen	Incidence in Bulk Milk - Percent (No. of samples)	Comments	Reference
<i>Salmonella</i> spp.	6 (15/248)	Bulk milk samples from 16 counties in Pennsylvania	Jayarao B.M. <i>et al</i> , 2006. A Survey of Foodborne Pathogens in Bulk Tank Milk and Raw Milk Consumption among Farm Families in Pennsylvania. <i>J. Dairy Sci.</i> 89:2451-2458.
<i>Yersinia enterocolitica</i>	6.1 (8/131)	Bulk milk samples from eastern South Dakota and western Minnesota	Jayarao B.M. and Henning D.R. 2001. Prevalence of Foodborne Pathogens in Bulk Tank Milk. <i>J. Dairy Sci.</i> 84:2157-2162.
<i>Yersinia enterocolitica</i>	1.2 (3/248)	Bulk milk samples from 16 counties in Pennsylvania	Jayarao B.M. <i>et al</i> , 2006. A Survey of Foodborne Pathogens in Bulk Tank Milk and Raw Milk Consumption among Farm Families in Pennsylvania. <i>J. Dairy Sci.</i> 89:2451-2458.

Table 2. Examples of recent raw milk-associated outbreaks in states where raw milk sale is permitted (2010 – September, 2014)

State	Raw milk sale status*	Outbreak Year/Pathogen/illnesses/Additional details	References (web links last accessed on 10/10/2014)
AK	Prohibits raw milk sales but allows herd-share**	2011 <i>Campylobacter</i>	<a href="http://www.epi.alaska.gov/bulletins/docs/b2011_18.pdf">http://www.epi.alaska.gov/bulletins/docs/b2011_18.pdf</a>

	<p>4 illnesses  (Raw milk was distributed through a cow share program.)  2013 <i>Campylobacter jejuni</i> 31 illnesses (included children) (Raw milk was distributed through a cow share program.)  2013 <i>Campylobacter jejuni</i> 5 illnesses  2013 <i>Campylobacter</i> 2 illnesses (children)</p>	<p><a href="http://content.govdelivery.com/bulletins/gd/A_KDHSS-7c57fa">http://content.govdelivery.com/bulletins/gd/A_KDHSS-7c57fa</a></p> <p><a href="http://www.epi.hss.state.ak.us/bulletins/docs/b2013_12.pdf">http://www.epi.hss.state.ak.us/bulletins/docs/b2013_12.pdf</a></p> <p><a href="http://www.epi.hss.state.ak.us/id/dod/campy/Update_RawMilk.pdf">http://www.epi.hss.state.ak.us/id/dod/campy/Update_RawMilk.pdf</a></p>	
CA	Allows the sales of raw milk at retail stores separate from the farm	<p>2011 <i>E. coli</i> O157:H7 5 illnesses (all children)  (Milk from McAfee's Organic Pastures Dairy Company was implicated.)</p>	<p><a href="http://www.cdph.ca.gov/pubsforms/Documents/fdbEIROPDC2011.pdf">http://www.cdph.ca.gov/pubsforms/Documents/fdbEIROPDC2011.pdf</a></p>

		<p>2012  <i>Campylobacter</i>          33 illnesses          1 hospitalization          (Ages 9 mo. to 66)</p> <p>(Raw milk, raw cream, and raw butter from McAfee's Organic Pastures Dairy Company and raw milk, raw nonfat milk and raw cream from Claravale Farm were implicated)</p>	<p><a href="http://www.outbreakdatabase.com/reports/2012_Organic_Pastures_Campy_Outbreak_final_report.pdf">http://www.outbreakdatabase.com/reports/2012_Organic_Pastures_Campy_Outbreak_final_report.pdf</a></p> <p><a href="http://www.cdfa.ca.gov/egov/press_releases/Press_Release.asp?PRnum=12-018">http://www.cdfa.ca.gov/egov/press_releases/Press_Release.asp?PRnum=12-018</a></p> <p><a href="http://www.cdph.ca.gov/pubsforms/Documents/fdbEIRCV2013.pdf">http://www.cdph.ca.gov/pubsforms/Documents/fdbEIRCV2013.pdf</a></p>
CO	Prohibits raw milk sales but allows cow-share operations	<p>2010  <i>Campylobacter</i> and <i>E. coli</i> O157:H7          30 illnesses</p>	<p><a href="http://www.bouldercounty.org/doc/public_health/epiconsep10.pdf">http://www.bouldercounty.org/doc/public_health/epiconsep10.pdf</a> (See file)</p>
KS	Restricts legal sales to occur only on the farm where the milk is produced	<p>2012 and 2013  <i>Campylobacter</i>          26 illnesses          (18 illnesses in 2012)</p>	<p><a href="http://www.kdheks.gov/epi/download/newsletter/EpiUpdatesDecember2013.pdf">http://www.kdheks.gov/epi/download/newsletter/EpiUpdatesDecember2013.pdf</a></p> <p><a href="http://foodpoisoningbulletin.com/2012/raw-milk-outbreak-in-kansas-january-2012/">http://foodpoisoningbulletin.com/2012/raw-milk-outbreak-in-kansas-january-2012/</a></p>
KY	Restricts legal sales to occur only on the farm where the milk is produced	<p>2014  <i>E. coli</i>          6 illnesses (4 children hospitalized, hemolytic uremic syndrome/HUS)</p>	<p><a href="http://foodpoisoningbulletin.com/2014/kentucky-e-coli-outbreak-sickens-6-children/">http://foodpoisoningbulletin.com/2014/kentucky-e-coli-outbreak-sickens-6-children/</a></p> <p><a href="http://wfpl.org/term/kentucky-department-health">http://wfpl.org/term/kentucky-department-health</a></p>
MN		2011	

	<p>Restricts legal sales to occur only on the farm where the milk is produced and restricts to incidental occurrences</p>	<p><i>E. Coli</i> O157:H7 8 illnesses 2010 <i>Campylobacter jejuni</i> and <i>Cryptosporidium parvum</i> 7 illnesses 2013 <i>Campylobacter jejuni</i> 6 illnesses</p>	<p><a href="http://www.health.state.mn.us/news/press_rel/2010/ecoli061110.html">http://www.health.state.mn.us/news/press_rel/2010/ecoli061110.html</a></p> <p><a href="http://www.health.state.mn.us/news/press_rel/2010/milk102810.html">http://www.health.state.mn.us/news/press_rel/2010/milk102810.html</a></p> <p><a href="http://www.health.state.mn.us/news/press_rel/2013/rawmilk062513.html">http://www.health.state.mn.us/news/press_rel/2013/rawmilk062513.html</a></p>
NY	<p>Restricts legal sales to occur only on the farm where the milk is produced</p>	<p>2010 <i>Campylobacter</i> 5 illnesses  (The implicated raw milk was from a farm that held a New York State Department of Agriculture &amp; Markets (NYSDAM) permit to legally sell raw milk at the farm.)</p>	<p><a href="http://www.agriculture.ny.gov/AD/alert.asp?ReleaseID=899">http://www.agriculture.ny.gov/AD/alert.asp?ReleaseID=899</a></p>
		<p>2011 <i>Campylobacter</i> 2 illnesses  (The implicated raw milk was from a farm that held a NYSDAM permit to legally sell raw milk at the farm.)</p>	<p><a href="http://www.agriculture.ny.gov/AD/alert.asp?ReleaseID=971">http://www.agriculture.ny.gov/AD/alert.asp?ReleaseID=971</a></p>
PA	<p>Allows the sales of raw milk at retail stores separate from the farm</p>	<p>2 clusters in 2010 <i>Campylobacter jejuni</i> 22 illnesses, 3 hospitalizations</p>	<p><a href="http://www.prnewswire.com/news-releases/pennsylvania-agriculture-">http://www.prnewswire.com/news-releases/pennsylvania-agriculture-</a></p>

		(1 elderly person was paralyzed by the Guillain-Barré syndrome due to the <i>Campylobacter</i> infection. The implicated raw milk was from a farm that held a state permit issue by the Pennsylvania Department of Agriculture at the time of the incidence.)  <i>Campylobacter jejuni</i> 4 illnesses, 1 hospitalization  2012 <i>Campylobacter jejuni</i> 148 illnesses (PA, MD, NJ, WV) 10 hospitalizations  2013 <i>Campylobacter</i> 5 illnesses  2013 <i>Campylobacter</i> 2 illnesses	<a href="http://www.pennlaw.edu/_file/aglaw/May_2010.pdf">department-suspends-raw-milk-sales-permit-of-pasture-maid-creamery-in-lawrence-county-90216057.html</a>  <a href="http://www.cdc.gov/foodborneoutbreaks/Default.aspx">http://www.cdc.gov/foodborneoutbreaks/Default.aspx</a>  <a href="http://law.psu.edu/_file/aglaw/May_2010.pdf">http://law.psu.edu/_file/aglaw/May_2010.pdf</a>  <a href="http://cid.oxfordjournals.org/content/early/2013/04/25/cid.cit231.full.pdf">http://cid.oxfordjournals.org/content/early/2013/04/25/cid.cit231.full.pdf</a>  <a href="http://files.painterinteractive.org/pr/Agriculture/2013/2013-05/Consumers%20Warned%20to%20Discard%20Raw%20Milk%20Purchased%20from%20Franklin%20County%20Farm.pdf">http://files.painterinteractive.org/pr/Agriculture/2013/2013-05/Consumers%20Warned%20to%20Discard%20Raw%20Milk%20Purchased%20from%20Franklin%20County%20Farm.pdf</a>  <a href="http://files.painterinteractive.org/pr/Agriculture/2013/2013-08/Consumers%20Warned%20to%20Discard%20Raw%20Milk%20Purchased%20from%20Franklin%20County%20Farm.pdf">http://files.painterinteractive.org/pr/Agriculture/2013/2013-08/Consumers%20Warned%20to%20Discard%20Raw%20Milk%20Purchased%20from%20Franklin%20County%20Farm.pdf</a>
TN	Prohibits raw milk sales but	2013	<a href="http://news.tn.gov/node/11697">http://news.tn.gov/node/11697</a>

	allows cow sharing	<i>E. coli</i> 9 illnesses (all children) 5 developed HUS	
TX	Restricts legal sales to occur only on the farm where the milk is produced	2011 <i>Salmonella</i> 4 illnesses, 3 of which children	<a href="http://www.wfaa.com/news/local/Raw-milk-under-scrutiny-after-North-Texas-illnesses-120321579.html"><u>http://www.wfaa.com/news/local/Raw-milk-under-scrutiny-after-North-Texas-illnesses-120321579.html</u></a>  <a href="http://www.dallascounty.org/department/hhs/press/documents/041911RawMilk.pdf"><u>http://www.dallascounty.org/department/hhs/press/documents/041911RawMilk.pdf</u></a>
UT	Allows the sale of raw milk at retail stores separate from the farm but requires the store to be owned by the producer, even though the store can be located off of the farm	2 clusters:  2010 <i>Campylobacter</i> 9 illnesses  2010 <i>Salmonella</i> 6 illnesses  (The implicated milk was purchased from local vendors licensed in the State of Utah to sell raw milk.)  2014 <i>Campylobacter</i> 80 illnesses (20% or 16 hospitalizations; 1 death of individual with underlying condition)	<a href="http://www.deseretnews.com/article/700033418/9-more-cases-of-raw-milk-illness.html"><u>http://www.deseretnews.com/article/700033418/9-more-cases-of-raw-milk-illness.html</u></a>  <a href="http://www.foodsafetynews.com/2014/10/raw-milk-blamed-on-80-illnesses-in-utah-outbreak/#.VEqPjP9xmzk"><u>http://www.foodsafetynews.com/2014/10/raw-milk-blamed-on-80-illnesses-in-utah-outbreak/#.VEqPjP9xmzk</u></a>  <a href="http://www.foodsafetynews.com/2014/10/raw-milk-blamed-on-80-illnesses-in-utah-outbreak/#.VEqPjP9xmzk"><u>http://www.foodsafetynews.com/2014/10/raw-milk-blamed-on-80-illnesses-in-utah-outbreak/#.VEqPjP9xmzk</u></a>  <a href="http://www.sltrib.com/sltrib/news/58524746-78/milk-raw-bacteria-dairy.html.csp"><u>http://www.sltrib.com/sltrib/news/58524746-78/milk-raw-bacteria-dairy.html.csp</u></a>  <a href="http://udohnews.blogspot.com/2014/08/outbreak-of-illness-associated-with.html"><u>http://udohnews.blogspot.com/2014/08/outbreak-of-illness-associated-with.html</u></a>

WA	Allows the sales of raw milk at retail stores separate from the farm	2010 <i>E. coli O157:H7</i> 8 illnesses	<a href="http://www.doh.wa.gov/Portals/1/Documents/1500/NewsReleases/2010/10-087RawMilk.pdf">http://www.doh.wa.gov/Portals/1/Documents/1500/NewsReleases/2010/10-087RawMilk.pdf</a>
WI	Restricts legal sales to occur only on the farm where the milk is produced and restricts to incidental occurrences	2011 <i>Campylobacter jejuni</i> 16 illnesses  (The farm was licensed and in good standing with the Wisconsin Department of Agriculture.)  2014 <i>Campylobacter jejuni</i> 38 illnesses (high school students) 10 hospitalizations	<a href="http://www.wisbusiness.com/index.iml?Article=239824">http://www.wisbusiness.com/index.iml?Article=239824</a>   <a href="http://www.fdlreporter.com/story/news/local/2014/11/16/raw-milk-blamed-outbreak-sickened/19143621/">http://www.fdlreporter.com/story/news/local/2014/11/16/raw-milk-blamed-outbreak-sickened/19143621/</a>  <a href="http://barfblog.com/2014/11/it-was-the-campy-in-raw-milk-provided-by-parents-that-sickened-38-related-to-a-wisconsin-high-school-football-team/">http://barfblog.com/2014/11/it-was-the-campy-in-raw-milk-provided-by-parents-that-sickened-38-related-to-a-wisconsin-high-school-football-team/</a>

\* Except where otherwise noted, raw milk sale status was obtained from the National Association of State Departments of Agriculture (NASDA) News Release on July 19, 2011. *NASDA Releases Raw Milk Survey* (<http://www.nasda.org/File.aspx?id=3916>).

\*\*State of Alaska Epidemiology Bulletin. 29. Oct 27. 2009. *Unpasteurized or “Raw” Milk – Health and Legal Issues in Alaska*. Available at: [http://www.epi.alaska.gov/bulletins/docs/b2009\\_29.pdf](http://www.epi.alaska.gov/bulletins/docs/b2009_29.pdf), last assessed on 10/31/2014.

Table 3. California quarantines (recalls) associated with raw milk and raw milk products 2006 to September, 2014

Reference	Date	Description	Web link (web links last accessed on 10/31/2014))
California Department of Food and Agriculture (CDFA) News Release #06-053	2006(a)	Organic Pastures raw milk recall ( <i>E.coli</i> 0157:H7)	<a href="http://www.cdfa.ca.gov/egov/Press_Releases/Press_Release.asp?PRnum=06-053">http://www.cdfa.ca.gov/egov/Press_Releases/Press_Release.asp?PRnum=06-053</a>
CDFA News Release #06-055	2006(b)	Quarantine of Fresno County raw milk producer extends to raw butter, raw buttermilk and raw whey ( <i>E.coli</i> 0157:H7)	<a href="http://www.cdfa.ca.gov/egov/Press_Releases/Press_Release.asp?PRnum=06-055">http://www.cdfa.ca.gov/egov/Press_Releases/Press_Release.asp?PRnum=06-055</a>
CDFA News Release #07-068.	2007	Organic Pastures raw cream recall ( <i>Listeria</i> )	<a href="http://www.cdfa.ca.gov/egov/Press_Releases/Press_Release.asp?PRnum=07-068">http://www.cdfa.ca.gov/egov/Press_Releases/Press_Release.asp?PRnum=07-068</a>
CDFA News Release #08-061	2008	Organic Pastures raw cream recall ( <i>Campylobacter</i> )	<a href="http://www.cdfa.ca.gov/egov/Press_Releases/Press_Release.asp?PRnum=08-061">http://www.cdfa.ca.gov/egov/Press_Releases/Press_Release.asp?PRnum=08-061</a>
CDFA News, November 23, 2010	2010	Bravo Farms voluntary cheese recall ( <i>Listeria monocytogenes</i> , <i>E. coli</i> 0157:H7)	CDFA News release on file; <a href="http://www.fda.gov/safety/recalls/ucm234691.htm">http://www.fda.gov/safety/recalls/ucm234691.htm</a>
CDFA News Release #11-064	2011	Organic Pastures raw milk recall ( <i>E. coli</i> 0157:H7)	<a href="http://www.cdfa.ca.gov/egov/press_releases/Press_Release.asp?PRnum=11-064">http://www.cdfa.ca.gov/egov/press_releases/Press_Release.asp?PRnum=11-064</a>
CDFA	2012	Claravale Farm recall of raw milk, raw nonfat milk, and raw cream	<a href="http://www.cdfa.ca.gov/egov/press_releases/Press_Release.asp?PRnum">http://www.cdfa.ca.gov/egov/press_releases/Press_Release.asp?PRnum</a>

News Release #12-008		( <i>Campylobacter</i> )	<u>m=12-008</u>
CDFA News Release #12-018.	2012	Organic Pastures recall of raw milk, raw nonfat milk, raw cream, and raw butter ( <i>Campylobacter</i> )	<u><a href="http://www.cdfa.ca.gov/egov/press_releases/Press_Release.asp?PRnum=12-018">http://www.cdfa.ca.gov/egov/press_releases/Press_Release.asp?PRnum=12-018</a></u>
CDFA News Release #12-033.	2012	Organic Pastures recall of raw milk, raw nonfat milk, and raw cream ( <i>Campylobacter</i> )	<u><a href="http://www.cdfa.ca.gov/egov/Press_Releases/Press_Release.asp?PRnum=12-033">http://www.cdfa.ca.gov/egov/Press_Releases/Press_Release.asp?PRnum=12-033</a></u>

Total of 9 California Quarantines (Recalls) from 2006 to September 2014

Table 4. Outbreaks associated with raw milk and raw milk products in California, 1971 to September 2014

<u>Year</u>	<u>Pathogen</u>	<u>Food Vehicle Implicated</u>	<u>CA Origin of Food Vehicle Implicated</u>	<u>Total Illnesses</u>	<u>Hospitalized</u>	<u>Death</u>	<u>References</u>
1971-1975	<i>Salmonella enterica</i> Dublin	Certified Raw Milk	Single certified raw milk dairy located in southern California	44		1	Werner et al. Association between raw milk and human <i>Salmonella</i> Dublin infection. Br Med J. 1979 July 28; 2(6184): 238–241. <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1595604/pdf/brmedj00084-0014.pdf">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1595604/pdf/brmedj00084-0014.pdf</a>
1973 - 1992 *	<i>Brucella spp</i> ; <i>Brucella melitensis</i>	Milk and Cheese (raw/unpasteurized milk)	Mexico	191			Chomel et al. 1994. Changing Trends in the Epidemiology of Human Brucellosis in California from 1973 to 1992: A Shift toward Foodborne Transmission. J. Infectious Diseases 1994;170:1216-23. <a href="http://jid.oxfordjournals.org/content/170/5/1216.full.pdf">http://jid.oxfordjournals.org/content/170/5/1216.full.pdf</a>

1976	<i>Campylobacter jejuni</i>	Certified Raw Milk	Los Angeles County, Certified Raw Milk Dairy	3			Taylor et al. Campylobacter fetus infection in human subjects: association with raw milk. Am J Med 1979 May; 66(5): 779-83 <a href="http://www.ncbi.nlm.nih.gov/pubmed?term=campylobacter%20los%20angeles%20raw%20milk">http://www.ncbi.nlm.nih.gov/pubmed?term=campylobacter%20los%20angeles%20raw%20milk</a>
1980 - 1997 *	<i>Mycobacterium bovis</i> , <i>Mycobacterium tuberculosis</i>	raw, unpasteurized milk	San Diego – Mexican Border	187			Danker and Davis. <u><i>Mycobacterium bovis</i> as a Significant Cause of Tuberculosis in Children Residing Along the United States-Mexico Border in the Baja California Region.</u> Pediatrics. 2000 Jun;105(6):E79. <a href="http://pediatrics.aappublications.org/content/105/6/e79.full.pdf">http://pediatrics.aappublications.org/content/105/6/e79.full.pdf</a>
1981 – 1983	<i>Salmonella enterica</i> Dublin	Certified Raw Milk	Certified Raw Milk Dairy	71 calculated	34 calculated	11 calculated	MMWR April 13, 1984 / 33(14);196-8 Salmonella Dublin and Raw Milk Consumption – California. <a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/00000318.htm">http://www.cdc.gov/mmwr/preview/mmwrhtml/00000318.htm</a>

1984	<i>Campylobacter jejuni</i>	Certified Raw Milk, Kefir, and Ice Cream	Southern CA Certified Raw Milk Bottling Plant	12			MMWR October 05, 1984 / 33(39);562. Epidemiological Notes and Reports Campylobacter Outbreak Associated with Certified Raw Milk Products – California.  <a href="http://www.cdc.gov/mmwr/p_review/mmwrhtml/00000412.htm">http://www.cdc.gov/mmwr/p_review/mmwrhtml/00000412.htm</a>
1985	<i>Campylobacter jejuni</i>	Raw Milk	San Joaquin County Dairy Farm	25			MMWR May 16, 1986 / 35(19):311-2. Epidemiologic Notes and Reports Campylobacter Outbreak Associated with Raw Milk Provided on a Dairy Tour – California.  <a href="http://www.cdc.gov/mmwr/p_review/mmwrhtml/00000734.htm">http://www.cdc.gov/mmwr/p_review/mmwrhtml/00000734.htm</a>
1985 *	<i>Listeria monocytogenes</i>	Mexican style cheese made with unpasteurized milk	Jalisco Products Inc. (raw milk source Alta-Dena	142		48	N Engl J Med. 1988 Sep 29;319(13):823-8 Linnan et al. Epidemic Listeriosis Associated with Mexican-Style Cheese. <a href="http://www.nejm.org/doi/full/10.1056/NEJM1988092931">http://www.nejm.org/doi/full/10.1056/NEJM1988092931</a>

		Certified Dairy)				<u>91303#t=article</u>  MMWR June 21, 1985/34(24);357-9 Epidemiologic Notes and Reports Listeriosis Outbreak Associated with Mexican- Style Cheese – California.  <u><a href="http://www.cdc.gov/mmwr/p_review/mmwrhtml/00000562.htm">http://www.cdc.gov/mmwr/p_review/mmwrhtml/00000562.htm</a></u>  <u><a href="http://articles.latimes.com/1988-09-29/local/me-5951_1_final-report-traces">http://articles.latimes.com/1988-09-29/local/me-5951_1_final-report-traces</a></u>
1995	<i>Salmonella enterica</i> Typhimurium var. Copenhagen	Raw milk and Mexican-style soft cheese made from raw milk	Los Angeles County	3	3	CA Record 15435 (on file)
1997 *	<i>Salmonella</i> Typhimurium DT104	Raw milk cheese	2 counties in San Francisco Bay area, Northern CA	79	10	Cody et al. Two outbreaks of multidrug-resistant <i>Salmonella</i> serotype typhimurium DT104 infections linked to raw-milk cheese in Northern California. JAMA. 1999 May 19;281(19):1805-10.

							<a href="http://jama.jamanetwork.com/article.aspx?articleid=189982">http://jama.jamanetwork.com/article.aspx?articleid=189982</a>
2001	<i>Brucella Sp.</i>	Homemade cheese, unpasteurized milk		4	0		CDC Foodborne Outbreak Online Database (FOOD) <a href="http://www.cdc.gov/foodborneoutbreaks/">http://www.cdc.gov/foodborneoutbreaks/</a>
2002	<i>Campylobacter</i>	Raw Milk	Dairy Farm in San Bernardino County	12			CA Record 13204 (on file)
2002	<i>Campylobacter unknown (confirmed)</i>	Other milk, unpasteurized		12	0		CDC Foodborne Outbreak Online Database (FOOD) <a href="http://www.cdc.gov/foodborneoutbreaks/">http://www.cdc.gov/foodborneoutbreaks/</a>
2003	<i>Campylobacter unknown (suspect)</i>	Raw milk Mexican-style queso fresco cheese		11	0		CDC Foodborne Outbreak Online Database (FOOD) <a href="http://www.cdc.gov/foodborneoutbreaks/">http://www.cdc.gov/foodborneoutbreaks/</a>
2003	<i>Salmonella Typhimurium (confirmed)</i>	Raw milk Mexican-style queso fresco cheese		50	7		CDC Foodborne Outbreak Online Database (FOOD) <a href="http://www.cdc.gov/foodborneoutbreaks/">http://www.cdc.gov/foodborneoutbreaks/</a>

2004	<i>Salmonella</i> <i>Typhimurium</i> (confirmed)	Raw milk Mexican-style queso fresco cheese		12	1	1	CDC Foodborne Outbreak Online Database (FOOD) <a href="http://wwwn.cdc.gov/foodborneoutbreaks/">http://wwwn.cdc.gov/foodbo rneoutbreaks/</a>
2005	<i>Salmonella</i> <i>Group B</i> (suspect)	Raw milk Mexican-style queso fresco cheese		12	2		CDC Foodborne Outbreak Online Database (FOOD) <a href="http://wwwn.cdc.gov/foodbo&lt;br/&gt;rneoutbreaks/">http://wwwn.cdc.gov/foodbo rneoutbreaks/</a>
2005	<i>Salmonella</i> <i>Typhimurium</i> (suspect)	Raw milk Mexican-style queso fresco cheese		3	0		CDC Foodborne Outbreak Online Database (FOOD) <a href="http://wwwn.cdc.gov/foodbo&lt;br/&gt;rneoutbreaks/">http://wwwn.cdc.gov/foodbo rneoutbreaks/</a>
2005	<i>Shigella</i> , <i>species</i> <i>unknown</i> (suspect)	Raw milk Mexican-style queso fresco cheese		2	0		CDC Foodborne Outbreak Online Database (FOOD) <a href="http://wwwn.cdc.gov/foodbo&lt;br/&gt;rneoutbreaks/">http://wwwn.cdc.gov/foodbo rneoutbreaks/</a>
2005	<i>Salmonella</i> . <i>species</i> <i>unknown</i>	Raw milk Mexican-style queso fresco cheese		2	0		CDC Foodborne Outbreak Online Database (FOOD) <a href="http://wwwn.cdc.gov/foodbo&lt;br/&gt;rneoutbreaks/">http://wwwn.cdc.gov/foodbo rneoutbreaks/</a>

2006	<i>E. Coli, Shiga-toxin producing O157:H7</i>	Raw Milk and Raw Colostrum	Organic Pastures, Fresno County	6	3	CA Record 15204 (on file); MMWR June 13, 2008/57(23):625-628. <i>Escherichia coli</i> 0157:H7 Infections in Children Associated with Raw Milk and Raw Colostrum From Cows – California, 2006. <a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5723a2.htm">http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5723a2.htm</a> CDC Foodborne Outbreak Online Database (FOOD) <a href="http://wwwn.cdc.gov/foodborneoutbreaks/">http://wwwn.cdc.gov/foodborneoutbreaks/</a>
2007	<i>Brucella sp. (confirmed)</i>	Queso fresco, unpasteurized		3	1	CDC Foodborne Outbreak Online Database (FOOD) <a href="http://wwwn.cdc.gov/foodborneoutbreaks/">http://wwwn.cdc.gov/foodborneoutbreaks/</a>
2007	<i>Campylobacter jejuni</i>	Raw Milk and Raw Colostrum	Organic Pastures,	11		CA Record 22690 (on file); CA EPI 08-03: Cluster of Campylobacter infections possibly associated with raw dairy products (PDF on file); CDC Foodborne Outbreak Online Database (FOOD) <a href="http://wwwn.cdc.gov/foodborneoutbreaks/">http://wwwn.cdc.gov/foodborneoutbreaks/</a>

							<u>rnneoutbreaks</u>
2008	<i>Campylobacter jejuni</i>	Raw milk	Alexandre Eco Dairy Farm, Del Norte County	16	2		<p>CA 22655 (on file); CDPH The Record CDPH CA EPI 08-10. Campylobacteriosis among Persons Consuming Unpasteurized Milk from a Cow-Leasing Program, Del Norte County, May-June 2008.</p> <p><a href="http://www.marlerblog.com/uploads/file/CDPH%20Report%20(Tardiff).pdf">http://www.marlerblog.com/uploads/file/CDPH%20Report%20(Tardiff).pdf</a></p> <p><a href="http://www.about-campylobacter.com/campylobacter_outbreaks/view/alexandre-ecodairy-farms-raw-milk-campylobacter-outbreak/">http://www.about-campylobacter.com/campylobacter_outbreaks/view/alexandre-ecodairy-farms-raw-milk-campylobacter-outbreak/</a></p> <p><a href="http://www.marlerclark.com/case_news/view/alexandre-ecodairy-campylobacter-outbreak-in-raw-milk">http://www.marlerclark.com/case_news/view/alexandre-ecodairy-campylobacter-outbreak-in-raw-milk</a></p>
2010	<i>E. coli</i> , Shiga toxin-producing 0157:H7	Gouda cheese made with raw/	Bravo Farms,	38	15		<p>CDC Foodborne Outbreak Online Database (FOOD)</p> <p><a href="http://www.cdc.gov/foodbo">http://www.cdc.gov/foodbo</a></p>

	Confirmed	unpasteurized milk	Traver				<p><u><a href="#">rneoutbreaks/</a></u></p> <p>CDC November 24, 2010. Investigation Update: Multistate Outbreak of <i>E. coli</i> 0157:H7 Infections Associated with Cheese.</p> <p><u><a href="http://www.cdc.gov/ecoli/2010/cheese0157/index.html">http://www.cdc.gov/ecoli/2010/cheese0157/index.html</a></u></p>
2011	<i>E. coli</i> 0157:H7	Raw milk	Organic Pastures, Fresno County	5	3		<p>CA EPI 11-03 Investigation report: Cluster of <i>Escherichia coli</i> 0157:H7 Infections Associated with Raw Milk Consumption, March 12, 2012.</p> <p><u><a href="http://www.marlerblog.com/uploads/image/CA%20EPI%2011_03%20Cluster%20of%20Escherichia%20coli%20157H7%20associated%20with%20raw%20milk%20Wendt.pdf">http://www.marlerblog.com/uploads/image/CA%20EPI%2011_03%20Cluster%20of%20Escherichia%20coli%20157H7%20associated%20with%20raw%20milk%20Wendt.pdf</a></u></p>

							<a href="http://www.outbreakdatabase.com/reports/2012_Organic_Pastures_Campy_Outbreak_final_report.pdf">http://www.outbreakdatabase.com/reports/2012_Organic_Pastures_Campy_Outbreak_final_report.pdf</a>
2012	<i>Campylobacter jejuni</i>	Raw milk	Organic Pastures, Fresno County and Claravale Farm, San Benito County	33	1		<p>CDFA 2012 (a). News Release #12-018. May 10, 2012. CDFA announces recall of raw milk products at Organic Pastures of Fresno County.</p> <p><a href="http://www.cdfa.ca.gov/egov/press_releases/Press_Release.asp?PRnum=12-018">http://www.cdfa.ca.gov/egov/press_releases/Press_Release.asp?PRnum=12-018</a></p> <p>CDFA 2012 (b). News Release #12-019. May 18, 2012. Quarantine lifted on Organic Pastures Raw Milk and Dairy Products.</p> <p><a href="http://www.cdfa.ca.gov/egov/Press_Releases/Press_Release.asp?PRnum=12-019">http://www.cdfa.ca.gov/egov/Press_Releases/Press_Release.asp?PRnum=12-019</a></p> <p>CDFA News Release #12-008. March 23, 2012. CDFA Announces Recall of Raw Milk Products at Claravale Farm of San Benito County</p> <p><a href="http://www.cdfa.ca.gov/egov/press_releases/Press_Releas">http://www.cdfa.ca.gov/egov/press_releases/Press_Releas</a></p>

							<p><u>e.asp?PRnum=12-008</u></p> <p>CDFA 2012. News Release #12-011. March 29, 2012.</p> <p>CDFA Lifts Quarantine of Claravale Farm Raw Milk Products</p> <p><u><a href="http://www.cdfa.ca.gov/egov/Press_Releases/Press_Release.asp?PRnum=12-011">http://www.cdfa.ca.gov/egov/Press_Releases/Press_Release.asp?PRnum=12-011</a></u></p>
<b>Totals</b>				<b>989</b>	<b>82</b>	<b>61</b>	<b>27 Outbreaks from 1971 to September, 2014</b>

\* Number of illnesses from science article reference

Table 5. Raw milk position statements from various organizations, including FDA

Organization	Title	Web links (last accessed on 10/31/2014 unless stated otherwise)
American Academy of Pediatrics	Advise Families Against Giving Children Unpasteurized Milk	<a href="http://aabnews.aappublications.org/content/29/12/29.full.pdf">http://aabnews.aappublications.org/content/29/12/29.full.pdf</a>
American Association of Public Health Veterinarians	Position Statement on Raw (Unpasteurized) Milk/Products	<a href="http://dairy.nv.gov/safety/Public_Health_Veterinarian_Coalition_Committee/">http://dairy.nv.gov/safety/Public_Health_Veterinarian_Coalition_Committee/</a>
American Medical Association	H-150.980 Milk and Human Health	<a href="http://www.ama-assn.org/ad-com/polfind/Hlth-Ethics.pdf">http://www.ama-assn.org/ad-com/polfind/Hlth-Ethics.pdf</a> (page 144)
American Veterinary Medical Association	Position on Pasteurization Reaffirmed	<a href="https://www.avma.org/News/JAVMANews/Pages/050601t.aspx">https://www.avma.org/News/JAVMANews/Pages/050601t.aspx</a>
Arizona Department of Health Services	The Dangers of Raw Milk	<a href="http://www.azdhs.gov/phs/oids/vector/brucella/pdf/DangersOfRawMilk.pdf">http://www.azdhs.gov/phs/oids/vector/brucella/pdf/DangersOfRawMilk.pdf</a>
Association of Food and Drug Officials	Position Statement of the Association of Food & Drug Officials on Raw Milk	<a href="http://afdo.org/Resources/Documents/4-news-and-events/AFDO-Position-Statement-Raw-Milk-Dec-2006.pdf">http://afdo.org/Resources/Documents/4-news-and-events/AFDO-Position-Statement-Raw-Milk-Dec-2006.pdf</a>
Canadian Institute of Public Health Inspectors	Position Statement Regarding the Sale and Distribution of Raw Milk	<a href="http://www.ciphi.nl.ca/CIPHI%20Raw%20Milk%20Position%20Statement%20Eng%20Version%20Aug%2031%20(2).pdf">http://www.ciphi.nl.ca/CIPHI%20Raw%20Milk%20Position%20Statement%20Eng%20Version%20Aug%2031%20(2).pdf</a>
Centers for Disease Control and Prevention	Got Raw Milk? Don't Drink It!	<a href="http://www.cdc.gov/media/matte/2012/02_Raw_Milk_Dontdrink.pdf">http://www.cdc.gov/media/matte/2012/02_Raw_Milk_Dontdrink.pdf</a>
Centers for Disease Control and Prevention	The Ongoing Public Health Hazard of Consuming Raw Milk	<a href="http://www.dhhs.gov/dphs/fp/dairy/documents/cdclettermilk.pdf">http://www.dhhs.gov/dphs/fp/dairy/documents/cdclettermilk.pdf</a>
Cornell University	Position Statement on Raw Milk Sales and Consumption	<a href="http://milkfacts.info/Current%20Events/Position%20Statement%20%20Raw%20Milk.pdf">http://milkfacts.info/Current%20Events/Position%20Statement%20%20Raw%20Milk.pdf</a>
Delaware Health and Social Services	Raw (Unpasteurized) Milk Consumption	<a href="http://www.dhss.delaware.gov/dph/files/rawmilkfaq.pdf">http://www.dhss.delaware.gov/dph/files/rawmilkfaq.pdf</a>

Food and Drug Administration	M-I-03-4: Sale/Consumption of raw Milk-Position Statement	<a href="http://www.fda.gov/food/guidanceregulation/guidancedocument/regulatoryinformation/milk/ucm079103.htm">http://www.fda.gov/food/guidanceregulation/guidancedocument/regulatoryinformation/milk/ucm079103.htm</a>
Health Canada	Statement from Health Canada About Drinking Raw Milk	<a href="http://www.hc-sc.gc.ca/fn-an/securit/facts-faits/rawmilk-laitcrueng.php">http://www.hc-sc.gc.ca/fn-an/securit/facts-faits/rawmilk-laitcrueng.php</a>
International Association for Food Protection	Milk Pasteurization and the Consumption of Raw milk in the United States	<a href="http://www.foodprotection.org/files/general-interests/Milk_Pasteurization_Paper.pdf">http://www.foodprotection.org/files/general-interests/Milk_Pasteurization_Paper.pdf</a>
Kentucky Public Health Association, Incorporated	Position Statement (2006-2007). Pasteurization of Raw Milk	<a href="http://www.kpha-ky.org/Portals/72/Policy/2001-2007%20Policy%20Statements.pdf">http://www.kpha-ky.org/Portals/72/Policy/2001-2007%20Policy%20Statements.pdf</a>
Michigan State University Extension	Myths and Facts About Raw Milk.	<a href="http://msue.anr.msu.edu/news/myths_and_facts_about_raw_milk">http://msue.anr.msu.edu/news/myths_and_facts_about_raw_milk</a>
National Conference on Interstate Milk Shipments	Resolution No. 10	<a href="http://www.ohiodairyvets.org/wp-content/uploads/2007/08/ncims-raw-milk-resolution.pdf">http://www.ohiodairyvets.org/wp-content/uploads/2007/08/ncims-raw-milk-resolution.pdf</a>
National Environmental Health Association	Position Regarding Sale or Distribution of Raw Milk	<a href="http://www.neha.org/position_papers/position_raw_milk.htm">http://www.neha.org/position_papers/position_raw_milk.htm</a>
National Mastitis Council	Position Statement on the Consumption of Raw Unpasteurized Milk	<a href="http://nmconline.org/docs/RawMilkStatement.pdf">http://nmconline.org/docs/RawMilkStatement.pdf</a>
University of Georgia	Unpasteurized Milk Poses Serious Health Risks	<a href="http://georgiafaces.caes.uga.edu/index.cfm?public=viewStory&amp;pk_id=3445">http://georgiafaces.caes.uga.edu/index.cfm?public=viewStory&amp;pk_id=3445</a>
Vermont Veterinary Medical Association	Raw Milk Sales and Consumption	<a href="https://www.vtvets.org/temp/ClientImages/VTVMA/93b763dd-25e2-4eef-a6cc-4e6a7055c7d2.pdf">https://www.vtvets.org/temp/ClientImages/VTVMA/93b763dd-25e2-4eef-a6cc-4e6a7055c7d2.pdf</a> or <a href="https://www.vtvets.org/eweb/DynamicPage.aspx?Site=vvma&amp;WebCode=RawMilk_and">https://www.vtvets.org/eweb/DynamicPage.aspx?Site=vvma&amp;WebCode=RawMilk_and</a>

		<u>click on VVMA Policy Statement and Fact Sheet</u> <u><a href="http://www.publichealthmdc.com/documents/RawMilkPolicy.pdf">http://www.publichealthmdc.com/documents/RawMilkPolicy.pdf</a></u>
Wisconsin Madison and Dane County Public Health	Policy Statement. The Consumption of Raw Milk	