



COUNTY OF HUMBOLDT

AGENDA ITEM NO.
H-1

For the meeting of: January 11, 2011

Date: December 28, 2010

To: Board of Supervisors

From: Phillip R. Crandall, Director
Department of Health and Human Services – Public Health Branch

Subject: Department of Health and Human Services' response to informational materials presented to the Board of Supervisors on August 24th, 2010 regarding the health and safety risks and benefits of raw milk.

RECOMMENDATION(S):

That the Board of Supervisors:

Receive the Department of Health and Human Services response to the raw milk materials presented to the Board on August 24, 2010 and take action as appropriate.

SOURCE OF FUNDING:

N/A

DISCUSSION:

On August 24, 2010, the Board heard from a raw milk vendor and raw milk advocates and received a packet of material from those advocates. The Board directed DHHS to "review the educational information provided at today's meeting and bring back to a future date, undetermined, for further discussion."

DHHS, Environmental Health Division staff reviewed the material as well as forwarded the material to the California Department of Food & Agriculture (CDFA), the California Department of Public Health (CDPH), the United States Department of Health and Human Services Food and Drug Administration (USFDA), Centers for Disease Control and Prevention (CDC) and the Western Institute for Food Safety and Security

Prepared by Karyn Davis, Admin. Analyst II

CAO Approval

Amy Nilsen

REVIEW:

Auditor _____ County Counsel _____ Personnel _____ Risk Manager _____ Other _____

TYPE OF ITEM:

Consent

Departmental

Public Hearing

Other _____

BOARD OF SUPERVISORS, COUNTY OF HUMBOLDT
Upon motion of Supervisor _____
Seconded by Supervisor _____

Ayes
Nays
Abstain
Absent

PREVIOUS ACTION/REFERRAL:

Board Order No. H-2

Meeting of: Aug. 24, 2010

and carried by those members present, the Board hereby approves the recommended action contained in this Board report.

Dated: _____

By: _____

Kathy Hayes, Clerk of the Board

(WIFSS) for their expert review to determine whether the material altered their agencies' positions on the risks of raw milk.

Responses from DHHS Division of Environmental Health staff, CDC, CDFA, USFDA and the WIFSS are attached to your Board packet. Of note the following excerpts are from those responses:

Centers for Disease Control and Prevention

"These materials do not change our position regarding the threat to public health posed by consuming raw milk because they do not **comprehensively and objectively** present the risks of infection with pathogens that may be present in raw milk."

California Department of Food & Agriculture

"California regulations, promulgated under the authority of the Health and Safety Code, therefore recognize a level of risk associated with raw milk products and specified in the required warning on consumer packages."

"Without official FDA authorization for specific health claims, CDFA would consider any reference to preventing, curing or mitigating a disease or health related condition on raw milk labels, or advertisements to be false and misleading and therefore prohibited by California law."

US Food and Drug Administration

"The U.S. Food and Drug Administration (FDA) has carefully reviewed these articles and found that none of the claims on the benefits of raw milk can withstand scientific scrutiny."

"The FDA strongly encourages Humboldt County to continue to protect public health by prohibiting the production and sale of raw milk."

WIFSS

"Each claim related to the beneficial effects [of raw milk] on lactose intolerance, asthma, osteoporosis, gastrointestinal health and immune augmentation has either been disproven or remains unsubstantiated in the medical literature. The claim, for instance, that raw milk consumption prevents lactose intolerance was soundly refuted this year in a Stanford Medical School clinical trial (Quyen Vu, *Mummah & Gardner*, 2010)."

FINANCIAL IMPACT:

None as a result of this current Board Directive.

OTHER AGENCY INVOLVEMENT:

CDC, CDFA, USFDA, WIFSS

ALTERNATIVES TO STAFF RECOMMENDATIONS:

N/A

ATTACHMENTS:

1. DHHS Environmental Health Division response
2. Centers for Disease Control and Prevention response
3. California Department of Food & Agriculture response
4. U.S. FDA response
5. WIFSS response



COUNTY OF HUMBOLDT
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Phillip R Crandall, Director

PUBLIC HEALTH BRANCH
Susan Buckley, Director

529 I Street Eureka, CA 95501
(707) 445-6200 Fax: (707) 445-6097

December 28, 2010

On direction from the Humboldt County Board of Supervisors, The Department of Health and Human Services, Division of Environmental Health reviewed the material on raw milk provided by Mr. McAfee to the Board on August 24, 2010. Melissa Martel, REHS, Environmental Health Director and Kevin Metcalf, REHS conducted the review of the materials listed below. Eight of 18 articles provided make no reference to raw or unprocessed milk.

Why is Raw Milk Good for Me? (www.realmilk.com)

This two-page article covers the health benefits of raw milk and refers to a European cross sectional, multi-centre study (PARSFAL) of 15,000 children to support the assertion that raw milk reduces asthma and allergic type conditions. The article also purports that raw milk users no longer suffer lactose intolerance, osteoporosis, GI tract conditions, ulcers, IBS, etc and is a great immune system builder for kids.

Original Paper – Inverse association of farm milk consumption with asthma and allergy in rural and suburban populations across Europe

This paper offers that “farm milk” may offer protection against asthma and allergy. Pasteurization was NOT considered in this study, but the outcome was suggested to be the same, whether milk was “boiled” or not. In direct contrast to statements made in the previous article, this article states that “raw milk is not recommended especially for young children.”

How Microbes Defend and Define Us

This article contains information about bacteria and probiotics but has no information about raw milk.

‘Friendly’ Bacteria Protect Against Type 1 Diabetes, Researchers Find

This article is about gut bacteria in normal vs. sterile environments. It does not contain information about raw milk.

Newsweek – Caution: Killing Germs May be Hazardous to Your Health

This article is about good bacteria, MRSA and our cultural of cleanliness that can lead to problems. It does not contain information about raw milk.

Probiotics show IBS benefits for children: Study

This is study about how a probiotic diet may ease the symptoms of IBS (Irritable Bowel Syndrome.) It does not contain information about raw milk.

Michigan Fresh Unprocessed Whole Milk Workgroup –web article

This article answers numerous questions including: What are the additional benefits of milk fresh from the cow? What is the impact of pasteurization on FUW milk's value? There is a detailed answer to the milk fresh from the cow question that discusses intrinsic and extrinsic enzymes, immune system enhancers, cellular elements, antibacterial components, beneficial microorganisms, folate binding protein, vitamin-cofactors, promoters or enablers, prebiotics, hormones, Vitamin B12, trace minerals and others. Similarly, the impact of pasteurization answer also goes into significant detail with the temperature and time effect on proteins, carbohydrates, fats, minerals, and an over one page list of elemental impacts. While references are cited for this article, standards for testing and laboratory analyses were not offered.

Humboldt Raw Milk – The Verbal Argument by Mark McAfee

The three main points made by Mr. McAfee are: 1) It's a choice of freedom not to be controlled by government, 2) it's a way to rebuild immune systems and prevent disease and 3) It's a right; people should be free to make food choices. Mr. McAfee also states: raw milk is highly regulated; not one pathogen was ever detected in raw milk from the two raw milk dairies in CA and no deaths; officials are comparing old history to new practices; raw milk increases bone density; the ordinance is illegal and market protectionism – we are ignoring the consumer; and doctors who support pasteurization are not informed and just repeating old information. Mr. McAfee lists (1973 to 2005) averaged CDC data: 49/year illnesses due to raw milk and 600/year illnesses due pasteurized milk.

CDPH October 2008 Del Norte Outbreak Investigation of an illegal cow share (pages 9 and 11 only)

Eleven persons became ill, four of them after consuming raw milk for the first time and seven who had consumed it for months to years. A statement that “it is unlawful for any person to sell, give away or deliver” milk that does not conform to CDFA standards was underlined.

National Center for Complementary and Alternative Medicine – web article

This article is an introduction to probiotics. It does not contain information about raw milk.

News Daily: Study – Could Gut Germs underlie Western Allergies?

This study is a comparison of Western and European Union diets and intestinal flora that suggests diets high in refined sugars, fats, and red meat are detrimental to normal flora and contribute to chronic diseases. It suggests a probiotic diet could re-establish proper beneficial bacteria improving health – eliminating chronic disease associated with diet. It does not contain information about raw milk.

Probiotics Effects on Cold and Influenza – like Symptoms Incidence and Duration in Children – web article

This article states Lactobacillus and Bifidobacterium added to one percent fat milk given to children ages three to five years of age reduced symptoms and duration of illness and use of antibiotics. Raw milk was not mentioned in the study.

KEZI web news article – Umpqua Dairy Salmonella Outbreak

The article states that 23 reported cases of Salmonella in Oregon lead to recall of milk by Umpqua Dairy (did not indicate whether this is raw or pasteurized milk). Salmonella was found on the tracking system that carries the milk cartons.

Federal Department of Health and Human Services line list of reported foodborne illness to CDC

The tables provided list data from 1973 to 2005 for outbreaks associated with pasteurized and unpasteurized milk and milk products. Several outbreaks noted for each. No attack rates or association to the number of persons consuming either pasteurized or unpasteurized milk products were included; no clear comparison or conclusions could be made.

Emerging Infectious Diseases May 2004 Article Multi-resistant Salmonella Typhimurium Infection from Milk Contaminated after Pasteurization

This article recounts an investigation of an outbreak associated with pasteurized milk. It concludes with the likely source of Salmonella-contaminated containers or post-pasteurized milk surface contact with contaminated raw milk. Raw milk has pathogens. Authors review suggests milk borne outbreaks due to inadequate pasteurization are a relatively uncommon event compared to contamination after pasteurization.

Two Raw Milks in America – no date or source indicated

This one-pager lists 27 pros and cons for raw milk for “people” versus raw milk for “pasteurization”. It shows that there are fewer standards or controls for raw milk before it is pasteurized than raw milk for consumers.

USFDA – CDC- Morbidity and Mortality Weekly Report- Sample listings of some recent outbreaks caused by Pasteurized Milk in the USA

Reports on seven outbreaks. Three indicate the likely source of the outbreak as post-pasteurization re-contamination. One report questions whether pasteurization is effective to eradicate a large amount of Listeria monocytogenes in raw milk. One study concludes that the multi-drug resistant Salmonella Typhimurium DT104 has become a widespread pathogen in the US.

Organic Pastures Dairy Company LLC – Food Safety Plan

The introduction states there is no induced kill step (i.e. pasteurization) – they rely upon the innate pathogen killing system in raw milk and pathogen detection from the testing of possible entry points of contamination. The plan includes practices, procedures, observations, checklists, record keeping, and testing for steps from pasture and grazing, milking, creamery, storage and distribution. Annual and bimonthly pathogen testing,

annual water quality testing, and visual observations for ill or distressed animals are indicated. Pathogen testing for raw milk or manure for E Coli 0157:H7 at the creamery. Procedures are included for rejecting milk at the creamery or when contamination is observed. The plan relies upon testing and observation of practice and procedures to detect a problem before product is marketed. It appears raw milk may be processed and distributed to consumers in 4 days or less.



Public Health Service
DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Disease Control and Prevention (CDC)

RECEIVED

DEC 02 2010

Humboldt Co. Public Health Branch
MAIN RECEPTION

Susan Buckley
Public Health Branch Director
Humboldt County Department of Health and Human Services
529 I Street
Eureka, CA 95501

November 29, 2010

Dear Ms. Buckley,

Thank you for the opportunity to review the materials you provided related to unpasteurized (raw) milk. These materials do not change our position regarding the threat to public health posed by consuming raw milk because they do not comprehensively and objectively present the risks of infection with pathogens that may be present in raw milk. CDC supports regulations to restrict the sale of raw milk. In jurisdictions in which the sale of raw milk is legal, it is important for consumers to be provided with a full and accurate analysis of the risks of raw milk consumption so that they can make an informed decision.

The role of unpasteurized dairy products, including raw milk, in the transmission of infectious diseases is well documented. Raw milk was recognized as a source of severe enteric infections over 100 years ago and pasteurization of milk to prevent these infections is one of the public health triumphs of the 20th century. Human pathogens such as *Escherichia coli* O157, *Campylobacter jejuni*, and *Salmonella* can contaminate milk during the milking process because they are shed in the feces of healthy-looking dairy animals, including cows and goats. They also have severe, long-term consequences including hemolytic uremic syndrome, which can result in kidney failure, and Guillain-Barré syndrome, which can result in paralysis. These infections are particularly serious in children, the elderly, and those who have impaired immune systems. They can even be fatal.

Adherence to good hygienic practices during milking can reduce but not eliminate milk contamination, and in order to be pasteurized, milk must meet the Grade A Standard for cleanliness. Pasteurization is the process of heating milk to a high enough temperature for a long enough time to kill disease-causing bacteria contained in the milk. Only when milk is pasteurized can the consumer be confident that harmful bacteria that may have been present in the raw milk have been killed. Routine pasteurization of milk began in the 1920s and became widespread in the United States by 1950 as a means to reduce contamination. This led to dramatic reductions in diseases previously associated with milk. Many consider pasteurization to be one of public health's most effective food safety interventions. Pasteurization is recommended for all milk consumed by humans by the Centers for Disease Control and Prevention, the Food and Drug Administration, the American Academy of Pediatrics, the American Veterinary Medical Association, the National Association of State Public Health Veterinarians, and many other medical and scientific organizations.

In 1987, the United States Food and Drug Administration (FDA) prohibited the distribution of unpasteurized dairy products across state lines for direct sale to consumers. Despite the federal ban on sale of unpasteurized products across state lines, and broad use of pasteurization by the dairy industry, human illness and outbreaks associated with consumption of unpasteurized products continue to occur. Raw milk is still available for sale in many states, and CDC data shows that three-quarters of raw milk-associated outbreaks occurred in states in which the sale of raw milk is legal.

From 1993-2006, the Centers for Disease Control and Prevention (CDC) National Outbreak Reporting System received reports of 73 outbreaks of infections due to consumption of raw milk or raw milk products (including cheese made with raw milk). These outbreaks resulted in 1571 infections, 202 hospitalizations (13%), and two deaths. Most of the outbreaks associated with unpasteurized milk products were caused by *Campylobacter*, *E. coli* O157, or *Salmonella*. The reported outbreaks represent the tip of the iceberg. For every outbreak and every illness that is reported, many others occur. It is important to note that a substantial proportion of the raw milk-associated disease burden falls on children; approximately 60% of outbreak-associated cases occurred in persons less than 20 years old.

In conclusion, to protect the health of the public, state regulators should consider further restricting or prohibiting the sale and distribution of raw milk and other unpasteurized dairy products in their states.

A listing of recent scientific resources and publications on illnesses associated with raw milk consumption is provided below. This information can be shared with persons involved in foodborne outbreak investigations and the regulation of unpasteurized dairy products.

Sincerely,



Christopher R. Braden, M.D.
Captain, U.S. Public Health Service
Director, Division of Foodborne, Waterborne, and Environmental Diseases
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS C-09
Atlanta, Georgia 30333

Resources

- **Resources for Consumers**
 - Questions and Answers About Raw Milk from CDC
 - http://www.cdc.gov/nczved/divisions/dfbmd/diseases/raw_milk/
 - http://www.cdc.gov/healthypets/cheesespotlight/cheese_spotlight.htm
 - FDA: The Dangers of Raw Milk: Unpasteurized Milk Can Pose a Serious Health Risk
 - <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm079516.htm>
 - Real Raw Milk Facts
 - <http://www.realrawmilkfacts.com/>
- **Resources for Public Health Officials**
 - AVMA Conference Presentations available at
 - <http://wifss.ucdavis.edu/pdf/AVMArawmilkconundrum.pdf>
 - MMWR Articles
 - CDC. *Campylobacter jejuni* infection associated with unpasteurized milk and cheese--Kansas, 2007. MMWR Morb Mortal Wkly Rep 2009;57:1377-1379. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5751a2.htm>
 - CDC. *Escherichia coli* O157:H7 infections in children associated with raw milk and raw colostrum from cows--California, 2006. MMWR Morb Mortal Wkly Rep 2008;57:625-628. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5723a2.htm>
 - CDC. Outbreak of multidrug-resistant *Salmonella enterica* serotype Newport infections associated with consumption of unpasteurized Mexican-style aged cheese--Illinois, March 2006-April 2007. MMWR Morb Mortal Wkly Rep 2008;57:432-435. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5716a4.htm>
 - CDC. *Salmonella* Typhimurium Infection Associated with Raw Milk and Cheese Consumption --- Pennsylvania, 2007. MMWR Morb Mortal Wkly Rep 56;1161-1164. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5644a3.htm>
 - CDC. *Escherichia coli* O157:H7 Infection Associated with Drinking Raw Milk --- Washington and Oregon, November--December 2005. MMWR Morb Mortal Wkly Rep 56;165-167. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5608a3.htm>

- CDC. Multistate Outbreak of *Salmonella* Serotype Typhimurium Infections Associated with Drinking Unpasteurized Milk --- Illinois, Indiana, Ohio, and Tennessee, 2002—2003. MMWR Morb Mortal Wkly Rep 52;613-615. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5226a3.htm>
 - CDC. Outbreak of *Campylobacter jejuni* Infections Associated with Drinking Unpasteurized Milk Procured through a Cow-Leasing Program --- Wisconsin, 2001. MMWR Morb Mortal Wkly Rep 51;548-549. <http://198.246.98.21/mmWR/preview/mmwrhtml/mm5125a2.htm>
 - CDC. Outbreak of Listeriosis Associated With Homemade Mexican-Style Cheese -- North Carolina, October 2000--January 2001. MMWR Morb Mortal Wkly Rep 50;560-2. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5026a3.htm>
 - CDC. Outbreak of *Escherichia coli* O157:H7 Infection Associated With Eating Fresh Cheese Curds --- Wisconsin, June 1998. MMWR Morb Mortal Wkly Rep 49;911-3. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4940a3.htm>
 - CDC. Campylobacteriosis Associated with Raw Milk Consumption -- Pennsylvania. MMWR Morb Mortal Wkly Rep 32;337-8,344. <http://www.cdc.gov/mmwr/preview/mmwrhtml/00000104.htm>
- Selected Publications (available online and through research libraries)
- Altekruze SF, Timbo BB, Mowbray JC, Bean NH, Potter ME. Cheese-associated outbreaks of human illness in the United States, 1973 to 1992: sanitary manufacturing practices protect consumers. J Food Prot. 1998 Oct;61(10):1405-7.
 - Fishbein DB, Raoult D. A cluster of *Coxiella burnetii* infections associated with exposure to vaccinated goats and their unpasteurized dairy products. Am J Trop Med Hyg. 1992 Jul;47(1):35-40.
 - Headrick ML, Korangy S, Bean NH, et al. The epidemiology of raw milk-associated foodborne disease outbreaks reported in the United States, 1973 through 1992. Am J Public Health. 1998 Aug;88(8):1219-21.
 - MacDonald PD, Whitwam RE, Boggs JD, et al. Outbreak of listeriosis among Mexican immigrants as a result of consumption of illicitly produced Mexican-style cheese. Clin Infect Dis. 2005 Mar 1;40(5):677-82.
 - Villar RG, Macek MD, Simons S, et al. Investigation of multidrug-resistant *Salmonella* serotype Typhimurium DT104 infections linked to raw-milk cheese in Washington State. JAMA. 1999 May 19;281(19):1811-6.
- Position Statements by National Organizations
- National Environmental Health Association Position Statement http://www.neha.org/position_papers/position_raw_milk.htm
 - American Association of Public Health Veterinarians

<http://www.dairy.state.nv.us/Position%20Statements/PUBLIC%20HEALTH%20VETERINARIAN%20COALITION%20COMMITTEE.pdf>

- American Veterinary Medical Association Position Statement
<http://www.avma.org/issues/policy/milk.asp>
- American Medical Association (AMA) – Page 144
<http://www.ama-assn.org/ad-com/polfind/Hlth-Ethics.pdf>
- International Association for Food Protection Position Statement
<http://dairy.state.nv.us/Position%20Statements/International%20Association%20for%20Food%20Protection%20position%20statement%20Final.pdf>
- National Conference on Interstate Milk Shipments
<http://www.ohiodairyvets.org/wp-content/uploads/2007/08/ncims-raw-milk-resolution.pdf>

○ FDA Health Education Materials

- Educator's Toolkit on Preventing Listeriosis in Hispanic Populations (in English and Spanish) <http://www.cfsan.fda.gov/~dms/lmp-toc.html>
- Food Safety for Moms-to-Be Educator's Toolkit with section on Listeriosis (in English and Spanish) <http://www.cfsan.fda.gov/~pregnant/whillist.html>
- Moms-to-Be video (with Listeria information section in English and Spanish) <http://www.cfsan.fda.gov/~pregnant/videomb.html>
- Food Fact sheet on the Dangers of Raw Milk (in English and Spanish) <http://www.cfsan.fda.gov/~dms/rawmilk.html>

○ Abuela Project <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1508756>

• Resources for Clinicians

- American Academy of Pediatrics Committee on Infectious Diseases. Appendix VIII. Prevention of Disease From Potentially Contaminated Food Products Red Book.; 2009: 857-859. [Subscription Required]
(<http://aapredbook.aappublications.org/cgi/content/full/2009/1/6.8>)



CALIFORNIA DEPARTMENT OF
FOOD & AGRICULTURE

A. G. Kawamura, Secretary

October 25, 2010

Ms. Susan Buckley
Public Health Branch Director
Humboldt County Dept. of Health and Human Services
529 I Street
Eureka, CA 95501

Dear Ms. Buckley:

This is in response to the letter received by our office on October 13, 2010, in which you requested the review of specific materials concerning unpasteurized milk, and inquired whether the documents would alter our agency's position regarding the risks associated with its consumption.

The position of the California Department of Food and Agriculture (CDFA) on milk sold raw to consumers is dictated solely by relevant sections of the California Food and Agricultural Code and California Code of Regulations. Pursuant to state law, raw milk may be sold for human consumption provided all applicable requirements for dairy farm and milk product plant licensing, sanitation, animal health testing, microbiological and compositional standards, and product labeling are complied with. In addition, California regulations (17 CCR §11380) currently require raw milk to bear a specific warning statement on the principal display panel of the product label as follows:

"WARNING

Raw (unpasteurized) milk and raw milk dairy products may contain disease-causing micro-organisms. Persons at highest risk of disease from these organisms include newborns and infants; the elderly; pregnant women; those taking corticosteroids, antibiotics or antacids; and those having chronic illnesses or other conditions that weaken their immunity."

California regulations, promulgated under the authority of the Health and Safety Code, therefore recognize a level of risk associated with raw milk products as specified in the required warning on consumer packages. Accordingly, CDFA views the suitability and safety of raw milk strictly within the context and scope of this and other current regulations and statutes governing its production, packaging, labeling and distribution within the state.



The materials provided with your letter allege a variety of health related claims for raw milk. Claims that explicitly or implicitly link the relationship of a food or food component to a disease or health related condition are subject to review and authorization by the U.S. Food and Drug Administration (FDA). CDFA would refer you to FDA's website at <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm079516.htm> where they concisely address several claims concerning raw milk under the title "*Raw Milk and Pasteurization: Debunking Milk Myths*". You may also view FDA's official position statement on raw milk as posted in their coded memorandum, "*M-I-03-4: Sale/Consumption of Raw Milk Position Statement*."

Pursuant to California Food and Agricultural Code (FAC) section 36061, no false, misleading, or deceptive name, picture, symbol, mark, word, or other representation shall appear on any milk bottle, or other container, nor on any advertisement for market milk. Furthermore, pursuant to FAC section 36062, a label or advertisement of market milk is false, misleading, or deceptive if in any particular it is untrue, or by ambiguity or inference creates a misleading or deceptive impression regarding the production, handling, processing, quality, composition, merits, or value of such market milk. Without official FDA authorization for specific health claims, CDFA would consider any reference to preventing, curing or mitigating a disease or health related condition on raw milk labels or advertisements to be false and misleading and therefore prohibited by California law.

Lastly, for additional information on raw milk science and policy, we respectfully suggest visiting <http://www.realrawmilkfacts.com>, a website developed and reviewed by credible scientists and health educators in universities, government, industry, and professional organizations such as the American Veterinary Medical Association and the International Association of Food Protection. The site describes itself as a clearinghouse for evidence-based studies, presentations, commentaries, regulations, and position statements on raw milk that might be of interest to you.

We hope this information is helpful to your agency as it works with local officials on this issue.

Sincerely,



Stephen Beam, Ph.D.
Chief, Milk and Dairy Food Safety Branch

cc: Dr. Annette Whiteford, Director
Animal Health and Food Safety Services Division



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Date: December 23, 2010

To: Susan Buckley
Humboldt County Department of Health and Human Services
Public Health Branch Director

From: Yinqing Ma, Ph.D.
Division of Plant and Dairy Food Safety
Office of Food Safety
Center for Food Safety and Applied Nutrition

Through: John F. Sheehan, Esq.
Director, Division of Plant and Dairy Food Safety
Office of Food Safety
Center for Food Safety and Applied Nutrition

Re: Materials on Raw Milk

This is in response to your request dated October 6, 2010, for a scientific review of articles relating to raw milk that were originally sent to your office by a raw milk vendor and a raw milk advocate. The U.S. Food and Drug Administration (FDA) has carefully reviewed these articles and found that none of the claims on the benefits of raw milk can withstand scientific scrutiny. The FDA continues to state that raw milk is inherently dangerous and should not be consumed directly.

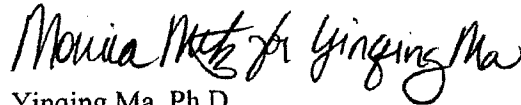
Raw milk may host a variety of human pathogens, including *E. coli* O157:H7, *Salmonella*, *Yersinia enterocolitica*, *Campylobacter jejuni*, *Staphylococcus aureus*, *Listeria monocytogenes*, *Mycobacterium tuberculosis*, and *Coxiella burnetti*, to name a few. Raw milk is a significant health risk when consumed directly or when used to manufacture certain types of milk products. Pasteurization effectively kills pathogens that may be present in milk without having any significant impact on the nutritional quality of milk. Pasteurization is the only practical means to assure the destruction of vegetative pathogens that might be present in raw milk.

The FDA has issued various written statements and testimonies that discuss the public health and food safety concerns of consuming raw milk and the importance of pasteurization. For your reference, attached is FDA testimony by John Sheehan, Esq., Director of the Division of Plant and Dairy Food Safety. The testimony was presented to the Wisconsin State Assembly in March 2010. Additional information on raw milk can

be found at <http://www.fda.gov/Food/FoodSafety/Product-specificInformation/MilkSafety/ConsumerInformationAboutMilkSafety/default.htm>

The FDA strongly encourages Humboldt County to continue to protect public health by prohibiting the production and sale of unpasteurized milk.

Sincerely yours,

A handwritten signature in black ink that reads "Yinqing Ma". The signature is written in a cursive, flowing style.

Yinqing Ma, Ph.D.

cc:

HFS-315 (Sheehan)

HFS-316 (Leonard)

HFS-316 (Metz)

Drafted: YMA: 12/22/2010

Edited: CLeonard: 12/22/10

Reviewed: MMetz: 12/23/2010

Testimony of
John F. Sheehan, B.Sc. (Dy.), J.D., Director, Division of Plant and Dairy Food Safety
Office of Food Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Before the
Committee on Rural Economic Development
Wisconsin State Assembly
March 10, 2010

Mr. Chairman and Members of the Committee, thank you for the opportunity to submit written testimony in which we will discuss the public health and food safety concerns of consuming raw milk and the importance of pasteurization. There is and has been a lot of misinformation published or otherwise communicated by various parties to the general public at large about raw milk and pasteurized milk. We very much welcome this opportunity to discuss with this Committee the reality of the dangers of raw milk consumption and the safety and healthfulness of pasteurized milk consumption.

Much of what I will present here today has been stated previously in our testimony provided to several other states.

RAW MILK IS INHERENTLY DANGEROUS

Raw milk is inherently dangerous and may contain a whole host of pathogens including Enterotoxigenic *Staphylococcus aureus*, *Campylobacter jejuni* (*C. jejuni*), *Salmonella* species, *Escherichia coli* (*E. coli* 0157H:7, Enterohemorrhagic *E. coli* - EHEC, Enterotoxigenic *E. coli* - ETEC), *Listeria monocytogenes*, *Mycobacterium tuberculosis*, *Mycobacterium bovis* (*M. bovis*), *Brucella species* (*B. abortus* being mainly associated with cattle and *B. melitensis* being mainly associated with goats), *Coxiella burnetii* and *Yersinia enterocolitica* to name but a few. Incidence rates for the presence of these pathogens in raw milk reported in the literature are variable. As one might expect, there are variations in incidence rates between countries and even within regions of countries. There are also variations in incidence rates reported for the three

main commercial milks (bovine [cow], ovine [sheep] and caprine [goat]). Van Kessel et al. (1) reported in 2004 on the prevalence of *Salmonellae* and *Listeria monocytogenes* in bulk tanks on U.S. dairies. They reported a 2.6% incidence rate for *Salmonellae* and a 6.5% incidence rate for *Listeria monocytogenes*. They commented that “although the prevalence of these organisms was low, inappropriate handling of raw milk could result in bacterial growth and substantially increase the potential risk to consumers of raw milk and raw milk products.” These incidence rates were reported even with very low standard plate counts (total bacterial counts) at <5000 cfu’s /ml (less than 5000 colony forming units per milliliter) being reported for the vast majority of samples analyzed for the pathogens. This is important to note because it is clear illustration of the fact that a simple standard plate count (or “bacteria count”) is not an indication of the safety of milk. A low standard plate count clearly does **not** mean that milk will be pathogen-free. Furthermore, even though Van Kessel et al characterized the incidence rate as "low," the mere possibility of Salmonella contamination often leads to food recalls even where Salmonella may not be present in all of the food recalled. For example, last year hundreds of firms recalled products made with certain peanuts and peanut products because of the possibility that they may have been contaminated with Salmonella.

Many of the above-mentioned microorganisms can cause very serious, sometimes life altering and sometimes even fatal disease conditions in humans. With pregnant women, *Listeria monocytogenes*-caused illness can result in miscarriage, fetal death, or illness or death of a newborn infant. Enterohemorrhagic *E.coli* (EHEC) infection has been linked to hemolytic uremic syndrome (HUS), a condition that can cause kidney failure and death. If infected with EHEC, young children are particularly susceptible to contracting HUS as unfortunately has recently happened in this country.

Raw milk should not be consumed by anyone, at any time, for any reason. FDA’s opinion in this matter is entirely consistent with that of the American Medical Association, which holds as policy the position that “all milk sold for human consumption should be required to be pasteurized” (H-150.980, Milk and Human Health). The aged, infirm, young and immunocompromised are most at risk for severe infections from pathogens that may be present in raw milk. Yet, oftentimes, we hear arguments made by raw milk advocates that these are the very people who should consume raw milk because of its alleged curative or medicinal properties.

Claims that raw milk has miraculous disease-curing properties are not supported by the scientific literature. The scientific literature is, however, rife with reports of foodborne illness attributed to the consumption of raw milk, including an article by Werner et al. (2) which reported on the incidence of *Salmonella* Dublin infections in California between 1971-1975. During that time, the mean annual incidence of *Salmonella* Dublin infections in California increased five-fold. Investigations of the cases showed an association with raw milk consumption and that all of the implicated raw milk came from just one dairy. Eighty-nine of the 113 victims were hospitalized and 22 of them died. Almost half of the patients had serious underlying, non-infectious diseases such as leukemias and lymphomas. As we know, the immune system with such persons is often compromised as a result of the treatments they are receiving.

In 1997, Keene et al. (3) reported on a prolonged outbreak of *E.coli* O157:H7 which was caused by the consumption of raw milk sold at Oregon grocery stores. Outbreaks began in 1992 and continued until June of 1994. When the dairy that was the source of the raw milk was identified, it was discovered that 4 of the 132 animals in the herd were initially positive for *E.coli* O157:H7. Despite public warnings, new labeling requirements and increased monitoring of the culprit dairy, illnesses continued until June 1994, when retail sales were finally stopped. The authors concluded that without restrictions on distribution, *E.coli* O157:H7 outbreaks caused by raw milk consumption can continue indefinitely, with infections occurring intermittently and unpredictably.

Proctor and Davis (4) reported on *E.coli* O157:H7 infections in Wisconsin between 1992-1999. During that timeframe, there were 1333 cases, even though the disease only became reportable in Wisconsin in April 2000. The highest age-specific mean annual incidence, at 13.2 cases per 100,000 population, occurred in children aged 3-5 years old. Among case patient identifiable exposures, consumption of raw milk/milk products was among the top three causes most frequently noted. Kernland et al. (5) reported on the causes of HUS in childhood in Switzerland. Among the causes was the consumption of raw milk, which resulted in the authors concluding that pasteurization of raw milk is likely to have a positive influence on the incidence of HUS. Allerberger et al. (6) reported on a specific incident in Austria in which two children contracted *E.coli* O157:H7 infection and subsequently developed HUS after consuming raw milk. The authors concluded that "it is prudent to remind them (parents and teachers) that

children should not be given unpasteurized milk.”

When one reads all the literature available on the association between *E.coli* O157:H7, HUS and raw milk, one wonders whether children themselves would choose to drink raw milk if they knew that raw milk might make them very ill, cause them to lose their kidneys, or even kill them. Given a child’s enthusiasm for life, I doubt very much that they would. Since children cannot and do not know about such matters, however, it is incumbent upon those of us who do know and are responsible for protecting them to ensure that the likelihood of their contracting foodborne disease from any food, including the milk that they drink, is an ever-diminishing prospect. Our collective actions should tend to make the food supply safer overall and not result in a lessening of the level of protection which we afford ourselves as a society. Permitting raw milk sales, or the operation of so-called “cow-share” schemes to occur within any given jurisdiction, will not result in the maintenance or further strengthening of our food safety systems. On the contrary, permitting such sales and schemes will inevitably result in an increased incidence of foodborne illness. Indeed, a farm operating a cow-sharing scheme in the state of Washington and which was engaged in the unlawful interstate distribution of raw milk, was relatively recently determined to have produced milk which was adulterated with *E.coli* O157:H7 and to have caused an outbreak of foodborne illness. There were eighteen victims identified in that outbreak, which represented 13% of those who reported consuming raw milk originating from the culprit farm. Unfortunately, the median age of the victims was just 9 years. Five of these victims, aged between 1-13 years, were hospitalized and four of these unfortunate children had HUS. Seventeen of the victims were farm “shareholders” or the children of “shareholders” and one other victim, a child of ten years of age, was a friend of a “shareholder.” The Centers for Disease Control and Prevention (CDC) issued, on March 2, 2007, a report on this outbreak in its Morbidity and Mortality Weekly Report (MMWR). That MMWR report may be found at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5608a3.htm> .

On the day of the publication of this MMWR, March 2, 2007, the state of Pennsylvania issued a press release announcing that a Pennsylvania farm engaged in the practice of selling raw milk had been determined to be responsible for an outbreak of Salmonellosis in that State. The CDC has since issued an MMWR describing the Pennsylvania outbreak in 2007. It may be found at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5644a3.htm> .

An outbreak of foodborne illness involving *E.coli* O157:H7 also occurred in California in 2006. This outbreak was determined by California to likely be caused by a dairy owned by a raw milk advocate. The evidence linking these illnesses to this dairy was strong enough to prompt California authorities to order the milk to be recalled. According to California authorities, all of the victims in this outbreak were children. FDA had previously issued a warning letter to this same dairy farm on February, 24, 2005, for the unlawful distribution of unpasteurized milk, buttermilk, butter, cream and colostrum in interstate commerce, in finished form for human consumption, an action which is in violation of the Public Health Service Act, Title 42, U.S. Code, Sections 264 (a) and 271 (a) and Title 21, Code of Federal Regulations, Section 1240.61 (a). A copy of this warning letter is available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2005/ucm075299.htm> .

E.coli O157:H7 is not the only pathogen of concern for the very young. Schmid et al (7) reported on *Campylobacter jejuni* infections in Dubuque, Iowa over a twelve-month period. Forty-six of 53 victims participated in the case control study performed. Twenty-one of the 46 cases occurred in children less than ten years of age. The age-specific attack-rate was highest for children aged one to four years. Fifteen of the 46 had consumed raw milk in the week before the onset of their illness. Twelve of the 15 who had consumed raw milk were less than 10 years old. The authors concluded "eliminating the consumption of raw milk will depend on educational efforts."

FDA agrees that continued educational efforts are needed to impart an understanding of the dangers of raw milk to all, but educational efforts alone will not suffice. In order to protect the public health, raw milk should not be permitted to be sold for human consumption, nor should people be allowed to attempt to skirt laws banning direct raw milk sales by operating so-called "cow share" schemes. The CDC agrees with FDA in this regard. In the March 2, 2007, MMWR discussed above, CDC stated that "State milk regulations and methods for their enforcement should be reviewed **and strengthened** to minimize the hazards of raw milk" (emphasis added). Assembly Bill 628 which is now before this body for consideration would operate to weaken Wisconsin laws governing public health protection by allowing sales of raw milk to occur. Allowing any type of raw milk sales directly to consumers does increase the probability of serious harm occurring to Wisconsin consumers, especially children, the aged,

infirm and immunocompromised.

Assembly Bill 628 would significantly distance Wisconsin's regulation of raw milk from the advice being given by the CDC, FDA, and many notable others. In a press release issued jointly by both CDC and FDA on March 1, 2007, the agencies noted that in addition to CDC and the FDA, "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 other organizations have endorsed the pasteurization of milk and prohibition of the sale of raw milk and products containing raw milk".

It is not only the very young, the aged, infirm and immunocompromised that can fall victim to the pathogens which may be present in raw milk. Anyone can be a victim, including healthy young adults, as was reported by Blaser and Williams (8) when they described how 19 of 31 college students developed an acute gastrointestinal illness caused by *C. jejuni* infection after a visit to an Oregon farm. It was determined that 3 others had an asymptomatic infection. Twenty-two of 25 students who had consumed raw milk for the first time became infected.

Raw milk advocates have claimed "It is not even clear that tuberculosis (TB) can be contracted from milk products" (Weston A. Price Foundation PowerPoint presentation available on-line entitled "Raw Milk and Raw Milk Products"). These advocates are wrong. It is clear to the medical community, to scientists, food technologists and those otherwise familiar with milk and milk products and the history of pasteurization that TB can be contracted from raw milk and raw milk products. Prior to the advent of pasteurization, *M. bovis* was reported to cause between 6-30% of all TB cases in the United States. (Karlsen and Carr) (9). De la Rúa-Domenech has also recently produced a very useful review on human *M. bovis* infections (10) which might be of further interest to this Committee.

STATISTICS ON DISEASE OUTBREAKS ASSOCIATED WITH RAW MILK OR RAW MILK PRODUCTS

CDC reported that during 1993 to 2006, there were 74 outbreaks associated with unpasteurized dairy products which included 1600 cases, 202 hospitalizations, and 2 deaths. Their data indicated that in states where it is legal to sell unpasteurized milk and dairy products there were nearly three times more outbreaks caused by unpasteurized milk and milk products and nearly twice as many outbreak-associated illnesses than in states where it was illegal to sell unpasteurized milk and milk products. (37) This CDC presentation can be found at http://wifss.ucdavis.edu/pdf/AVMA_caseybahravesh.pdf.

CDC's MMWR for the week of March 2, 2007, which I discussed above, reported that from 1998 to May 2005, 45 outbreaks of foodborne illness implicated unpasteurized milk, or cheese made from unpasteurized milk. Those outbreaks accounted for 1,007 illnesses, 104 hospitalizations, and two deaths. The CDC also noted that between 1973-1992, 87% of the raw milk outbreaks occurred in those states which allowed for raw milk sales to consumers while consumption of raw milk was estimated to have been less than 1% of the total milk sold in those states.

Raw milk advocates have claimed that "between 1984 and 2002, reports of outbreaks associated with raw milk produced in the U.S. are almost non-existent". (Weston A. Price Foundation PowerPoint presentation available on-line entitled "Raw Milk and Raw Milk Products") This is not the case. FDA's review of outbreaks for this period indicates that there were 35 outbreaks attributed to raw milk, an average of two outbreaks per year.

When considering these statistics, it is important to consider that not all outbreaks are actually recognized and that, even when they are recognized, not all of them are reported to CDC. Additionally, it is impossible to capture all of the incidents of individual illness that occur. Generally, outbreaks indicate a much greater incidence of unreported sporadic illness from a food, such as raw milk.

PASTEURIZATION

Pasteurization is required for all milk and milk products in final package form intended for direct human consumption which move in interstate commerce. (21 CFR 1240.61) The only exceptions to this requirement are for certain cheeses and those exceptions are not absolute but

come with certain other requirements relative to the manner by which any raw milk cheese must be ripened. In promulgating this regulation, FDA made a number of findings relative to raw milk, including the following: "Raw milk, no matter how carefully produced, may be unsafe" (52 FR 29514, Aug. 10, 1987).

The case that prompted FDA to promulgate 21 CFR 1240.61 was Public Citizen v. Heckler, 653 F. Supp. 1229 (D.D.C. 1986). In its holding, the federal district court concluded that the record presented "overwhelming evidence of the risks associated with the consumption of raw milk, both certified and non-certified." Id. at 1238. The court stated that the evidence FDA has accumulated concerning raw milk has "conclusively shown.... raw milk is unsafe" and that "[t]here is no longer any question of fact as to whether raw milk is unsafe". Id. at 1241.

Pasteurization will destroy all of the pathogens that I have mentioned thus far and others that I have not mentioned. For example, pasteurization is also destructive of *Mycobacterium paratuberculosis*, the causative organism of Johne's disease in cattle. Clearly, pasteurized milk rationally can never be considered more hazardous than raw milk, contrary to the claims of raw milk advocates. In fact, it is universally agreed within the scientific community that pasteurization has made milk a much safer food for human nutrition.

Raw milk advocates have mentioned that *Bacillus cereus* and *Clostridium botulinum* spores may survive pasteurization, labeling these microbes as "heat-resistant pathogens." Microbial endospores are indeed very resistant to heat and chemical treatments, but the vegetative cells of these microbes are not heat resistant and will be destroyed by pasteurization.

B. cereus spores are quite common in milk, raw or otherwise and are thus a common cause of spoilage concerns within the dairy industry. However, the presence of *C. botulinum* spores in milk is not a very common occurrence. Before either of these microbes can pose food safety concerns with milk or milk products, very high population levels must be reached, a condition that does not ordinarily occur in the collection and processing of milk and milk products. Interestingly, in alleging that consumers are avoiding commercial milk because it is pasteurized (which is not true insofar as FDA is aware), raw milk advocates also claim that consumers do not like the fact that cows are allegedly kept in confinement, and fed rations designed to enhance milk production, a situation which they claim causes poor health and disease. In support of such a notion, raw milk advocates claim that Dutch researchers found

much lower rates of *Salmonella* infections in dairy herds and cows with access to pasture, but they neglect to mention, or are perhaps unaware, of other Dutch research (Slaghuis et al.) (11) that indicates that cows fed on pasture during the summer had **higher** levels of *B. cereus* spores in their milk than cows which were housed during the summer. Thus, it appears that raw milk advocates are somewhat selective about the research which they choose to discuss when it comes to the subject of cattle feeding and its impact upon milk microflora.

CLAIMS ABOUT RAW MILK AND PASTEURIZED MILK

Raw milk advocates are wont to claim that pasteurization, in addition to killing any pathogens which might be present, also destroys the nutritive value of milk. Nothing could be further from the truth.

Because there is so much misinformation currently circulating about raw milk and pasteurized milk, I developed a presentation which was given at the biennial meeting of the National Conference on Interstate Milk Shipments at Columbus, Ohio in May 2005 by Ms. Cynthia Leonard, M.S., who is a member of my Division. In that presentation, we addressed several of the more common and egregious fallacies about pasteurization that one is presently likely to encounter. Due to the constant and heavy demand for that presentation, we have placed it on the FDA website. It can be found at: <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/ConsumerInformationAboutMilkSafety/ucm165048.htm> .

In addition to the fallacies that we addressed in the presentation, we have been made aware of several other erroneous statements being made by raw milk advocates about raw milk and pasteurized milk and it may be useful for me to address some of these here:

RAW MILK IS NOT A “MAGIC FOOD FOR CHILDREN”

Relatively recently a raw milk advocate has claimed that “Raw milk is a magic food for children”. There is nothing magical about the possibility of contracting foodborne disease from raw milk, having that progress into hemolytic uremic syndrome, ending up having to fight for your young life as best you can and, if you are fortunate enough to survive, having to suffer

lifelong complications from your illness, knowing all the while that your life likely has been appreciably shortened as a result of your illness.

Raw milk advocates have mischaracterized scientific literature in the past and indeed, where we have seen them do so, we have publicly pointed out as much previously. Their mischaracterization of the article on the PARSIFAL study (Waser et al) is therefore not at all surprising and indeed the journal article on the PARSIFAL study has been mischaracterized by raw milk advocates since it first appeared. The study is about farm milk and not raw milk. The authors of the study took great pains to explain as much in the Clinical and Experimental Allergy article which they published on the study and indeed the article title even specifies that the report is about farm milk. The authors clearly state within that article that "The present study does not allow evaluating the effects of pasteurized vs. raw milk consumption because no objective confirmation of the raw milk status of the farm milk samples was available." They go on to say that "About half of the parents indicated that they usually did not boil the milk before consumption but no differential effects were observed between those boiling and those not boiling the milk. This might be a result of biased parental answers or may indicate that pasteurization is not of key importance because compounds other than microbes play a role." They also go on to say that "raw milk may contain pathogens such as Salmonella or EHEC and its consumption may therefore imply serious health risks". Finally, the authors state that "At this stage, consumption of raw farm milk cannot be recommended as a preventive measure." The study does not indicate, as some raw milk advocates claim, that raw milk prevents allergies and asthma in children.

RAW MILK DOES NOT KILL PATHOGENS

The claim that raw milk per se kills pathogens and thus is safe is simply incorrect. Milk contains certain indigenous enzymes to which antimicrobial properties have been ascribed, and milk may contain certain strains of bacteria which might be able to produce anti-bacterial compounds known as bacteriocins, but these enzymes and microbes (if present) do not render raw milk safe. With raw milk, the temperature of storage coupled with the nature and composition of the microflora initially present and simple microbial competition and outgrowth all play an important part in the determination of which microbes will grow and which will not.

Some micro-organisms are more fastidious than others. Some do not grow well in cold temperatures, whereas others do. Some pathogens can survive and grow at refrigeration temperatures.

Another version of the claim that raw milk kills pathogens is that “pathogens can multiply in pasteurized milk and other foods but not in raw milk.” That too is untrue. In support of this claim, we have seen raw milk advocates cite a 1982 study by Doyle and Roman (12) and selectively present data from that study which, at first glance, appears to support raw milk advocates’ claim. However, the authors of that study found and reported in that same article that “[s]urvival of the eight *Campylobacter* strains in refrigerated unpasteurized milk varied greatly.” Furthermore, the authors stated that “one strain of *C. jejuni*, bovine isolate FRI-CF147B, survived exceptionally well in unpasteurized milk at 4° C. A less than 2-log reduction in cells occurred after 14 days, indicating that under the appropriate conditions, large numbers of campylobacters may survive in raw milk for several days.” The authors also determined that “[i]nactivation of *Campylobacter* strains in unpasteurized milk paralleled but was greater than the inactivation of strains in sterile milk.” Note that the authors report **an inactivation** in sterile (not merely pasteurized) milk. Finally, the authors concluded: “The presence and possible persistence of *C. jejuni* in raw Grade A milk reaffirms the need for pasteurization.” Thus, far from providing a support for raw milk advocates, the Doyle and Roman study clearly advocates pasteurization of raw milk.

PASTEURIZATION DOES NOT DESTROY THE ENZYMES IN MILK

The claim that pasteurization destroys all the “built-in safety systems” or “enzymes that kill pathogens” also is simply not supported by the scientific literature. For example, it has been claimed that pasteurization inactivates lactoferrin. Lactoferrin is an iron-binding protein believed to have dual roles; the one being a facilitator of iron absorption and the other a bacteriostatic role. Paulsson et al (13) determined that “unheated and pasteurized bLf (bovine lactoferrin) preparations showed similar antibacterial properties and caused an effective metabolic inhibition with a moderate bacteriostasis.” They further stated that “pasteurization seems to be the method of choice (when making a lactoferrin product) because it did not alter either the bacterial interactive capacity or the antibacterial activity of bLf.” Tomita et al (14) discussed how a

pasteurization process was developed for lactoferrin in order to apply active lactoferrin usage to various products. Plainly, lactoferrin is not destroyed or inactivated by pasteurization.

Similarly, lactoperoxidase, an enzyme which is integral to the lactoperoxidase system of milk preservation, has been described as being "inactivated" by pasteurization, when actually lactoperoxidase is a very heat stable enzyme which is not destroyed by minimum legal pasteurization conditions, although some literature indicates moderate inactivation. In fact, because it will survive pasteurization intact, measurement of residual lactoperoxidase activity has been proposed as a means of indicating if a heat treatment applied to milk has exceeded high temperature short time (HTST) pasteurization conditions. Contrary to the claim that the lactoperoxidase system can be an alternative to pasteurization, the lactoperoxidase system is not, and could never be an alternative to pasteurization. (Some researchers do consider that it might possibly be used synergistically with pasteurization to extend the shelf life of dairy products).

The lactoperoxidase system, which requires the addition of hydrogen peroxide and thiocyanate ion to milk to be activated, functions as a bacteriostatic mechanism generally, i.e., it serves to keep microbial populations from growing and spoiling milk. It is used in regions of the world where it is difficult, if not impossible, to cool milk, due either to a lack of electricity or cooling equipment or both. It is reported by some researchers to be bactericidal to certain enteric pathogens. Seifu et al (15), in 2005, published an excellent review article on lactoperoxidase, which may be of further interest to this Committee. The claim that lysozyme, which, in conjunction with lactoferrin does have a bactericidal effect, is destroyed by pasteurization is also simply not true. In excess of 70% of bovine milk lysozyme will survive normal HTST conditions, as reported by Griffiths (16).

With respect to indigenous dairy enzymes in general, Stepaniak (17), in 2004, published an excellent review article of the literature available to which I would refer anyone interested in learning what the current science is on the effect of pasteurization on milk enzymes.

Claims have been made by raw milk advocates that Immunoglobulin G (referred to as "IgG antibodies" by raw milk advocates) is destroyed by pasteurization. However, Kulczycki (18) reported in 1987 that his research on bovine IgG suggested "the possibility that pasteurization of milk (and condensed milk) may not destroy the receptor-binding ability of IgG, but instead might enhance its binding by causing aggregation of the bovine IgG."

PASTEURIZATION DOES NOT CAUSE LACTOSE INTOLERANCE

Raw milk advocates have also claimed that pasteurized milk causes lactose intolerance, (which is an inborn error of metabolism), despite the fact that all milks, raw or pasteurized, contain lactose and that pasteurization does not change the concentration of lactose. A person who is lactose intolerant has a reduced ability to synthesize the enzyme Beta-galactosidase, which hydrolyzes the disaccharide lactose into its monosaccharide constituents, glucose and galactose. Any such person might be expected to experience the symptoms of lactose intolerance when consuming either raw or pasteurized milk.

Recently, a new version of this fallacy has been brought to our attention. A raw milk advocate has begun to claim that raw milk does not cause lactose intolerance because it contains bacteria (which he describes as being “bifido and lacto”) which he believes create their own lactase (beta-galactosidase) when consumed, thus allegedly preventing the symptoms of lactose intolerance. Among the numerous difficulties with this proposition is the fact that the Bifidobacteria in the gastrointestinal tracts of humans are different to those found in animals (Gavini et al) (24) and thus the milk from animals. Furthermore, if Bifidobacteria consumed as a therapeutic or prophylactic measure are to be of any benefit, they must be consumed in appreciable quantities (as might be found, for example in a fermented milk product containing an adjunct Bifidobacteria culture) as well as be of human origin, in order to withstand transit through the intestinal tract (Arunachalam) (25). Finally, it has actually been proposed that the Bifidobacteria present in bovine milk be used as indicator organisms to gauge the extent of fecal contamination of milk.(Beerens et al.) (26). Thus, far from being of any health benefit, the Bifidobacteria present in raw milk are considered by scientists to be an indication of the extent to which it has been contaminated with manure.

Although many potential health benefits have been ascribed to Bifidobacteria in the literature, curing lactose intolerance is not among them. (Arunachalam) (22). De Vrese et al (27) published a useful paper entitled “Probiotics- compensation for lactase insufficiency” wherein they synopsise some of the research done on the utility of Bifidobacteria as promoters of lactose hydrolysis and state that Bifidobacteria “affected lactose digestion less than did lactobacilli or had no effect at all.”

Although we are uncertain just what the raw milk advocate in question is referring to when he mentions “lacto bacteria,” if we assume that he is referring to *Lactobacillus* species, it is true that several *Lactobacillus* species are generally considered to be probiotic and that among the possible benefits suggested as being conferred by consumption of fermented dairy products containing appreciable quantities of Lactobacilli are reduced symptoms of lactose intolerance, as reported by De Vrese et al, Holzapfel and Schillinger, McBean and Miller, Savaiano et al. (27, 28, 29, 30) However, *Lactobacilli* typically are but a small portion of the microflora in milk.

RAW MILK IS NOT A PROBIOTIC FOOD

While making the above claims and perhaps because of them, this same raw milk advocate has recently been describing his milk as being “probiotic.” Raw milk is certainly not a probiotic food, as that term is defined within the FAO/WHO Guidelines for the Evaluation of Probiotics in Food, which was published in 2002 (31), and it is scientifically improper to describe raw milk as being probiotic. That document defines probiotics as being “[l]ive microorganisms which when administered in adequate amounts confer a health benefit on the host”. According to FAO/WHO, in order for that term to be used, stringent requirements must be met, including strain identification, functional characterization, a safety assessment, efficacy studies, and comparison with standard treatments as well as labeling requirements. None of that has been done for raw milk.

PASTEURIZATION DOES NOT DESTROY MILK PROTEINS

Raw milk advocates claim that pasteurization either destroys the proteins of milk or that it renders milk proteins more allergenic, even though the milk proteins that cause allergic reactions (including lactoferrin) in dairy-sensitive people are present in raw milk as well as pasteurized milk. Interestingly, these same sorts of claims were addressed directly over twenty years ago by Coveny and Darnton-Hill (19) when they wrote in their article entitled “Goat milk and infant feeding” that “there are some who feel that pasteurization is unnecessary and even detrimental. Concern appears to centre (sic) on possible increased allergenicity and nutrient losses. However, studies show that the sensitizing capacity of cow’s milk is retained or – more

usually – reduced after heat treatment (cites) while pasteurization minimizes the heat destruction of nutrients (cite). There would appear to be little advantage therefore in the use of raw milk.”

Caseins, the major family of milk proteins, are largely unaffected by pasteurization (Farrell and Douglas) (20). Any changes which might occur with whey proteins are barely perceptible.

PASTEURIZATION DOES NOT DESTROY VITAMINS AND MINERALS IN MILK

With respect to vitamins, the claims about the destructive capacity of pasteurization have been many and varied and virtually none of what has been said is accurate.

Milk is a good source of the B-complex vitamins thiamine, folate and riboflavin. Pasteurization will result in losses of each of these of anywhere between zero to 10 percent, which most would consider to be merely a marginal reduction (17), (21). Pasteurization does not cause appreciable losses of the fat-soluble vitamins, A, D, E and K (21). Milk does contain a small amount of Vitamin C, but it is not considered to be a good dietary source of that vitamin.

Pasteurization will result in a loss of anywhere from 0-10% of the Vitamin C present (21). Most vitamin C losses in milk occur during storage and such will occur whether milk is pasteurized or not.

With respect to the minerals present in milk, raw milk advocates have made several different claims about the allegedly destructive impact of pasteurization. FDA has not been able to substantiate any of these claims. In fact, the scientific literature that we have reviewed thus far contradicts most of the claims being made. Where raw milk advocates indicate that “no significant change” occurs with sodium, potassium and magnesium, FDA would agree, however. Williamson et al. (22) and Zurera-Cosano et al. (23).

RAW MILK IS RAW MILK

Finally, raw milk advocates have recently begun to claim that only raw milk produced at large commercial dairy farms, which is intended to be subsequently pasteurized, is unsafe and that raw milk produced at small farms is safe. The history of raw milk outbreaks, however, does not support such claims. Additionally, literature indicates that somatic cell counts, which are a

measure of dairy herd health (with lower counts being better), tend to be lower in larger, high intensity dairy farming operations as reported by Windig et al., Norman et al., Berry et al. and Oleggini et al. (32, 33, 34, 35).

Another variation on this theme that we sometimes encounter is the claim that raw milk is safe if it originates from "certified" dairies. That is simply not correct. As was stated above, in Public Citizen v. Heckler, 653 F Supp. 1229 (D.D.C. 1986), the court was clear in its holding that there existed "overwhelming evidence of the risks associated with the consumption of raw milk, both certified and non-certified." Id. at 1238.

SUMMARY

Raw milk is inherently dangerous and should not be consumed. Raw milk continues to be a source of foodborne illness and even a cause of death within the United States. Despite the claims of raw milk advocates, raw milk is not a magical elixir possessing miraculous curative properties. Pasteurization destroys pathogens and most other vegetative microbes which might be expected and have been shown to be present in milk. Pasteurization does not appreciably alter the nutritive value of milk. Claims to the contrary by raw milk advocates are without scientific support. FDA encourages everyone charged with protecting the public health to prevent the sale of raw milk to consumers and not permit the operation of so-called "cow-sharing" or other schemes designed as attempts at circumventing laws prohibiting sales of raw milk to consumers. To do otherwise would be to take a giant step backwards with public health protection.

We would like to thank the Committee for affording us the opportunity to provide this information to the Committee and trust that the above will prove useful to you in your deliberations. If we may be of any further assistance to the Committee, we will be happy to do so.

REFERENCES:

1. Van Kessel et al. J. Dairy Sci. 2004. 87:2822-2830.
2. Werner et al. Br. Med. J. 1979. July 28:2(6184):238-241.
3. Keene et al. J. Infect. Dis. 1997. 176: 815-8.
4. Proctor and Davis. WMJ. 2000. Aug; 99:5:32-7.

5. Kernland et al. Schweiz Med. Wochenschr. 1997. 127:1229-33.
6. Allerberger et al. Int. J. Infect. Dis. 2003. 7:42-45.
7. Schmid et al. J. Infect. Dis. 1987. 1 July:156.
8. Blaser and Williams. JAMA. 1987. 257:1; 43-6.
9. Karlsen and Carr. Ann. Intern. Med. 1970. 73:979-983
10. de la Rúa-Domenech. 2005. Tuberculosis. (2006) 86, 77-109.
11. Slaghuis et al. Int. Dairy J. 1997. 7:4:201-205.
12. Doyle and Roman. Applied and Environmental Microbiology. 1982. 44:5:1154-1158.
13. Paulsson et al. J.Dairy Sci. 1993. 76:3711-3720.
14. Tomita et al. Biochem. Cell Biol. 2002. 80:1:109-112.
15. Seifu et al. 2005. Trends in Food Science & Technology. 16:137-154.
16. Griffiths. J. Food Prot. 1986. 49:696-705.
17. Stepaniak. Int. J. of Dairy Technology. 2004. 57:2/3:153-171.
18. Kulczycki, Jr. Molecular Immunology. 1987. 24:3:259-266.
19. Coveny and Darnton-Hill. Med. J. of Australia. 1985. 143:508-510.
20. Farrell and Douglas. Kiel. Milchwirtsch. Forschungsber. 1983. 35:345-356.
21. Fox. Heat-Induced Changes in Milk, 2nd ed. P.F. Fox, ed. IDF.
22. Williamson et al. Arch. Dis. Child. 1978. 53:7:555-563.
23. Zurera-Cosano et al. Food Chemistry. 1994. 51:75-78.
24. Gavina et al. Int. J. Systemic Bacteriology.1991. 41:4:548-557.
25. Arunachalam. Nutrition Research. 1999. 19:10:1559-1597.
26. Beerens et al. Int. J. Food Microbiology. 2000. 54:163-169.
27. de Vrese et al. Am. J. Clin. Nutr. 1001. 73:421S-429S.
28. Holzapfel and Schillinger. Food Research Int. 2002. 35:109-116.
29. McBean and Miller. J. Am. Dietetic Assoc. 1998. 98:671-676.
30. Savaiano et al. Am J. Clinical Nutrition. 1984. 40:6:1219-1223.
31. FAO/WHO. Report of a Joint FAO Working Group on Drafting Guidelines for the Evaluation of Probiotics in Food. April 30 and May 1, 2002.
32. Windig et al. J. Dairy Sci. 2005. 88:335-347.
33. Norman et al. J. Dairy Sci. 2000. 83:2782-2788.

34. Berry et al. J. Dairy Sci. 2006. 89:4083-4093.
35. Oleggini et al. 2001. J. Dairy Sci. 84:1044-1050.
36. Waser et al. Clinical and Experimental Allergy, 37, 661-670
37. Behravesch "Outbreaks Due to Unpasteurized Dairy Products in the United States"
American Veterinary Medical Association (AVMA), July 12, 2009,

From: Payne, Michael [mailto:mpayne@ucdavis.edu]
Sent: Friday, December 24, 2010 4:08 PM
To: Martel, Melissa
Subject: Payne Information on Raw Milk: Response to Humboldt County Request

December 23, 2010

Susan Buckley
Humboldt County Department of Health and Human Services
Public Health Branch Director

Dear Ms. Buckley,

Thank you for your October letter requesting review of materials related to the safety of raw milk. If I understand correctly, your Department has been asked to consider Humboldt County's current prohibition on the production and sale of raw milk and you are seeking analysis of materials supplied to you by advocates for raw milk sales.

By way of background: I am an employee of the University of California's School of Veterinary Medicine. I hold two doctorates, one in veterinary medicine and a second doctorate in comparative pathology. I became familiar with the issue of raw milk safety when I was asked to provide testimony to the California State Senate and House Ag committees. Later I served as an expert witness for the state in a lawsuit against the California Department of Food and Agriculture, in which California's two raw milk producers sought judicial repeal of recently enacted raw milk hygiene standards, a lawsuit which ultimately failed.

UC educators and investigators are frequently asked by regulatory agencies and legislators to provide background and context on complex scientific issues. It is appropriate then that in response to your request I provide whatever assistance I can. Before going further however, I should offer the following caveat: what follows is my own evaluation, based on my education, professional experience and research of some twenty five years. They are my own opinions and may or may not represent the positions or policies of the University of California.

The packet you mailed contained documents totaling just short of 100 pages. Many of the issues raised in these documents are extremely complex and there exists a robust body of literature examining them. In the interest of being respectful of your staff's time I have endeavored to condense my response into summaries addressing the most important individual documents:

Why is Raw Milk Good for Me? (Weston A. Price Foundation)

This one page flyer is a product of a raw milk advocacy organization. Each claim related to the beneficial effects on lactose intolerance, asthma, osteoporosis, gastrointestinal health and immune augmentation has either been disproven or remains unsubstantiated in the medical literature. The claim, for instance, that raw milk consumption prevents lactose intolerance was soundly refuted this year in a Stanford Medical School clinical trial (*Quyên Vu, Mummah & Gardner, 2010*). Related to osteoporosis, while it is true that the phosphatase enzyme is inactivated by pasteurization, the enzyme is also denatured in the high acidity of the stomach juices (*Rankin, 2010*), meaning raw milk consumers do not enjoy exposure to additional phosphatase. In addition a computer-assisted search

of the medical literature reveals no studies showing that *"Raw milk consumers enjoy rapid bone density increases that can be measured over time."* as maintained in the WAPF pamphlet. Similarly, while probiotic treatment has shown promise in treating GI disorders like Irritable Bowel Syndrome (Aragon 2010), the mixture of pathogenic and non-pathogenic bacteria excreted from a cow's rectum meets neither the legal nor scientific threshold as a "probiotic" (Douglas, 2008). Lastly, as described in the PARSIFAL study submitted to you (Waser, 2006), while some pilot investigations have raised some intriguing possibility that early exposure to farms and possibly raw milk may reduce the incidence of allergic disease, the authors of these studies, while recommending further investigation, uniformly advise that *"the consumption of raw milk cannot be recommended as a preventive measure for allergic diseases"* until such time that it can be made safe for children (Braun-Fahrlander, 2010).

Michigan Fresh Unprocessed Whole Milk Workgroup (website materials)

Following regulatory actions taken in Michigan, friction between raw milk advocates and the regulatory and public health communities became pronounced. In an effort to resolve the stalemate, a bipartisan workgroup was formed in 2007 to see if consensus and/or compromise could be reached on some fundamental issues. This effort to has largely stalled and most of the workgroup's website links are currently "dead". The Michigan workgroup materials supplied to you are, for the most part, a review of the components and nutritional value of milk and the potential effect pasteurization might have on them. FDA and CDC cite nutritional analyses showing that the losses in nutritional content after pasteurization are negligible for the key nutrients that milk provides in the human diet. In fact a comparison between nutrient content between commercial pasteurized milk and licensed raw milk sold show no substantive difference in critical nutrients (<http://www.marlerblog.com/lawyer-oped/comparing-the-food-safety-record-of-pasteurized-and-raw-milk-products---part-4/>). Why these particular website materials were submitted to your agency is not clear to me, unless it was to provide support for the idea that pasteurization removes components which naturally kill dangerous bacteria that might reside in raw milk. In fact the notion that raw milk can clear milk of pathogens has been decisively rebutted in numerous studies, (Payne, 2010 see attached) including at least one funded by the raw milk industry. Suffice it to say, in laboratory trials conducted in both private and university labs, when pathogens are added to commercial unpasteurized raw milk, no substantive or clinically important decrease in pathogen numbers is observed.

RAMP – Risk Analysis & Management Program (Organic Pastures Dairy Company)

Organic Pastures is one of only two licensed raw milk dairies in California. As a licensed raw milk dairy in this state the farm enjoys a number of food safety protections, overseen primarily by the California Department of Food and Agriculture. These include monthly facility evaluations by professional dairy inspectors, annual testing for tuberculosis and periodic testing for bacteria content and pathogen presence. The RAMP document submitted to your office details many of these controls, many or most of which are required of all Grade A dairies. These precautions, whether on raw milk or conventional dairies, are good and important protections and assist in keeping a completely unsanitary conditions from developing. Such unsanitary conditions were in evidence in a recent raw milk related outbreak in Minnesota (MN Depart of Ag v. Hartmann) where 8 people became ill and one child developed complete kidney failure <http://www.thecompletepatient.com/storage/MNraw-milk-ruling.pdf> .

Two pages attached to the submitted RAMP program however lead the reader to believe that the program somehow constitutes a complete HACCP plan. In fact there are (at least) several obvious deficiencies evident, such as details as to which chemicals and concentrations are used to clean the milking equipment. Critically the assay reported to be used to test for pathogenic E. coli has never been approved by any academic or regulatory agency to be effective in detecting that bacteria in milk.

Similarly no mention of which tests are used to assay for listeria or campylobacter. Most importantly I was unable to find any reference to which third party was reviewing the plan and facility annually or semi-annually, a prerequisite for any credible HACCP plan.

None of this is to say that there is not sound information included in this plan, just that it does not meet muster as a HACCP program, the recognized gold standard for food protection. While submission of this sort of document does advise your agency of what procedures a company *intendeds*, simply having a paper plan does not necessarily mean that the company will follow through with it. In the case of the particular dairy submitting the RAMP plan, there was a long history of sanitation problems and high bacterial contamination. Attached is a report from the California Department of Food and Agriculture with photos depicting dead rodents and rodent dropping in the milk process area, rodent dropping touching retail milk containers and evidence of inadequately cleaned pipes conveying milk.

The lesson to be learned from this is that a having a food safety plan does not necessarily translate into on-farm implementation.

With unanswered questions relative to the effectiveness of program implementation, perhaps it should have not surprise us that on at least four occasions the dairy which submitted this RAMP program has been linked to either outbreaks or recalls:

- Listeria in cream recall 2005
<http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2005/ucm112271.htm>
- E. coli outbreak 2006 (see attached outbreak report from state department of public health).
- Campylobacter outbreak 2007 (see attached outbreak report from state department of public health).
- Campylobacter in cream recall 2008
http://www.cdffa.ca.gov/egov/Press_Releases/Press_Release.asp?PRnum=08-061

In the 2006 E. coli outbreak 5 of 6 children (average 8 years old, range 6-18) reported bloody diarrhea after consuming same Fresno dairy brand raw products. These cases were spread hundreds of miles apart having only in common the consumption of same raw dairy brand products. Although there were no milk samples still available to test, fecal samples showed the same genetic fingerprint for the E. coli further indicating a common source. Three children were hospitalized, two with complete kidney failure. You will find a graphic describing the outbreak in the attached slide set. One of the three children was a 12-year old girl. The emotional, medical and financial costs to the family have also been summarized in the attached slide set. Another of the three children was a 7-year old boy. You can view a video describing what happened to this boy at <http://www.realrawmilkfacts.com/real-life-stories/#RawMilkFactsVideo4> You can find several other videos detailing the potential consequences at a website which seeks to inform people of the risks associated with raw milk consumption, particularly for raw milk consumption by children <http://www.realrawmilkfacts.com/>. Whole Foods Markets became so concerned about their legal liability that they stopped carrying raw milk in 2010. You can find out more about the that decision at <http://www.foodsafetynews.com/2010/03/why-did-whole-foods-stop-selling-raw-milk/> as well as a power point explaining shared liability in food bourn outbreaks .

Humboldt Raw Milk – The Verbal Arguments (Mark McAfee)

Ultimately it will be the county's elected officials who will be faced with the weighty decision of whether or not to permit raw milk sales in Humboldt county. As they weigh the competing interests of business liberties and public health protection, they will surely be examining not only scientific but regulatory, legal and ethical considerations as well. I am not qualified to speak to any of the issues other than to help clarify the scientific background.

While not specifically related to any raw milk dairies in California, below is some general information on raw milk safety:

- In 2010 alone, there have been at least 10 raw dairy outbreaks:
<http://www.realrawmilkfacts.com/updated-2010-table-of-raw-and-pasteurized-milk-dairy-outbreaks-and-recalls/>
- Even through legal raw milk accounts for less than ½% of all fluid milk sales in the U.S., it causes 2 to 10 times as many outbreaks as do pasteurized products.
- There are excellent reasons pasteurization was uniformly adapted in the middle of the last century. For example in 1938 (before the widespread application of pasteurization) one fourth of all food and water borne illnesses resulted from dairy products, where now the figure is less than one percent
- Even through legal raw milk accounts for less than ½% of all fluid milk sales in the U.S., CDC estimated that from 1993 to 2006 raw dairy consumption resulted in at least 1,600 illnesses, 202 hospitalizations and 2 deaths.
- Almost 90% of raw milk associated outbreaks have occurred in states that permit legal raw milk sales.
- One reason for the abysmal safety record of raw milk is the virtual impossibility of ensuring that milk taken from cows in a farm environment is free of dangerous bacteria. Surveys of farm milk on dairies show up to 32% contamination with pathogens such as Salmonella and E. coli.
- Even well cared for, healthy appearing cows raised organically on pasture can harbor pathogens such as E. coli O157:H7 (see attached NMC paper).
- Raw milk consumption by children, the elderly and the immune compromised represents an immediate health threat, not only to consumers of raw milk products but to others in close association with them. The phenomenon of "secondary infection" to family, friends and caregivers is well established in raw milk outbreak case files.
- A list position statements from various public health groups on raw milk (such as the American Academy of Pediatrics and the Food, the American Medical Association and the Food and Drug Association can be found here: <http://www.realrawmilkfacts.com/position-statements/>

Thank you for your interesting submission and if you decide you need any additional information please don't hesitate to contact me.

Michael.

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