

# **Unpasteurized Milk Outbreaks: An Assessment of the Legal Landscape, Outbreak Investigations, and Prevention at the State Level**

OSTLTS Generic Information Collection Request  
OMB No. 0920-0879

## **Supporting Statement – Section A**

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- **Purpose of the data collection:** The purpose of this data collection is to assess how state health and agriculture officials prevent outbreaks linked to unpasteurized milk consumption and barriers to prevention through assessment of the legal landscape, outbreak investigations, and other outbreak prevention work. In addition to current prevention work, this survey will assess the capacity these departments have to conduct prevention initiatives surrounding this topic.
- **Intended use of the resulting data:** The Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) will use this information to learn about the current work conducted at state health and agriculture departments to prevent outbreaks linked to unpasteurized milk consumption, barriers to outbreak prevention, and identify state capacity to conduct prevention initiatives. This information will be used to identify how DFWED can better support state prevention work through improved guidance to states and communication materials.
- **Methods to be used to collect data:** Data will be collected via electronic assessment, which will be emailed to participants.
- **Respondent Universe:** Data will be collected from 700 respondents across state health and agriculture departments with knowledge of unpasteurized milk outbreak response and prevention efforts in 50 states and the District of Columbia. Respondents acting in their official capacities include foodborne disease epidemiologists and environmental health specialists.
- **How data will be analyzed:** Data analysis will consist of descriptive statistics and will be run examining response frequencies.

## Section A – Justification

### 1. Circumstances Making the Collection of Information Necessary

#### Background

This information collection is being conducted using OMB No. 0920-0879 “Information Collections to Advance State, Tribal, Local and Territorial Governmental Agency System Performance, Capacity, and Program Delivery” nicknamed the “CSTLTS Generic.” The respondent universe for this information collection aligns with that of the CSTLTS Generic. Data will be collected from up to 700 respondents across state health and agriculture departments with knowledge of unpasteurized milk outbreak response and prevention efforts in 50 states and the District of Columbia. Respondents acting in their official capacities include food safety epidemiologists and environmental health specialists.

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). This information collection falls under the essential public health service(s) of

- 1. Monitoring health status to identify community health problems
- 2. Diagnosing and investigating health problems and health hazards in the community
- 3. Informing, educating, and empowering people about health issues
- 4. Mobilizing community partnerships to identify and solve health problems
- 5. Development of policies and plans that support individual and community health efforts
- 6. Enforcement of laws and regulations that protect health and ensure safety
- 7. Linking people to needed personal health services and assure the provision of health care when otherwise unavailable
- 8. Assuring a competent public health and personal health care workforce
- 9. Evaluating effectiveness, accessibility, and quality of personal and population-based health services
- 10. Research for new insights and innovative solutions to health problems <sup>1</sup>

Illness outbreaks of enteric pathogens, such as *Campylobacter* and *Salmonella*, linked to consumption of unpasteurized milk have continued to increase in the United States over the past decade. It has been recommended that public health officials should continue to educate both legislators and consumers about the dangers associated with the consumption of unpasteurized milk, and federal and state regulators should continue to enforce existing regulations to prevent the distribution of unpasteurized milk.<sup>1</sup>

Interstate sale of unpasteurized milk for direct human consumption is illegal; at the state level, laws governing unpasteurized milk sales vary, and this can impact the ability of state health and agriculture agencies to prevent and respond to outbreaks associated with unpasteurized milk. With the legal context of unpasteurized milk sales and distribution varying from state to state it can be difficult to assess what is contributing to an increase of outbreaks. In addition to varying state laws, in some studies, consumers of unpasteurized milk were more likely to be less educated than non-drinkers, implying there is an increasing demand for consumer education as outbreaks linked to unpasteurized milk consumption continue to trend upwards.<sup>2,3</sup> Currently it is unknown how state health and agriculture departments are working to prevent outbreaks linked to the consumption of unpasteurized milk across varying state legislation and what needs they may have to effectively prevent additional outbreaks. .

The purpose of this data collection is to assess how state health and agriculture officials prevent outbreaks linked to unpasteurized milk consumption and barriers to prevention, through assessment of the legal landscape, outbreak investigations, and other outbreak prevention work. In addition to current prevention work, this survey will also assess the capacity and needs these departments have in conducting prevention initiatives surrounding this topic.

Data will be used by Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) to assess the current work conducted at state health and agriculture departments to prevent outbreaks linked to unpasteurized milk consumption, barriers to outbreak prevention, identify

state capacity to conduct prevention initiatives, and identify how DFWED can better support state prevention work.

This data will be analyzed and prepared into a report by a staff and fellows within DFWED, including a fellow with Oak Ridge Associated Universities (ORAU). DFWED already works with ORAU through training of fellows on a variety of projects, including outbreak response efforts, health communications, and various other projects.

### **Overview of the Information Collection System**

Data will be collected up to 700 respondents across state health and agriculture departments in 50 states and the District of Columbia via web assessment (see **Attachment A—Unpasteurized Milk Outbreak Prevention Survey (Screenshots)** and **Attachment B—Unpasteurized Milk Outbreak Prevention Survey (Word)**). State health and state agriculture personnel with foodborne and environmental health responsibilities will be emailed the survey link and will be asked to forward the survey to other state representatives with knowledge of the survey content. Respondents acting in their official capacities include food safety epidemiologists and environmental health specialists. The instrument is designed to assess current prevention work at state health and agriculture departments surrounding outbreaks linked to unpasteurized milk consumption. In addition to current prevention work, this survey will assess the capacity and needs these departments have to conduct prevention initiatives surrounding this topic.

The information collection instrument was reviewed by 7 state health epidemiologists and 2 state agriculture environmental health specialists for feedback on the relevance and clarity of the questions. Official pilot testing was done by 5 CDC public health professionals. Feedback from the pilot testers was used to ensure accurate programming and skip patterns, and establish the estimated time required to complete the information collection instrument.

### **Items of Information to be Collected**

The data collection instrument consists of 39 main questions of various types, including dichotomous (yes/no), multiple response, interval (rating scales), and open-ended. An effort was made to limit questions requiring narrative responses from respondents whenever possible. The instrument will collect data on the following:

- Legal context of unpasteurized milk sales and distribution
- Response process for outbreak investigations
- Current and future prevention initiatives

## **2. Purpose and Use of the Information Collection**

The purpose of this data collection is to assess how state health and agriculture officials prevent outbreaks linked to unpasteurized milk consumption and barriers to prevention through assessment of the legal landscape, outbreak investigations, and other outbreak prevention

work. This survey will also assess the capacity these departments have to conduct prevention initiatives surrounding this topic.

DFWED will use this information to learn about the current work conducted at state health and agriculture departments to prevent outbreaks linked to unpasteurized milk consumption, barriers to outbreak prevention, identify state capacity to conduct prevention initiatives, and identify how DFWED can better support state prevention work.

### **3. Use of Improved Information Technology and Burden Reduction**

Data will be collected via a web-based assessment. This method was chosen to reduce the overall burden on respondents by allowing respondents to complete the survey anywhere and at any time. The data collection instrument was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 39 questions).

### **4. Efforts to Identify Duplication and Use of Similar Information**

The information gathered through this data collection request is not available from other data sources or through other means nor does it duplicate any information currently being collected. No assessments past or planned have assessed the prevention capacity at state health and agriculture departments for outbreaks linked to unpasteurized milk consumption. This project is being done in conjunction with a legal assessment completed by the CDC Public Health Law Program. This information collection is intended to compliment the legal assessment through the collection of information that is unable to be captured by the legal assessment. The Public Health Law Program has reviewed the data collection instrument and has provided feedback on the questions to ensure there is no duplication of information collected.

### **5. Impact on Small Businesses or Other Small Entities**

No small businesses will be involved in this information collection.

### **6. Consequences of Collecting the Information Less Frequently**

This request is for a one time data collection. There are no legal obstacles to reduce the burden. If no data are collected, CDC will be unable to:

- Identify current prevention work at state health and agriculture departments around outbreaks associated with unpasteurized milk
- Assess state capacity to conduct prevention projects around unpasteurized milk outbreaks
- Identify how DFWED can better support state efforts to prevent unpasteurized milk outbreaks

### **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

There are no special circumstances with this data collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

#### **8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

This data collection is being conducted using the Generic Information Collection mechanism of the CSTLTS Generic Information Collection Service (CSTLTS Generic) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on April 27, 2017, Vol. 82, No. 80, pp 19371-19373. One non-substantive comment was received. CDC sent forward the standard CDC response.

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

#### **9. Explanation of Any Payment or Gift to Respondents**

CDC will not provide payments or gifts to respondents.

#### **10. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

The Privacy Act does not apply to this data collection. STLT governmental staff and / or delegates will be speaking from their official roles.

This data collection is not research involving human subjects.

#### **11. Institutional Review Board (IRB) and Justification for Sensitive Questions**

No information will be collected that are of personal or sensitive nature.

#### **12. Estimates of Annualized Burden Hours and Costs**

The estimate for burden hours is based on a pilot test of the data collection instrument by 5 CDC public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 15 minutes (range: 10–20). For the purposes of estimating burden hours, the upper limit of this range (i.e., 20 minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) Bureau of Labor Statistics for occupational employment for Epidemiologists (19-1012) and Environmental Scientists and Specialists, Including Health (19-2041) [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm). Based on DOL data, an average hourly wage of \$36.39 is estimated for 500 epidemiologist respondents and \$37.30 is estimated for 200 environmental health specialists. Table A-12 shows estimated burden and cost information.

There will be a total of 700 respondents and 700 responses.

**Table A-12:** Estimated Annualized Burden Hours and Costs to Respondents

Data collection Instrument: Form Name	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Unpasteurized Milk Outbreak Prevention Survey	State health epidemiologists	500	1	20 / 60	167	\$36.39	\$6,077
	State agriculture environmental health specialists	200	1	20 / 60	67	\$37.30	\$2,499
	<b>TOTALS</b>	<b>700</b>	<b>1</b>		<b>234</b>		<b>\$8,576</b>

### 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no direct costs to the respondents other than their time to participate in each data collection.

### 14. Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government would be the salary of CDC staff and fellows to develop the data collection instrument, collect data, and perform data analysis. The total estimated cost to the federal government is \$2,201. Table A-14 describes how this cost estimate was calculated.

**Table A-14:** Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Total Average Cost
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<b>Prevention Team Lead – GS-13 Step 4</b> Development of survey tool, dissemination of survey tool, plan and implement data collection/analysis	20	\$50.66 /hour	\$1,013
<b>Behavioral Scientist/ORAU-</b> Development of survey tool, data analysis and report preparation	40	\$29.70 / hour	\$1,188
<b>Estimated Total Cost of Information Collection</b>			<b>\$2,201</b>

### 15. Explanation for Program Changes or Adjustments

This is a new data collection.

### 16. Plans for Tabulation and Publication and Project Time Schedule

Information collected from the online survey will be stored in a secure environment on the password-protected computers of DFWED staff and on secure CDC servers. Once the survey is closed, responses will be downloaded from EpiInfo. Data analysis will consist of descriptive statistics and will be run examining response frequencies. Following analysis of responses, key findings will be shared in aggregate form with project staff and DFWED senior leadership. Findings may also be disseminated through presentations at foodborne-outbreak and health communication meetings and manuscript publication in scientific journals. Data collected will inform capacity building to inform and improve prevention initiatives aimed at decreasing outbreaks linked to the consumption of unpasteurized milk by 1) Identifying current prevention work at state health and agriculture departments 2) Assessing state capacity to conduct prevention projects, and 3) Identifying how DFWED can better support state prevention work.

#### Project Time Schedule

- ✓ Design instrument ..... (COMPLETE)
- ✓ Develop protocol, instructions, and analysis plan ..... (COMPLETE)
- ✓ Pilot test instrument ..... (COMPLETE)
- ✓ Prepare OMB package ..... (COMPLETE)
- ✓ Submit OMB package ..... (COMPLETE)
- OMB approval ..... (TBD)
- Conduct data collection ..... (Open 4 weeks)
- Conduct quality control and analyze data..... (2 months)
- Prepare summary report(s) ..... (1 month)
- Disseminate results/report ..... (1 month)

### **17. Reason(s) Display of OMB Expiration Date is Inappropriate**

We are requesting no exemption.

### **18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

## **LIST OF ATTACHMENTS – Section A**

Note: Attachments are included as separate files as instructed.

- A. Attachment A – Unpasteurized Milk Outbreak Prevention Survey (Screenshots)**
- B. Attachment B – Unpasteurized Milk Outbreak Prevention Survey (Word)**

## **REFERENCE LIST**

1. Centers for Disease Control and Prevention (CDC). "National Public Health Performance Standards Program (NPHPSP): 10 Essential Public Health Services." Available at <http://www.cdc.gov/nphpsp/essentialservices.html>. Accessed on 8/14/14.
2. Buzby JC, Gould LH, Kendall ME, Jones TF, Robinson T, Blayney DP. Characteristics of consumers of unpasteurized milk in the United States. J Consum Aff. 2013 Jan 7; 47(1):153-66.
3. Headrick ML, Timbo B, Klontz KC, & Werner SB. Profile of raw milk consumers in California. Public Health Rep. 1997 Sep; 112(5):418-422.