

## Reason for Proposal (Include significant policy and programmatic impacts)

To provide consumers with information so they can make an informed decision about purchasing and consuming Retail Raw Milk (unpasteurized milk). Retail raw milk is a raw animal food similar to meat and eggs. Unlike meat and eggs Retail Raw Milk is intended to be consumed without cooking. Because of the similarity between Retail Raw Milk and pasteurized milk, consumers may be confused and believe that these products are as safe to consume or to serve to children as pasteurized milk. The department wishes to replace the current consumer advisory, **“Raw milk is not pasteurized, pasteurization destroys organisms that may be harmful to human health.”** with **“Warning: Raw Milk has not been pasteurized and may contain harmful bacteria. Pregnant women, children, the elderly and persons with lowered resistance to disease have the highest risk of harm from use of this product.”** The consumer advisory we propose is stronger than the current advisory and similar to Washington State’s.

Numerous scientific studies and food borne illness outbreaks associated with unpasteurized milk, conclusively prove that Retail Raw Milk, at any time, may contain one or more species of pathogenic bacteria. These human pathogens include but are not limited to: *Listeria monocytogenes*, *Salmonella spp*, *enterohemorrhagic Escherichia coli*, *Yersinia enterocolita*, *Campylobacter jejuni* and *Staphylococcus aureus*, which, in high enough quantities produces a toxin that results in food poisoning. Pregnant women, children, the elderly and immune compromised individuals are most susceptible to contracting an illness through the consumption of Retail Raw Milk.

The Department believes it is a prudent step to limit sales of Retail Raw Milk to “on farm” sales only. Retail Raw Milk packaging and appearance is similar to pasteurized milk products. The department believes that consumers may be confused by these similarities especially because Retail Raw Milk is presented to the consumer in much the same manner as pasteurized milk or presented to the consumer in a display case along side pasteurized milk. Consumers who are unfamiliar with Retail Raw Milk and the potential health consequences may believe that Retail Raw Milk is as safe for their children or themselves as pasteurized milk. Only a very small number of consumers of milk purchase retail raw milk. Currently there are 14 producers licensed to produce Retail Raw Milk in Connecticut. Approximately seventy eight million (78,000,000) gallons of pasteurized milk is consumed in this state each year. Retail raw milk producers in this state market approximately one hundred seventy-five thousand (175,000) gallons of milk a year or .22% of the all the milk sold in this state.

### ADDITIONAL BACKGROUND:

A June/July 2008 food borne illness outbreak in Connecticut was caused by a shiga toxin producing enterohemorrhagic *E. coli* O157 specifically *E. coli* O157:NW. A genetic fingerprint match definitively linked Retail Raw Milk produced by a permitted Retail Raw Milk producer to this outbreak. This producer went beyond the current testing requirements and weekly on their own had samples of their Retail Raw Milk analyzed at a private laboratory. Their own test results revealed elevated levels of Coliform bacteria and they voluntarily stopped the sale of Retail Raw Milk the week before DAG was notified by DPH epidemiologists of the possible association between 2 reported cases of Hemolytic Uremic Syndrome (HUS) and milk produced by the farm. DAG monthly regulatory samples taken in June 2008 were not in violation of our Coliform bacteria standard and coincidentally a regulatory sample taken July 10<sup>th</sup> 2008 (before we knew of the outbreak and after the sickened individuals had purchased milk) to determine if the farm could resume selling Retail Raw Milk did exceed our Coliform bacteria standard. The sample results (the farm’s own late June and early July samples and the department’s July 10<sup>th</sup>, 2008 sample) that indicated a potential problem were obtained after the sickened individuals had purchased and consumed the tainted Retail Raw Milk.

The Retail Raw Milk was purchased by consumers from the farm itself and from 3 retail locations during the month of June and early July 2008. Two of the retail locations where the retail Raw Milk was purchased were owned by a major natural foods retailer. The contaminated Retail Raw Milk resulted in 7 confirmed illnesses and 7 illnesses strongly linked to the Retail Raw Milk, for a total of 14, which includes 1 secondary and 1 tertiary case linked to one of the confirmed cases. Several sickened individuals, children and adults required hospitalization.

Enterohemorrhagic *E. Coli* O157 infections can cause disorders known as Hemolytic Uremic Syndrome (HUS) and Thrombotic Thrombocytopenic Purpura (TTP). HUS is a disorder that occurs when an infection in the digestive system produces toxic substances that destroy red blood cells. It often affects the kidneys. This disorder is most common in children. It often occurs after a gastrointestinal (enteric) infection, which is often caused by *E. coli* O157:H7. Unpasteurized (Raw) milk has been associated with several outbreaks of *E. coli* O157 infections in the U.S. Other outbreaks of *E. coli* O157:H7 have been associated with undercooked or raw hamburger (ground beef), unpasteurized fruit juices, alfalfa sprouts, dry-cured salami, lettuce, game meats and from transmission from animals to humans from contact with infected animals. HUS also can be caused by other enteric infections, including Shigella and Salmonella, and some non-enteric infections. Patients with TTP have clinical and pathologic features similar to patients with HUS.

The investigation by DAG of this food borne illness outbreak involved 6 DAG staff at various times, took 136 total man-hours, 26 hours of overtime at an approximate cost of \$3200 and resulted in 169 samples of various types (milk, fecal, environmental) being analyzed which cost approximately \$3600. DAG found no significant deficiencies in the management and sanitation practices of this Retail Raw Milk dairy. DAG ultimately obtained a genetic fingerprint match between *E. coli* O157:NM isolated from the feces of 1 animal that was being milked at the time the sick individuals obtained the Retail Raw Milk and *E. coli* O157:NM isolated from several of the sick individuals.

In addition to Enterohemorrhagic *E. Coli* a human pathogen known as *Listeria monocytogenes* is routinely found in unpasteurized milk. *Listeria monocytogenes* is a bacterium commonly found in soil, stream water, sewage, plants, and food. *Listeria monocytogenes* is the bacteria responsible for listeriosis, a rare but sometimes lethal food-borne infection that has a fatality rate approaching 25%. (Salmonella, in comparison, is less than 1%). The Listeria organism is very hardy and able to grow in temperatures ranging from 4°C (39°F) (the temperature of a refrigerator) to 37°C (99°F) (the body's internal temperature). Furthermore, listeriosis's deadliness can be partially attributed to the infection's ability to spread to the nervous system and cause meningitis. Finally, Listeria has a particularly high occurrence rate in newborns because of its ability to infect the fetus by penetrating the placenta. In infections during pregnancy, the mother usually survives.

*L. monocytogenes* has been associated with such foods as unpasteurized milk and improperly processed milk, improperly processed cheeses (particularly soft ethnic varieties), raw vegetables, raw and undercooked poultry, raw meats (all types), and raw and smoked fish.

Due to the outbreak described DAG conducted a thorough review of scientific literature. Additionally we consulted with experts at the University of Connecticut and Cornell University. A few recent notable outbreaks of food borne illnesses linked to the consumption of unpasteurized milk:

- 2000 N. Carolina, Ethnic cheese manufactured from unpasteurized Milk, Listeria, 12 ill, 11 were women, median age 21**
- 2005 Washington State, Unpasteurized Milk, E. Coli O157:H7 18 ill, median age 9**
- 2006 California, Unpasteurized Milk, E. coli O157:H7, 6 ill, median age 8**
- 2006, Illinois, Ethnic cheese manufactured from unpasteurized Milk, Multidrug-Resistant Salmonella, 85 ill, median age 34**
- 2008 California, Unpasteurized Milk, Campylobacter, 15 ill**
- 2008 Connecticut, Unpasteurized Milk, E. coli O157:NM, 14 ill, median age 2**

These proposed standards attempt to balance the very real threat that consumption of Retail Raw Milk poses to public health. The proposed new standards are consistent with standards used in New York state and are similar to those in California and Washington state. Currently our regulations have retail raw milk bacteria standards for routine milk quality indicators which include the standard plate loop count ( $\leq 30,000/\text{ml}$ ), thermotolerant bacteria plate count ( $\leq 1,000/\text{ml}$ ), coliform bacteria count ( $\leq 50/\text{ml}$ ), direct microscopic somatic cell count ( $\leq 750,000/\text{ml}$  cattle,  $\leq 1,000,000/\text{ml}$  goats), added water (none), temperature ( $\leq 40^\circ\text{F}$ ) and drug residues (none above tolerance). The proposed new standards are intended to be more protective of human health.

Currently the department samples all Retail Raw Milk quarterly for the presence of pathogens and the DPH laboratory analyzes these samples. The sampling frequency for human pathogens is inadequate to conduct meaningful surveillance on Retail Raw Milk when in many cases the quarterly sample represents only 1 out of 90 potential batches of Retail Raw Milk a farm may produce during that quarter. Other monthly sampling and analysis for routine quality indicators required by regulation will remain the same. The proposed new standards supplement the existing standards.

Scientific literature suggests that most common method of introduction of human pathogens into Retail Raw Milk is from contamination of the milk from infected or carrier animals shedding human pathogens in their feces. While good management practices can reduce and minimize the potential for contamination the very nature of a farm environment and species of animals producing Retail Raw Milk makes eliminating contamination impossible. In general the department does believe the management and sanitation practices of our Retail Raw Milk producers is exceptional. We believe fecal analysis will provide better information and will aid producers of Retail Raw Milk to identify animals shedding pathogens and take appropriate measures to protect human health.

The presence of Coliform bacteria in milk may be an indication of an infection of the mammary system, poor sanitation and/or contamination by fecal matter. Fecal coliform bacteria namely *Escherichia coli* (generic *E. coli*) bacteria are not normally present in milk, their presence in unpasteurized milk means it is extremely likely the retail raw milk was contaminated by fecal matter. The infective dose of shiga toxin producing *E. Coli O157* is thought to be as few as 10 organisms. *Staphylococcus aureus* bacteria present in retail raw milk in quantities above 100,000 per ml. may result in sufficient enterotoxin formation to cause food poisoning. The proposed new standards for fecal coliform (generic *E. Coli*) and *Staphylococcus aureus* similar to New York state's standard.

The Connecticut Department of Agriculture, Connecticut Department of Public Health and the Food and Drug Administration, and other public health authorities such as the American Medical Association, the American Academy of Pediatrics, the National Conference on Interstate Milk Shipments, the National Association of State Departments of Agriculture, the Association of Food and Drug Officials, and National Association of State Public Health Veterinarians all oppose the consumption of unpasteurized milk because of the health risks.

The fact that Retail Raw Milk is easily contaminated with pathogens from the feces of infected animals is intended to be consumed without cooking and that it is consumed by children makes it particularly dangerous. No amount of sampling and testing can ensure the safety of Retail Raw Milk because the sample is only snapshot of the conditions at the time the sample was taken. Because of the time it takes to take samples and, analyze the sample and obtain results, sampling and testing can only retrospectively assess what was contained in the retail raw milk. Imposing stricter standards cannot eliminate the threat. Increasing the surveillance and testing of Retail Raw Milk and, stricter standards are prudent and reasonable in order to limit exposure to the consumption of human pathogens.

11/14/08

## Significant Fiscal Impacts

**Municipal:** None

**Federal:** None

**State:** None

## An Act Concerning Raw Milk

1           **Section 1. Sec. 22-173a. Registration of retail raw milk producers and retail**  
2 **raw milk cheese manufacturers. Consumer advisory. Denial, suspension and**  
3 **revocation of permits. Cheese manufacturing. Regulations.** (a) No person, firm or  
4 corporation shall engage in the production of retail raw milk or the manufacture of retail  
5 raw milk cheese, which retail raw milk or retail raw milk cheese or the products thereof  
6 are to be used or disposed of elsewhere than on the premises where such retail raw milk  
7 or retail raw milk cheese is produced, without first registering with the Commissioner of  
8 Agriculture in a manner prescribed and on forms furnished by the commissioner for such  
9 registration. Such registration may be renewed annually not later than the thirtieth day of  
10 June. The commissioner shall establish fees for such registration pursuant to section 22-  
11 128a.

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13           (b) Registrations required pursuant to subsection (a) of this section shall be  
14 designated "Retail Raw Milk Producer Permit" or "Retail Raw Milk Cheese Manufacturer  
15 Permit" and may be denied, suspended or revoked by the commissioner for cause.

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17           (c) Retail raw milk shall only be offered for sale in its unprocessed state, with no  
18 ingredients added or removed.

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20           (d) The manufacturing of cheese from unpasteurized milk shall be conducted only  
21 on premises and by firms or individuals authorized by the commissioner to produce retail  
22 raw milk.

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24           (e) The Milk Regulation Board [shall] may adopt regulations, in accordance with  
25 the provisions of chapter 54[, establishing standards for sanitation, production, sale,  
26 labeling, handling and storage of retail raw milk and the manufacture of raw milk  
27 cheeses] to carry out the provisions of this section.

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29           (f) A consumer advisory shall be placed on all containers of retail raw milk as  
30 follows:

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32           (1) Each container of retail raw milk shall be labeled with the following consumer  
33 advisory "Warning: Raw Milk has not been pasteurized and may contain harmful  
34 bacteria. Pregnant women, children, the elderly and persons with lowered resistance to  
35 disease have the highest risk of serious illness from use of this product."

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37           (2) The consumer advisory stated on the label shall comply with the following:  
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39 (A) be prominently printed on the principal display panel of each container of retail  
40 raw milk or when it is impractical, the consumer advisory shall be securely affixed to the  
41 container by a hang tag;

42 (B) be a type face not less than one-eighth (1/8) inch in height, conspicuous and in  
43 contrasting color from other labeling and the background color; and

44 (C) be clearly legible.

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46 (3) Wherever retail raw milk is offered for sale or sold, a sign displaying a  
47 consumer advisory shall be posted in plain view within five (5) feet of any cooler, product  
48 display, refrigerated storage case or location where retail raw milk is accessed by  
49 consumers. The posted consumer advisory shall comply with the following:

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51 (A) The posted consumer advisory shall state "Warning: Raw Milk has not been  
52 pasteurized and may contain harmful bacteria. Pregnant women, children, the elderly  
53 and persons with lowered resistance to disease have the highest risk of serious illness  
54 from use of this product.";

55 (B) the posted consumer advisory shall be at least eight and one-half inches by  
56 eleven inches (8 1/2 x 11);

57 (C) the lettering of the posted consumer advisory shall be in a typeface at least  
58 one-half (1/2) inch tall, in contrasting color to the background; and

59 (D) shall be clearly legible.

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61 (g) Retail raw milk shall only be sold or, offered for sale, transferred, exchanged or  
62 bartered on the premises where the retail raw milk is produced.

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65 **Section 2. (NEW) Testing and Analyzing Retail Raw Milk and Animals Producing**  
66 **Retail Raw Milk. Standards.**

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68 (a) Each retail raw milk producer permitted pursuant to section 22-173a at their own  
69 expense shall test and have analyzed retail raw milk and animals producing retail  
70 raw milk as follows.

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72 (1) each month a comingled sample of retail raw milk representing all the retail raw  
73 milk produced shall be tested for the presence of *Listeria monocytogenes*,  
74 *Salmonella* spp., enterohemorrhagic *Escherichia coli*, *Yersinia enterocolita*,  
75 *Campylobacter jejuni*, fecal coliform and *Staphylococcus aureus* bacteria;

76 (2) on a quarterly basis, a feces specimen from each milking aged animal shall be  
77 tested for the presence of *Listeria monocytogenes*, *Salmonella* spp.,  
78 enterohemorrhagic *Escherichia coli*, *Yersinia enterocolita* and *Campylobacter*  
79 *jejuni*.

80 (3) all samples and specimens shall be taken, prepared and sealed by the  
81 commissioner's designee; and

82 (4) all samples and specimens shall be tested or analyzed in a laboratory acceptable  
83 to the commissioner or the commissioner's designated agent. Each laboratory  
84 performing testing or analysis pursuant to this section shall report the results of  
85 all tests or analysis promptly to the commissioner or the commissioner's  
86 designated agent, such report shall be in a manner and form acceptable to the  
87 commissioner or the commissioner's designated agent;

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89 (b) The fecal coliform count in retail raw milk shall not exceed ten (10) per milliliter.

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91 (c) The *Staphylococcus aureus* count in retail raw milk shall not exceed one hundred  
92 thousand (100,000) per milliliter.

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- 94 (d) For the purposes of section 22-129a, the presence of any human pathogen in retail  
95 raw milk or violation of subsections (b) or (c) of this section shall constitute  
96 adulteration of the retail raw milk.  
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- 98 (e) Whenever any animal producing retail raw milk is found positive for the presence of a  
99 human pathogen, such animal shall be quarantined on the premises of the retail raw  
100 milk producer. Any retail raw milk produced by such animal shall be discarded. At the  
101 owner's expense a licensed veterinarian shall examine the quarantined animal and if  
102 necessary treat the cause of the infection. The quarantine shall be released when  
103 the commissioner or the commissioner's designated agent determines that the  
104 animal no longer poses a threat to public health but not before a subsequent test is  
105 negative for human pathogens.  
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- 107 (f) Nothing in this section shall be construed to limit or prevent the commissioner or the  
108 commissioner's designated agent from obtaining and testing any sample or  
109 specimen.  
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- 111 (g) After July 1, 2009, any individual or entity applying for a permit to produce retail raw  
112 milk pursuant to section 22-173a shall at their own expense have two (2) separate  
113 samples of retail raw milk collected in two (2) consecutive weeks and one set of fecal  
114 specimens from each milking aged animal, tested in accordance with this section  
115 and the Regulations of Connecticut State Agencies. No permit required by section  
116 22-173a shall be issued to a new retail raw producer until all required tests, analysis,  
117 inspections and examinations are complete and comply with this chapter and the  
118 Regulations of Connecticut State Agencies.  
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- 120 (h) No permit required by section 22-173a shall be renewed unless all testing and  
121 analysis required in this section is complete and the last available test result  
122 complies with this chapter and the Regulations of Connecticut State Agencies.  
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- 124 (i) The commissioner may adopt regulations in accordance with the provisions of  
125 chapter 54 to carry out the provisions this section.  
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127 **Section 3. Sec. 22-203a. Testing of milk and milk products for drug residues or**  
128 **other inhibitory substances. Maintenance of records.** (a) Any person, firm or  
129 corporation engaged in receiving, handling, processing or packaging milk or milk  
130 products shall test each tank truck load of milk or milk products for the presence of drug  
131 residues or other inhibitory substances upon receipt of such milk or milk product at the  
132 receiving plant prior to processing. In the case of interplant shipments of bulk milk or milk  
133 products, each bulk tank load, or portion thereof, shall be tested prior to processing for  
134 the presence of drug residues or other inhibitory substances. The Commissioner of  
135 Agriculture or the commissioner's designated agent may require a [milk  
136 producer]producer of milk for pasteurization holding a permit issued under section 22-  
137 172 or a retail raw milk producer holding a permit issued under section 22-173a [who  
138 violates section 22-129 to test milk produced by him for]whose milk is tested and found  
139 to be positive for the presence of drug residues or inhibitory substances to test milk  
140 produced on their farm for the presence of drug residues or inhibitory substances prior to  
141 shipment. For purposes of this section and sections 22-203b to 22-203d, inclusive,  
142 "drug" means (1) articles recognized in the Official United States Pharmacopoeia,  
143 Official Homeopathic Pharmacopoeia of the United States, or Official National  
144 Formulary, or any supplement to any of them; (2) articles intended for use in the  
145 diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals;  
146 (3) articles, other than food, intended to affect the structure or any function of the body of  
147 man or other animals; or (4) articles intended for use as a component of any articles  
148 specified in subdivision (1), (2) or (3), but does not include devices or their components,  
149 parts or accessories.

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(b) Any test administered pursuant to this section shall be approved by the Commissioner of Agriculture and shall be capable of determining compliance with [standards for]the drug residue tolerance levels recommended by the United States Food and Drug Administration. Any test approved by the commissioner shall be rapid and economically feasible and shall be performed at a facility or location and in a manner acceptable to the commissioner. The results of any test required shall be recorded by the person administering such test and kept on file at the location where the test was conducted or at the processing plant for not less than two years.

(c) ~~[Each retail]~~Retail raw milk ~~[producer]~~producers and intrastate ~~[dealer]~~milk dealer's with ~~[ten]~~twelve or fewer milking[ age] animals shall be exempt from this section provided they maintain records[,] which shall available for inspection by the commissioner[,] or the commissioner's designee[, for each individual animal treated with a drug]and such records are kept in a manner and form acceptable to the commissioner or the commissioner's designated agent. Such records shall include the identification of the treated animal, name of the drug or drugs administered, withdrawal time required for each drug, treatment dates, and, after completion of such treatment, the date such animal's milk is offered for sale. ~~[Retail raw milk producers and intrastate dealers with more than ten milking age animals shall comply with this section.]~~

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