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Farm-to-Consumer Legal Defense Fund

Legal Representation ◆ Political Action ◆ Education

September 29, 2009

Attn: Paul Hoge
Pennsylvania Department of Agriculture
Bureau of Food Safety
Division of Milk Sanitation
2301 North Cameron Street
Harrisburg, PA 17110-9408

Dear Mr. Hoge:

The Farm-to-Consumer Legal Defense Fund (FTCLDF) submits the following comments on PDA's proposed regulations under the milk sanitation laws. The FTCLDF is a non-profit organization made up of farmers and consumers joining together and pooling resources to protect the constitutional right of the nation's family farms to provide processed and unprocessed farm foods directly to consumers through any legal means, and to protect the constitutional right of consumers to obtain unprocessed and processed farm foods directly from family farms. The FTCLDF has both farmer and consumer members in the state of Pennsylvania, as well as other concerned members in neighboring states. On behalf of our members, we urge the agency to address the issues listed below.

I. Change "test for pathogens" to "test for pathogens that cause illness in humans"

Several sections in the proposed regulations require that the milk be tested for "pathogenic bacteria" or refer to "disease causing organisms." *See* 59a.404(e)(1)(v) ("no pathogenic bacteria" may be present); 59a.409(d), (d)(4) & (d)(5) (requires testing for "pathogenic bacteria or other disease-producing organisms" and then lists some pathogens).

Not all "pathogens" or "organisms" cause illness in humans. It is not reasonable to use state resources to test for things that don't cause illness in people and that therefore pose no public health threat. Shutting down a farmer for something that poses no human health risk hurts the farmer, the consumers, and the local economy.

In addition, the proposed regulatory language implies a scientifically unachievable standard of zero tolerance. Laboratories do not report that there are "no pathogens present," because that is a false finding. Laboratories use phrases like "none found" or "none within detectable limits."

The FTCLDF urges the agency to specify that the testing is for "pathogens that cause illness in humans" and use language consistent with standard laboratory procedure. The relevant sections would thereby read as follows:

59a.404(e)(1)(v): If the first of the three required samples is tested as described in subparagraph (iii), and concludes that no pathogenic bacteria that cause illness in humans are ~~present~~ detected, the second and third samples need not be tested for the presence of pathogenic bacteria that cause illness in humans. If a sample test concludes that there are pathogenic bacteria that cause illness in humans ~~are present~~, a raw milk permit will not be issued until two separate consecutive tests for pathogenic bacteria that cause illness in humans, from samples drawn at least 7 days apart, show none detected ~~conclude that no pathogenic bacteria are present.~~

And

§ 59a.408 (last item in table):

At least twice annually	Test for pathogenic bacteria ~~including Salmonellae, *Lysteria monocytogenes*, *Campylobacter*, and *E. Coli* O157:H7.~~ Samples shall be collected from the bulk tank	There may be no detectable pathogenic bacteria that cause illness in humans ~~present~~

and

59a.409(d): Disease-producing organisms. If a raw milk sample tests positive for ~~the presence of~~ pathogenic bacteria that cause illness in humans ~~or other disease-producing organisms such as Salmonellae, Listeria monocytogenes, Camphylobacter or E. Coli O157:H7~~, the raw milk permitholder shall do the following:

....

(4) Following the initial sampling described in the preceding requirement, have an approved sampler collect an additional sample, at least 1 day after the previous sample, and submit it to a Pennsylvania-approved dairy laboratory for testing for ~~the presence of~~ pathogenic bacteria that cause illness in humans.

(5) Refrain from selling raw milk until and unless two consecutive tests, from samples drawn at least 1 day apart, show that raw milk produced at the dairy operation that is the subject of the raw milk permit does not contain detectable ~~is free from~~ human-disease-producing organisms~~, and~~. ~~t~~The Department ~~reviews these test results and~~ shall approves the resumption of raw milk sales after reviewing the test results.

II. Exempt direct farm-to-consumer transactions from state regulation

The FTCLDF contends that direct farm-to-consumer transactions are not within the agency's jurisdiction. The U.S. Supreme Court has repeatedly found that there is a fundamental right to the integrity of one's own body and to the custody and care of one's children. Individuals thus have the right to obtain the food of their choice from the source of their choice, whether that source is licensed or not.

The FTCLDF urges PDA to acknowledge the limited scope of the regulatory provisions by adding the following section:

> Section 59a.____. This chapter does not apply to direct transactions between a producer and a consumer. Direct transactions between a producer and a consumer, including but not limited to the sale, offer for sale, or other distribution of raw milk and value-added raw dairy products, are exempt from regulation.

This change not only respects individuals' constitutional rights, but is good public policy. Direct transactions between the producer and the consumer do not impact the "public's" health, safety or welfare and are purely private in nature. People who know the producer of their food and have the opportunity to look at that producer's operation can make an informed decision on whether to buy from that producer.

Sales of raw dairy products directly to the consumer and directly to members of private buyers clubs have been a boon to the Pennsylvania economy. The increased sales would also provide increased tax revenues for the State. Particularly with the current crisis facing dairies in this country, creating an exemption for direct transactions would provide a critical boost to the farms and the local rural economies.

The unlicensed producers distributing raw dairy to consumers have a good track record for producing healthy food; there have been few incidences of foodborne illness caused by the consumption of raw milk obtained from any dairy in Pennsylvania. In addition, other states that allow the unlicensed sale of raw milk direct from farmer to consumer, such as Missouri, have a good track record for food safety.

III. Additional recommended changes to the proposed regulations

Several sections of the proposed regulations include language that is ambiguous, overly broad, or unnecessarily burdensome for small farms. The FTCLDF recommends the agency make the changes set out below.

1. 59a.402(a) defines "sell" as "the selling, exchanging, delivering, or having in possession, care, control, or custody with intent to sell, exchange, or deliver, or to offer or to expose for sale."

This definition is overbroad. For example, a person who gives raw milk to a neighbor could be construed to be "delivering" raw milk. Also, a person who brings raw milk to a friend's house for dinner arguably could be "exchanging" the raw milk for their dinner. Such non-commercial

activity is not subject to the agency's jurisdiction. The FTCLDF recommends that the words "exchanging," "delivering," "exchange" and "deliver" be deleted from this definition.

2. 59a.402(b) authorizes a raw milk permit holder to sell raw whole milk and to obtain a permit for the sale of raw hard cheeses.

The FTCLDF urges the agency to expand the scope of this Section to authorize the permit holder to produce other dairy products, such as yogurt, kefir, butter, cottage cheese, etc. These value-added products are in great demand by consumers. The FTCLDF recommends the following change to the proposed language:

> (b) Actions authorized under a raw milk permit. A raw milk permit authorizes the permitholder to lawfully produce and sell (within this Commonwealth) raw whole milk and other raw dairy products for human consumption. It also authorizes the permit holder to obtain an additional permit, issued by the Department under authority of 21 CFR 133.150 (relating to hard cheeses), authorizing the sale of aged cheese manufactured from raw milk.

3. 59a.404(d)(1) and (2) requires that the water supply on the farm "is bacteriologically safe" and references section 59a.407 for the testing protocol.

"Bacteriologically safe" is not clearly defined. Section 59a.404 should be changed to read: "Water will be deemed 'bacteriologically safe' if it meets the requirements of 59a.407."

4. 59a.404(e) and 59a.408 provide for the collection of samples and establish a testing protocol.

The regulations should specify that the sample shall be collected from the bulk tank, rather than from other locations.

5. 59a.404(f)(2) requires "separate rooms for bottling, single service container storage, and bottle washing." Similarly, Section 59a.410(a) requires the permit holder to have "separate rooms for bottling, single service container storage, and bottle washing" and to utilize a "mechanical means of filling and capping bottles."

The requirement for separate rooms is onerous and there is no scientific or rational basis behind this requirement. Bottles will not be contaminated simply from being handled or stored in the same room. This requirement should be deleted.

In addition, many farmers in PA use manual means of bottling and there have been no reports of health problems due to these means. Mechanical bottling equipment is an unnecessary additional expense. The requirement for "mechanical means" should be deleted or this phrase should be changed to read "mechanical or manual means of filling and capping bottles."

6. 59a.409(b) mandates certain action to be taken by the permit holder when a sample "tests positive for the presence of a pesticide."

The mere presence of a pesticide should not warrant the remedial action specified by the Section. Instead, and using 59a.409(b)(4) as a guide, such remedial action should be taken only when the sample "tests positive for the presence of a pesticide that is above the actionable levels established for the pesticide."

7. 59a.409(c) mandates certain action to be taken by the permit holder when a sample "tests positive for the presence of a growth inhibitor."

The mere presence of a growth inhibitor should not warrant the remedial action specified by the Section. Instead, and using 59a.l409(c)(4) as a guide, such remedial action should be taken only when the sample "tests positive for the presence of a growth inhibitor that is above the actionable levels established for the inhibitor."

8. 59a.411(a)(1) requires the submission of a warning label to the Department before the product can be placed in commerce and also provides that the label cannot be "misbranded or contain any false or misleading statements."

The regulations do not specify a timeline under which the Department has to act on the submitted label. Farmers could effectively be shut down simply due to an intentional or unintentional delay by the Department. An additional sentence should be added which states "If the Department does not deny the submitted label within thirty days of receipt then it is deemed approved."

In addition, the controversies surrounding rBGH and labeling claims should be addressed. We urge the Department to specifically acknowledge that labels with the statements, "no RBST", "no rBGH" or "from cows not treated with rBGH" are allowed and do not constitute misbranding or mislabeling.

9. 59a.411(a)(3)(iv) provides for "monitoring" by the Department by the collection of samples from a "distributor," and imposes potential reductions in the "sell by" date.

There is no way to determine whether the samples collected from the distributor were from products that were kept in accordance with applicable law or were tampered with. Imposing a penalty on a producer by a shortened "sell by" date due to the negligence or carelessness of a distributor would be a denial of due process. This Section should be deleted in its entirety or it should be modified to allow the collection of samples from producers only and not from distributors.

10. 59a.412 mandates that a permit holder "shall allow" Department representatives to conduct an inspection, take samples, etc. upon pain of revocation or suspension of their permit.

This Section violates the Fourth and Fourteenth Amendments to the United States Constitution. A permit holder has the right to refuse access or entry by Department personnel absent a validly

issued criminal or administrative search warrant. Thus, this Section should be modified to read as follows: "The Department and its personnel have the authority to inspect the dairy operation that is the subject of the permit, review records, draw samples, conduct tests and take other actions necessary to the Department's performance of its responsibilities under the act, the Food Act or any other applicable statute or regulation." The last sentence in this Section, which states "the Department may take steps to revoke or suspend the raw milk permit" upon the permit holder's refusal to allow access or sampling, should be deleted.

11. 59a.413(b)(1) and (2) provide a procedure for initiating a suspension or revocation of a permit.

The regulations should also clearly provide that the notice sent to the permit holder will set out the method for the permit holder to request a hearing in accordance with applicable law.

12. 59a.413(c) provides that the permit is the property of the Department and shall be returned immediately upon suspension or revocation.

This Section is a violation of the Due Process clause of the Fourteenth Amendment to the United States Constitution. A license or a permit is a property interest that can be revoked or suspended only in accordance with due process. This Section should either be deleted or it should be modified to state that surrender is required only after an administrative hearing and all appeals have been exhausted finding the permit should be suspended or revoked.

13. 59a.416(a) authorizes the Department to condemn, seize, destroy or denature "a given supply of raw milk or illegally-produced raw milk products" if it is "considered unsafe."

This Section is too broad and should apply only to raw milk or dairy products that are "sold" to a third party. The Department lacks any jurisdiction over an individual's own, private supply of raw milk or dairy. This Section should be modified as follows: "Whenever, in the opinion of the Secretary, a given supply of raw milk or illegally-produced raw milk products that is sold to a third party is considered unsafe or a menace to public health, the Secretary may . . ."

Sincerely,

Pete Kennedy

Pete Kennedy
President, FTCLDF

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