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From: Louise S. Smith [louisess@verizon.net]
Sent: Monday, September 21, 2009 10:20 PM
To: phoge@state.pa.us
Cc: IRRC
Subject: Dairy Regulations -

Dear Mr. Hoge:

As a concerned resident of Pennsylvania, I support all of the comments and questions as submitted by Brian Snyder, Executive Director of PASA as outlined below. The Proposed Rulemaking regarding Milk Sanitation standards recently issued by the Pennsylvania Department of Agriculture (PDA) should be improved by addressing these twelve issues prior to approving any new regulations.

Thank you for considering the concerns of PA residents.

Sincerely,
Louise Smith

Further Extension of Public Comment Period and Additional Hearings
It was refreshing to read in the stated *Purpose* of the new regulations, as published in the *Pennsylvania Bulletin*, PDA's impression that "The regulated community is quite diverse, with the size and sophistication of dairy production and processing operations varying dramatically." But this introduction seems to be where such awareness – or at least any accommodation to it – stopped rather abruptly.
Pennsylvania certainly is home to one of the most diverse agricultural communities in our nation – if we are not, in fact, the top of the list in that regard. In our survey of member dairy farmers who would be impacted by the proposed regulations, we have found profound confusion about what is happening and how folks should proceed to have their voices heard in the process. We find it unacceptable that information has been made available only via the Internet, particularly when a not-insignificant portion of the Commonwealth's dairy farmers have poor access to such information, and indeed, very many live with cultural inhibitions or restrictions in this regard.
We also note that, while one hearing on these new regulations has been held, the notice period was very short, the hearing was held in a month when most farmers are extremely busy, and the topics covered at that hearing were, by clear public notice, to be very restrictive. As your notice of the hearing stated, "This hearing will be focused only on the proposed changes to bacterial standards – and not on the entire proposed new regulation." The distance involved for many farmers to attend that hearing, along with the relentless schedule of most dairy farmers, were also limiting factors for those wishing to know more about the intended regulatory changes.
We propose that a) the public comment period on this proposed rulemaking be extended an additional 30 – 60 days, to as late as the end of November, b) that open, free-ranging public hearings be scheduled in three locations across the Commonwealth, in the eastern, central and western regions specifically, and c) that "redline" versions of the new regulations, highlighting all significant changes being proposed, be made available, both online and in hardcopy, to whomever should request them in advance of those hearings. 3

PASA does hereby offer to help publicize, and even to co-host such regional information sessions, should they occur. We also welcome the participation and assistance of other agricultural organizations that may have a stake in the outcome of such hearings.

2. Prohibition of "False or Misleading Material" from Product Labels.

With respect to §59a.14(f), PASA supports the idea that blatantly incorrect information should neither be represented on product labels of any kind, nor used in the marketing of food products whatsoever. However, we heavily doubt the ability of PDA to be a fair arbiter in every possible question of what might constitute information that is indeed "false" or "misleading." This is particularly the case since disputed scientific opinion or even spiritual considerations may be the basis for such determinations – or those to the contrary. The mere mention of "false or misleading material" sounds like tabloid-speak and, depending on how this language is applied by future PDA administrations, could easily reopen the wounds from recent years within the farming community and dairy industry that have not entirely healed. We believe that the burden of PDA to make such determinations, now and in the future, should be a bit steeper than the proposed language would seem to demand.

We propose that the language of this section, and other sections where the "false and misleading" designation occurs (e.g. in Subchapter F), be changed to read "Material, marks, words or endorsements that are blatantly false according to prevailing scientific opinion and common public understanding, or that intend to mislead the consuming public in a grossly negligent manner, are prohibited." Language included as such will restore a proper perspective to the role of PDA in determining what is true or false in our society, especially with regard to the food we eat, while not at all diminishing the department's ability to maintain the safety and security of the food supply as defined elsewhere by the statutes of this nation and commonwealth.

3. Regulation of Somatic Cell Count in Small Ruminants

In §59a.110(c), and elsewhere in the proposed regulations, a Somatic Cell Count reading of more than 750,000/ml is defined as an "excessive somatic cell count." Our understanding is that, in accordance with the *Pasteurized Milk Ordinance*, the same designation with respect to dairy goats would be 1,000,000/ml and may even increase in the near future to 1,500,000/ml. Please confirm if this is true, and if so, if this same consideration will be applied to dairy sheep, and what the process might be for determining such designations for other species in the future. Please also confirm what, if any, different standards might apply to milk intended for sale as fluid raw milk or as raw milk to be used in cheese production. Our immediate recommendation is that the standards for sheep should closely track those designated for goats.

4. Testing of Drug Residue Level

§59a.111(a)(1)(i) states that "Milk shipped for processing or intended to be processed on the farm where it was produced shall be sampled and tested, prior to processing, for *beta* 4

lactam drug residue." We feel it is not proper to consider milk being "shipped for processing" and milk that is to be "processed on the farm" in exactly the same way as currently indicated by the proposed rule. We also feel that there are different styles of farming involved that should be considered separately, whether the milk is to be shipped or kept on the farm for processing. Accordingly, our recommendations are twofold, as follows:

First, we feel it should be clarified exactly what is expected of farmers who process their own milk into cheese and other products on their own farms and, given that traceability is a prime concern, major consideration and reduction of testing burden applied to those farms primarily selling directly to the public and/or with their farm name and/or location clearly indicated on product labels. These considerations should aim especially to relieve such farmers from testing each and every batch of milk before it is processed on the farm.

Second, we feel that such testing should not be required at all when two conditions are met: a) the milk, whether shipped or kept on the farm, is not commingled with other milk and b) the milk comes from a farm that is certified organic, biodynamic or sustainable, where the potential for undesirable drug residues would in any case be eliminated by farming methods governed by best management practices, especially regarding use of therapeutic agents, and verified by independent, third-party inspection services.

As a more general consideration, we feel that PDA should consider anywhere else in the proposed regulations where farmers whose primary markets are direct to the public, with appropriate labeling, and/or those whose operations have been certified by independent third parties, should be relieved from costly extra testing or unnecessary repetitive procedures.

5. Location of Packaging-Related Facilities and Equipment for Raw Milk Bottling

The proposed regulations governing packaging-related facilities and equipment, which occur identically in §59a.404(f)(1-2) and §59a.410(a-b), are insufficient in addressing current realities on farms with raw milk permits. First, however, we'd like to ask, is it really necessary to repeat this language, and in reverse order? We think it more suitable to address these issues under one section only, probably the latter. Other issues here are much more complex, as indicated in the following discussion.

Anyone trying to evaluate these sections needs to understand that when regulations for raw milk sales were first implemented, and for most of the time since then, there were two general kinds of containers used for such sales – those that were owned, returned to, washed and re-used by the farmer (i.e. the "permitholder"), and those brought in by the "customer" for use and reuse by themselves as they saw fit. These categories still apply, but a third category of containers has gained favor among many, if not most, raw milk permitholders in recent years, i.e. the pre-sanitized, one-time-use plastic jug that is sold by the farmer to the consumer along with the milk. This third category of container is not explicitly addressed by the proposed rulemaking at all. 5

For the sake of simplicity – not requiring much additional regulatory language – we feel that pre-sanitized, one-time-use plastic jugs should be explicitly designated as "containers owned by the customer," since they are in fact intended for ownership by the customer once the milk has been sold. Most significantly, this would mean that farmers using this method of packaging and selling raw milk would not be subject to the extra requirements as specified under the "containers owned by the raw milk permitholder" section. This single item alone would likely have a greater positive impact on public safety than any of the other proposed changes to the regulations because it would discourage direct, public access to the milk rooms and bulk storage tanks on the farms of permitholders. Fortunately, it would also avoid requiring such farmers to have costly, separate bottling facilities and equipment in order to fill these one-time-use, customer-owned jugs themselves.

6. Summary Criminal Prosecution

Under the *Purpose* section of the proposed rulemaking as published in the *Pennsylvania Bulletin,* we read about two aims PDA is attempting to achieve in this process, i.e. "the protection of the health and safety of persons who consume milk, milk products and manufactured dairy products" and the aim "to provide the regulated community--persons who produce milk, milk products and manufactured dairy products within this Commonwealth for sale--with clearer standards that facilitate the production and sale of Pennsylvania-produced dairy products."

This dual purpose is appropriate, and reasonably well-stated. We at PASA especially appreciate the intention of PDA to "facilitate" the efforts of our hardworking dairy farmers to serve the public while also keeping their farms economically viable. But we are very concerned about the apparent change of tone that occurs in various places throughout the *Subchapter F. Raw Milk for Human Consumption*, and we strongly question the advisability or effectiveness of the defensive tone that can be found therein.

In particular, §59a.409(a)(2) states that "If three of the last five tested raw milk samples exceed the bacterial count, somatic cell count or coliform count standards or cooling temperature requirements described in §59a.408, the Department will proceed to revoke or suspend the raw milk permit, and the raw milk permitholder shall be subject to summary criminal prosecution under the act." Taken literally, this means that a farmer can be put in jail for failing a milk test, and one begins to wonder where the facilitated partnership highlighted in the *Purpose* has gone.

We feel it is counterproductive to use such language in these regulations, either here, or in the section especially reserved for it, §59a.414. If used at all, such a statement should come only as a precursor to the entire document. At very least, the repetition should be eliminated, especially the very awkward language found in §59a.409(a)(2). However, we fundamentally believe that the point has already been implied well enough by the context of the proposed rulemaking without this explicit statement appearing anywhere. Any person involved in this process understands that there are intended consequences if the rules of the game as stated are not followed explicitly. 6

7. Alternative Written Means of Risk Notification

In two places within §59a.411 the following statement appears: "The Department will consider alternative written means of notification of consumers of the potential risks associated with the consumption of raw milk by highly-susceptible populations." Is this repetition, within the same section, necessary? Furthermore, can PDA be more specific about what "alternative means" are appropriate, perhaps with just a few examples? The suggested consumer advisory is long and cumbersome . . . not an appropriate addition to any label. Would it be appropriate for consumers to be directed to the PDA website or, for anyone without Internet access, to a PDA phone number where further information can be made available as a service to both permitholders and consumers? It is not productive to require a statement as long as this on a label, and then to suggest finding an alternative means of communication without any specific guidance.

8. Suspension or Revocation of a Raw Milk Permit

§59a.413(b)(2) and its further subsections go on at length regarding the procedural steps PDA will take in the event of a perceived "threat to the health or safety of those persons who consume" raw milk, including the notification of the permitholder and various other authorities that may have jurisdiction. However, there is no mention here of how, when, where and under what circumstances the press will be notified or other means employed to inform the general public.

As this has been a very problematic area of concern in the past, particularly when public notices appear upon discovery of an alleged problem, and without corresponding coverage if the problem is later resolved or found not to be credible, we propose that some clear guidelines be made explicit. In particular, we believe it is incumbent on PDA to make an extra effort, on behalf of the farmer involved, to overcome the tendency of the press to only cover the more flamboyant statement of a problem – as opposed to its resolution – and to get the word out with any means possible whenever a perceived threat to the public has been resolved.

9. "Illegally Produced" Raw Milk Products

§59a.416 is without much doubt the most controversial section of the proposed rulemaking, signaled both by its strong language and ominous appearance right at the end of this very long document. It would be hard to get more negatively-charged words in a single heading than "Enforcement: Seizure, condemnation, denaturing or destruction of raw milk; exclusion from sale." Also, while the phrase "illegally-produced raw milk products" appears in this section three times, with various consequences noted, we find no specific definition of that term here or elsewhere. Yet, our reading of this section as a whole is that milk products may be seized, condemned, denatured, destroyed or excluded from sale if, and only if, the farmer is not following the provisions of these proposed regulations and/or the Secretary has reason to believe they are unsafe. 7

By itself, this section might have enough wiggle room for Pennsylvania farmers, who are already working hard to meet the growing demand for raw, value-added dairy products other than fluid milk and aged cheese, to continue their rapid growth in this regard. We therefore hesitate to draw attention to and challenge what seems to be a carefully worded statement. Perhaps this was intended to walk a fine line between complying with federal expectations and supporting dairy farmers who, despite widespread economic hardship, are often benefiting from this positive trend in the marketplace. But in our daily interactions with such farmers, we hear again and again about the desire they have to operate more in the open, without needing to hide or mischaracterize their sales activities. Some of our most innovative dairy farmers need the support of a government that wishes to see them succeed, not only by increasing sales but also by assuring the public of the safest, most wholesome food products possible. Pennsylvania as a whole is benefiting tremendously from the influx of interest in raw dairy products, both from among our own population, and also from consumers in neighboring states who come here to buy the products they seek and for which they are willing to pay very good money. It is time for PDA and the Pennsylvania state legislature to stand with our smaller dairy farmers in particular in acknowledging one of the most promising trends to come along in many years.

It is our understanding that Pennsylvania statutes do not prohibit any individual from purchasing milk, or using milk from a cow he/she owns, and making with it the desired products. It is also true that other persons can be hired without limitation to make such products on behalf of an owner of milk or cow for his/her own use. We therefore now have a tremendous opportunity to clearly state in these regulations what is technically true, that *permitholders who enter into and hold private contracts on behalf of individual consumers, where said contracts clearly establish the prior ownership of the cow and/or milk involved, and the intentions with regard to the products desired for manufacture, may provide such products to these individuals on the basis of their private agreement.*

Appropriate statements can be added, as advisable, to specify the conditions under which contract files are to be confidentially maintained, and/or to hold the Commonwealth of Pennsylvania harmless in the event of unanticipated illness or other problems traced to such products.

We would not expect such clear statements in regulation to satisfy everyone, nor to eliminate the belief held by some that such private contracts are not within the purview of the Commonwealth to regulate – this opinion deserves more scrutiny and a fair hearing in the legislature or appropriate court of law someday in the future. However, we do believe that PDA, along with Pennsylvania consumers and raw milk permitholders, would substantially benefit from a clear declaration of how value-added, raw dairy products can be "legally produced," as opposed to providing unclear, unconstructive instructions that will be almost impossible to enforce regarding "illegally-produced" raw milk products. We also believe that such an effort would be more in keeping with the dual purpose as stated in this proposed rulemaking: i.e. to protect the public and to facilitate the production and sale of wholesome dairy products in the Commonwealth of Pennsylvania. 8

10. Pesticide Levels

§59a.409(b) lists various procedures that must be followed if the presence of pesticides is detected in milk samples, but no specific testing regimen is required or recommended. Please clarify if and when such testing might be required. Also please comment upon the circumstances under which pesticides or other adulterating substances might be present, and/or detected, in milk.

11. Potential Costs to Consumer

In the introduction to the Proposed Rulemaking document, under the section entitled *Fiscal Impact*, the statement is made that "The proposed rulemaking would impose no costs and have no fiscal impact on the general public." This statement seems inadvisable at best and totally inaccurate at worst. If the other public and private costs reported in this section of the proposal are indeed incurred, along with the costs to farmers of additional testing that will be necessary, it is unreasonable to assume that consumers would see no impact on state taxes owed or the retail price of milk and other dairy products, including prices related to sales directly from the farms involved.

12. Single Cow Exemption

§59a.12(b)(5) states that "A person producing and selling milk from a single cow" is an "exception" with respect to the requirement of obtaining a permit. However, §59a406 states in three places that animal health reporting requirements for the holder of a raw milk permit are relative to the "animal or herd" from which the raw milk is being produced. Please clarify whether or not such statements establish a different standard for potential raw milk permitholders as compared to others who possess only a single animal, and if the "single cow" exemption applies to other species as well (e.g. single goat, single sheep, etc...). Also, the logic of this section seems circular in nature – i.e. a person is an "exception" if already "exempted." Please clarify exactly what is intended by this confusing language.