#2777

Record of Public Meeting

This document is a copy of the entire record of a public hearing that was convened by the Pennsylvania Department of Agriculture (PDA) on August 18, 2009.

The hearing was convened to consider proposed changes to bacterial standards for milk. The changes are among the numerous changes proposed by PDA in a notice of proposed rulemaking that was published in the August 1, 2009 edition of the Pennsylvania Bulletin. (A copy of the entire proposed regulation appears as "Document 2" in the record that follows).

The document consists of the hearing transcript and copies of the various documents that were offered into the record at the hearing.

Interested persons should be aware that they have the opportunity to offer formal written comments on the proposed bacterial changes described in the attached hearing transcript, *and on any aspect of the proposed regulations* described above.

Although the proposed regulations reflect a 30-day comment period (that would have expired August 31), the comment period has been extended by an additional 30 days. It shall run through September 30, 2009. Interested persons have until that date within which to direct written comments to:

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

COMMONWEALTH OF PENNSYLVANIA

DEPARTMENT OF AGRICULTURE

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IN RE: PROPOSED REGULATION CHANGES IN BACTERIAL STANDARDS FOR MILK

PUBLIC MEETING

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BEFORE: DWIGHT SMITH, Chair
Paul Hoge, Member
Mike Hydock, Member
Bill Chirdon, Member

HEARING: Tuesday, August 18, 2009
1:00 p.m.

LOCATION: Pennsylvania Department of Agriculture Bldg
Room 202
Harrisburg, PA

WITNESSES: Paul Hoge

Reporter: Cynthia Piro-Simpson

I N D E X

E X H I B I T S

Number	Description	Page Offered
	NONE OFFERED	

P R O C E E D I N G S

CHAIR:

Good afternoon, everyone. We're about to get started. My name is Dwight Smith, welcome to the Department of Agriculture. Today is the advertised date, time and place for a meeting of the Pennsylvania Department of Agriculture, addressing proposed changes to bacterial standards for milk. This meeting was originally advertised to the place in Room 202, and for the record we've posted signs on the outside of the building, the elevator and at Room 202 itself and our paralegal has checked Room 202 and everyone who is here for the meeting apparently has been directed to the right place. An advanced notice of this meeting was published in accordance with the requirements of the Sunshine Act. It was published in the Patriot News on August 1.

As I said, I'm Dwight Smith. I'm the hearing officer for today's hearing. I'm with the Governor's Office of General Counsel and Detail to the Pennsylvania Department of Agriculture as an assistant counsel. I'm also this agency's regulatory coordinator. Every Commonwealth agency has one regulatory coordinator who is sort of the point person

for that agency's regulations. I've been here for 19 years, been involved personally in the promulgation of over 50 regulations. Some of them thick, some of them thin, all have been following essentially the same process. And I've assisted other counsel in our office on their regulatory projects. I'll be facilitating the meeting today just as an overview.

We'll be hearing from the Bureau of Food Safety and Laboratory Services on the proposed changes to the bacterial standards. There will be an opportunity for interested persons in the audience to ask questions of our subject matter experts. You will also have the opportunity to testify, offer comments each of you. If anyone would like to offer written comments, we'll submit them into the record in this case. When the hearing is over, we'll have the transcript prepared. Any documents we talk about today we'll include in the record. If someone submits written testimony we'll include that in the record. And within about two weeks or so, we'll be posting this on our agency website, so that interested persons can see the transcript of today's hearing and look at all the documents and perhaps base further comments on our proposed regulations on what they see there.

A couple of housekeeping details for

those of you who haven't been here before. The restrooms are out the door and down the hall, at the end of the hall. We have a snack bar, water, drinks, refreshment in the basement. Just take the elevator to the basement and a quick right gets you there. So it will be comfortable, come and go as you wish. If we're here at three o'clock I'll try to remember we'll take a five minute break or so. If I go through that or we're here then and I forget, someone can please remind me, we'll take a little break then. We have two handouts. I don't know if everyone has them, but there's a copy of the proposed regulation itself. That's the thicker of the two handouts you have.

And we're going to include that in the record of today's hearing. We're going to call that document one. And that will be posted with a record of this on our agency website. But that is the entirety of the proposed changes the Department of Agriculture seek to do to its milk sanitation regulations. We also have a smaller handout, and that's titled Proposed Regulatory Changes to Bacterial Standards for Milk. This kind of picks through the proposed regulation that identifies the changes to bacterial standards. There are a lot of changes and a lot are the same in the proposed regulation. But we

just kind of filtered through to the changes to bacterial standards.

And the presentation from our Bureau of Food Safety will be working off of this handout. And I hope it's helpful to you in focusing today's hearing. As I mentioned, there's a regulatory revision under way. We published our proposed regulation on August 1. A point of clarification, when we published it, the statute --- the Regulatory Review Act requires that we let the public comment for at least 30 days. And that was the initial comment period we established. Deputy Secretary Redding signed an order this morning, we're going to extend that comment period an additional 30 days. So if you're representing a group or you have a constituency or other interested persons who might want to comment on the proposed regulation, the window was August 1 to August 31. It is now August 1 to September 30th. So they have an extra month to do that. The Bureau of Food Safety is going to mail notice of that to every person who has a milk permit and will do some other outreach as well I understand to make sure people know about that. But it's an extra long opportunity to comment. It will give commentators the chance to look at the record from today's hearing if they want to put

that in their comments. And I encourage people to take advantage of the regulatory comment process. If we get a written comment, the Department is required by statute to respond to the comment in writing. And a comment can have a few different effects. It can result from a change to the regulation, or if it doesn't, the agency, Department of Agriculture has to state why it is does not have documented changes in its comment and response document so there will be a record of why decisions were made one way or the other.

So with that, the purpose of today's hearing, it's a little unusual in that the milk sanitation regulations have two statutes that justify them. We have our Milk Sanitation Law, which is a statute from 1935. It's one of the oldest statutes administered by the Department and it predates a lot of the modern regulatory type of language and regulatory type of process we have. And we have the Food Act that identifies milk as a potentially hazardous food and lets the Department regulate under that.

But the Milk Sanitation Law contains a provision that says --- I'm paraphrasing, but when the Secretary proposes to change bacterial standards for

milk, he'll do it with a public meeting like we're having here today. So because that statute back in 1935 made that requirement, we have two parallel processes going on here today. We have this narrowly focused meeting on bacterial standards, but you have a more expansive chance to comment in writing on anything in the proposed regulation. So again, I just wanted to emphasize that today's hearing is narrow in scope.

As far as outreach for today's hearing goes, I understand that written notice of today's hearing was mailed to our current list of raw milk permit holders. I mentioned that we were going to include the regulation in our list of documents. We're also going to include our meeting handouts. That will be our document number two. The sign-in sheet today will be our document number three. And that list of raw milk permit holders I was just talking about, that will be our fourth document, so people online can view the names of the persons to whom notice was sent. We also maintain an e-mail directory of laboratories and the like. Apparently 77 or 78 entities are on that list. And they were forwarded notice. That list will be incorporated in our record as document number five.

Our agency has a legislative liaison who liaises with the legislature. And she has contacted the minority and majority chairpersons of the house and senate agriculture and rural affairs committees, as well as Senators Mike Fulmer, Representative Sam Rohrer and Representative Bryan Cutler. Each of these gentlemen has an interest in food safety issues, milk sanitation and/or raw milk issues. So we wanted to notify them. Also, cheese manufacturers, ice cream processors, producer processors, co-chairs of the Pennsylvania Association of Milk and Food Sanitation were notified of today's meeting. And the list of those types of addresses is included in our record as document number six.

So you'll be able to look at this online and see everyone who received notice. That's kind of the housekeeping part of today's meeting. Let me introduce the attendees from the Pennsylvania Department of Agriculture. On my far right is Bill Chirdon, who is the director of our Bureau of Food Safety and Laboratory Services. To his left is Mike Hydock, who is the chief of the Laboratory Division in the Bureau of Food Safety. And to my immediate right sits Paul Hoge who is the dairy program specialist for the Bureau of Food Safety.

Mr. Hoge is also the contact person on our proposed regulation. If you look at the first couple of pages of the handout, it has a section talking about to whom to direct comment. And Mr. Hoge's mailing address and name are on there. So if you'd like to offer comment on the proposed regulation, he is the one who will be receiving it. And Mr. Hoge will also be doing the bulk of the presentation for the Bureau of Food Safety this afternoon. So again, we'll hear from the Bureau of Food Safety. There will be an opportunity for attendees to ask questions. Let's just take a minute while these other folks sign in, so we can get ---.

OFF RECORD DISCUSSION

CHAIR:

Why don't we take a minute and go around the room. And people can introduce themselves if you're representing a group or you have a particular type of dairy operation you'd like us to know about, would you please do so? Why don't we start from the front and just work our way back. Sir?

MR. STRICKER:

I'm Forrest Stricker from Berks County. I'm raw milk dairy producer for an organic dairy farm.

CHAIR:

Thank you. Sir?

MR. MILLER:

I'm James Miller. I'm a sanitarian. I work for Organic Valley. And I'm also here representing U.S. Food and Dairy Laboratories.

MR. MULLET:

I'm Stanley Mullet. I'm here from Ohio. I'm representing Steiner Cheese.

MR. YODER:

Ivan Yoder, representing Steiner Cheese.

CHAIR:

Sir?

MR. EDWARDS:

Amos Ebersole as raw milk.

MR. A. MILLER:

Amos G. Miller, Misty Creek Goat Dairy and raw milk and cheese.

MR. STOLFUS:

Lester Stolfus from Colonial Goat Dairy.

MS. WALKER:

Candace Walker, Caprine Delight Goat Dairy, raw milk and aged cheese.

MR. BASIAL:

John Basial from Senator Folmer's office.

DR. BEAL:

I'm Doctor Susan Beal. I'm the agriculturalist.

MR. KERR:

I'm Ralph Kerr, Titusville Dairy.

MR. BREINER:

Don Breiner, Land O'Lakes.

MS. BAUERMASTER:

Janice Bauermaster, Lancaster DHIA.

MR. PCSOLAR:

John Pcsolar, QC Laboratories.

MR. ANGSTADT:

Tom Angstadt, Dairylea.

CHAIR:

Thank you, much. It sounds like we have a pretty good cross section of the regulated community here today. With that, we're going to hear from Paul Hoge. And I think he'll probably be walking us through our handout to explain the bacterial changes. Mr. Hoge?

MR. HOGE:

Thank you, Attorney Smith. And welcome to everyone. I welcome you here and I'm glad to be here myself today as well. We would like to take a few minutes and walk you through the significant changes that Attorney Smith has brought to your

attention as part of the revised regulations. First I thought I would just take --- preface those remarks with a few other remarks as part of introductory as to our background on these regulations. Pennsylvania you know is a very large dairy state. I think we're now fifth largest dairy state in the nation. And I think it's easy to conclude that we operate in Pennsylvania a very vigorous and vibrant dairy industry and processing industry producing both milk for pasteurization, manufacturing as well as process dairy products of all sorts and descriptions.

A very large portion of Pennsylvania's dairy industry produces and processes milk and milk products that are eligible or actually required to be eligible for interstate sale, because so much of milk and milk products does move to interstate now. And therefore these products, this milk and milk products are referred to as Grade A-1 certified. And they are regulated under a corroborative federal state program known as the Interstate Milk Shipper's program. And of course the governing rules for that program entitled a Grade A pasteurized milk ordinance.

Now Chapter 59, the basic Pennsylvania State regulation references the 1978 version of the pasteurized milk ordinance. And therefore 31 years

have passed since we last updated our regulations, at least as far as the provisions of the Grade A PMO or concern. Many things have changed in the PMO during the time. The PMO, pasteurized milk ordinance is a cooperative program between states and FDA, as I said, and it is actually worked on or updated every two years during a national conference attended by delegates from each of the 50 states, as well as FDA and the dairy industry as well. So many of those conferences have come and gone in the time frame since we significantly updated our regulation.

Now with respect to that Grade A program we are --- we receive oversight and evaluation from the FDA. And FDA has in fact many times commented to us that our regulations are in need of updating. And of course we knew that. We've also received these types of comments from a regulated industry. Each three years the FDA is required to complete what they call a state program evaluation for each of those states that they oversee. And we received ours this year as well.

One of the most significant findings in that state program evaluation was that our regulations were based on the 1978 PMO. Obviously much has changed. And so our regulations were not considered

to be in compliance with the state --- with the program criteria, which in fact requires that states should reference a PMO that is no older than six years from the previous conference. Now our most recent conference was in April of this year, 2007. So the criteria would say that we should be updated and referencing a PMO no older than six years back. So roughly at least to the 2001 time frame.

Again, 1978 is far different from that time. So in terms of FDA and our regulated industry, they were very interested in our --- completing this task. And it's something that we actually have been working on for I would say at least the last three years in earnest. We do this along with all the other functions that we do and the inspection ratings, certifications, et cetera. So it's always a site thing that we're working on, at the same time it's our regular duties as well.

Now while updating PMO, there's several other sections of Chapter 59 that we wanted to give attention to, and needed to, in fact. In 1985 we for the first time adopted manufacturing grade milk regulations for a manufacturing sector of the dairy industry. And that was covering both milk for manufacturing as well as milk for processing and

manufactured dairy products. We did that by adopting the recommended USDA rules of 1985. Like FDA or the PMO, those rules get updated as well. And yet our statute or our regulations, which is dated 1985, the USDA rules have been updated fairly regularly from what I can tell from 1991, '93, '96, 2002 and 2005. There have been regular updates of those standards. But again, we had not completed that task.

And so this represented an opportunity to do that as well. So we have been working for the 2005 revision of that, those standards. And finally the raw milk permit is here and our --- the Bureau resides with our dairy section. And I think one of the comments that I recall us making early on was that the rules for a raw milk permit were kind of scattered within the regulation. And they weren't easy to follow. One of our objectives in the revision was to pull all the regulations pertained to raw milk in one section. And that gives the regulated industry an easier time in terms of understanding what the regulations are, completely all the regulations that they have to follow in order to obtain and maintain a raw milk permit.

So those are the three sections that basically talked about that. As you see in the

purpose and the proposed rule making, the two basic objectives we have in doing this are to protect the health and safety of the persons who consume milk and milk products and manufacture dairy products. That's our primary purpose to make this regulation revision. And then the secondary purpose is to provide the regulating committee with a document that is actually clear and easy to follow and easy to understand than what the current regulations may be. So with that as a basic introduction, I'd like to just take a few minutes to go through the handout that you should all have by now. If anybody doesn't have it, let us know, we can walk another one back.

Again, these changes --- I think I'll probably just go ahead and refer to about halfway down. Today's meeting will focus on the changes, including bacterial standards that are summarized below. and then in greater detail the chart that follows. So I'll be talking about each of these four --- each of these four bullet points. And with that I'll go ahead and turn to the next page, page two. Under number one, the way this is set up is on the left column is the current regulatory requirement. The center is proposed and then the far right column is the rationale or reason for our purposed changing.

In Subchapter E of Chapter 59, milk for manufacturing, there's a bacterial estimate classification. And this is the language of USDA.

And it classified producer's milk as undergrade when a direct microscopic clump count, a standard plate count or a plate loop count result is over one million per milliliter. Now our proposed revision will be in Subchapter C, Chapter 59a, processing of milk for manufacturing purposes. And that 59a.109(c), titled bacterial (sic) estimate classification, excessive bacteria. Our charge would be to decrease the manufacturing grade milk bacterial limit for an individual producer from one million per milliliter to 500,000 per milliliter.

Now again, reviewing that rationale, since 1985 we have adopted and applied the bacterial standards set forth by the USDA recommended requirements, formerly titled the milk for manufacturing purposes and its production and processing recommended requirements. We've adopted these as the standards for manufacturing grade milk and manufacturing grade dairy products. The USDA recommended requirements were revised in 2005 and as I alluded to earlier previous times as well, that's not the only revision. But in any case, their current

bacterial level for a producer of milk resides at 500,000 per milliliters standard as the recommended standard for bacterial classification. And that's found in Section C4, a line through the C and the M. C4 of the proposed provision. So the proposed 500,000 per milliliter standard would be bringing Pennsylvania back into conformity with the current listing in the recommended requirements.

Okay, number two. Number two pertains to Subchapter G and our current Chapter 59 manufacturing plants. And in Chapter 59.708, titled raw product storage, there's a Subsection B that provides that --- the bacteriological quality of commingled milk in storage tanks shall be three million per milliliter or lower. In our propose regulatory revision, Subchapter E manufacturing plants, we would insert --- we would have Section 59a.308 entitled raw product storage. Subsection (b), entitled bacteriological quality would provide that --- the bacteriological quality of commingled milk and storage tanks must be one million per milliliter or lower.

And again, like the earlier change, number one, this change is also in keeping with the direct updated USDA recommended requirements as referenced above. The USDA recommended requirements

have established this one million per milliliter standard as the recommended standard for bacterial quality of commingled milk in storage tanks. And that would be found in Sections E1.8(b) of that document. Okay, number three pertains to milk for pasteurization and somatic cells. Now, realizing that somatic cells aren't bacterial cells, we decided that since there was a relationship we wanted to make sure that we had left no confusion.

We went ahead and included somatic cells with the topic of today, the bacterial changes, even though they're technically not bacterial cells. With that said, Subchapter A of the current Chapter 59.52 titled table, the portion of that referenced table addresses somatic cell count or milk for pasteurization and provides that samples of exceeding 18 milliliters WMT to be confirmed by DMSEC or acceptable tests, not to exceed one million per milliliter. In Subchapter A of revised Chapter 59a, familiar with the preliminary provisions, specifically 59a.19, titled standards for Grade A raw milk for pasteurization, ultra-pasteurizing or aseptic processing.

Subsection (b) incorporates the applicable standards set forth in a Grade A PMO. The

Grade A PMO establishes the following maximum somatic cell count for Grade A raw milk and milk products for pasteurization, ultra-pasteurization or aseptic processing. Somatic cell for an individual producer of milk, not to exceed 750,000 per milliliter. And then a footnote to that standard provides there's a standard where goat milk is not to exceed one million per milliliter. We note that --- we note that the PMO does contain an asterisk for billed milk and does allow an elevated count on somatic cells for billed milk. And we would not take exception to that allowance. So you can expect that our updated Chapter 59 will incorporate that footnote for the one million per milliliter.

Now again, the rationale here, current regulation was written in mirror of the somatic cell count standards that were recommended in the 1978 version of the Grade A PMO, which was the current recommended standard when the regulation was promulgated. The Grade A PMO has since been revised and lowered the referenced somatic cell standard many years ago. Actually to detail that by saying that in 1991 the National Conference of Interstate Milk Shippers lowered somatic cell count for Grade A milk from a million to 750,000. So it was 1991 and that

went into effect in 1993. And again, that's to 750,000. This standard appears in Section 7, Table 1 of the 2007 Grade A PMO on pages 28 and 29. Anybody that's not seen a Grade A PMO, you're welcome to look at it after our meeting today.

Now this 750,000 milliliter standard is also recommended throughout the USDA recommended requirements. And a proposed regulation seeks to adopt the most current version of a Grade A PMO and therefore establishes the most current milk quality standards for milk in Pennsylvania.

Okay, turning to page four, item four, this pertains to the raw milk somatic cell standard in subchapter A, preliminary provisions and Table 59.52. The portion of the referenced table addressing somatic cell count for raw milk provides that samples exceeding 18 milliliters WMT to be confirmed by DMSCC or acceptable tests not to exceed one million per milliliter. Now our advised Chapter 59 Subchapter F, raw milk for human consumption, specifically in Seven Code 598a.408(c), titled regular testing of raw milk, testing schedule and standards. This subsection requires that at least twice each month raw milk for human consumption be tested for somatic cell count and that the somatic cell count may not exceed 750,000.

Our rationale is that both Grade A PMO and the USDA recommended requirements make repeated references to a 750,000 per milliliter somatic cell count standard for milk. The vast majority of dairy producers produce milk that meets or is in compliance with this 750,000 per milliliter somatic cell count standard. And in fact I would add they produce generally significantly lower somatic cells than that. Much lower. So PDA seeks a uniform somatic cell count standard across the entire spectrum of milk for pasteurization and raw milk for human consumption. And the 750,000 per milliliter standard is the preeminent national standard for the somatic cell count in milk.

AUDIENCE MEMBER:

Can we ask questions now or do you want to wait 'til the end?

CHAIR:

Why don't we wait until we go through all six, and then everyone will have an opportunity to ask any questions; is that okay?

AUDIENCE MEMBER:

All right.

CHAIR:

Okay, thanks.

MR. HOGE:

Okay, five, item five on that below there is pertaining to milk for manufacturing the somatic cell standard. That is found in Subchapter E of milk for manufacturing and the current Chapter 59, whereby in 59.509 titled abnormal milk, table four addresses somatic cell count for milk for manufacturing and provides that samples exceeding 18 WMT to be confirmed by DMSCC or acceptable tests not to exceed one million per milliliter. In our revision in Chapter 59a, Subchapter C, production and processing of milk for manufacturing purposes, Section 59a.110, titled somatic cell count, this section would establish a somatic cell count in excess of 750,000 per milliliter for any legal producers milk as excessive and prescribes specific actions, mainly excluding the milk from the market after three out of five when this count is exceeded.

So in fact the USDA standards have adopted basically the PMO language for two out of four and three out of five. And the milk for manufacturing standard also provides for an elevated goat milk standard. And again, we would not take exception to that. My own rationale there is as stated above, the proposed regulation seeks to reference the most current version of the USDA recommended requirements.

The USDA recommended requirements have been updated and are now parallel to the current PMO with regard to the 750,000 per milliliter somatic cell count standard. This standard appears in Section C11 of the USDA recommended requirements.

Okay, and finally, turning over to page five, item six, this pertains to raw milk and pathogen testing requirements. Although there is currently no regulatory requirement for pathogen testing for raw milk, there is a statutory requirement in Milk Sanitation Law that milk be clean and free from disease producing organisms, disease producing organisms are pathogens that are of greatest concern to the regulation, and our main are salmonella, listeria monocytogenes, Campylobacter and E. Coli 0157:H7. Our Subchapter F, Chapter 59a, milk for human consumption, specifically in section 59a.409(c), titled regular testing of raw milk-testing schedule and standards.

This subsection requires that at least twice annually --- we would actually like to rephrase that to say each six months. Raw milk for human consumption be tested for the presence of pathogenic bacteria, including salmonella, listeria monocytogenes, Campylobacter and E. Coli 057:H7. And

of course the standard will be that there may be no pathogenic bacteria present or found. And our rationale here is that the department has been conducting pathogen surveys of milk samples from our milk permit holders on both tanks for several years. These tests have been positive for one or several raw milk pathogens on more than one occasion. While periodic testing for pathogens cannot guarantee the safety of raw milk, we believe there's ample public health justification for requiring permit holders to be monitored for the presence of pathogens on a periodic basis. So in summary that is are summary of the bacteriological changes. Thank you, Attorney Smith.

CHAIR:

Now if members of the audience have any questions, this would be the time to ask them. And sir, you had the first question.

MR. MILLER:

James Miller. I just have a question in reference to 59a.408(c), regular testing-raw milk testing standards. And you mentioned specifically that 750,000 somatic cell count for raw milk. And I do not see in the reports here where there is a an exception for goat milk. So is that making --- is

there going to be written into in it an exception for goat milk up to a million or is it going to be 750,000?

MR. HOGE:

I might actually be able to answer that, because I think it's a draftsman's error. What happened was that throughout the regulation we incorporate the Grade A PMO just by referencing, by saying whatever that says, those are our standards. With respect to raw milk, we wanted to try to put everything in one place. And in doing that, there's a chart in the Grade A PMO --- well, not a chart, but took that information. But the exception for goat milk is in a footnote to that chart that did not get in there. So for the record of this hearing, and on the record I can say it's our intention to bring that standard into line with the Grade A PMO. That was actually --- literally it's a footnote at the bottom of the page on the standards. So that was Scribner's error on my part. For the raw milk, folks, you should know that we'll be in line with these standards for goat milk, which allow one million per milliliter standard. And again ---.

MR. MILLER:

I just wanted to clarify that.

MR. HOGE:

I'm glad you did. That was a mistake.

CHAIR:

Doctor Beal.

DR. BEAL:

Just for the record, and I know you've spoken about that before, but you comment some on sheep milk as well?

CHAIR:

There are exceptions in the recommended requirements I believe. Maybe the subject matter experts can talk about this a little better. But it's our intention, if the whole objection of the exercise is to bring us into national standards, and they have exceptions with a particular species, it's not our intention to vary from that. If it's omitted, please submit a --- and you see it, please submit a written comment and remind. But we intend to do a look through to make sure we accomplish that. Gentlemen, does that fill that answer?

MR. HOGE:

Yes, we talked about this very briefly. And just comment on the fact that we haven't had a lot of experience with sheep milk in Pennsylvania. I know there are a couple of facilities that are doing some

sheep milk. And we think that they're doing it basically for making cheese. So you feel that they fall under and look for manufacturing standards. And as per USDA, we would follow that same standard.

CHAIR:

So, if I understand it right, that's milk for manufacturing. And the proposed regulation just makes a general reference to that standard. It's automatically the standard for goat's milk.

MR. HOGE:

Yes.

CHAIR:

Unless it's raw goat's milk for human consumption.

MR. HOGE:

We don't know it to be different from cow's milk, so we actually need to verify with USDA what is that standard for somatic cells for sheep.

CHAIR:

Ma'am.

MS. WALKER:

Candace Walker. I understand that the newest update for PMO is going to go to 1.5 million for goat's milk; is that correct?

MR. HOGE:

Yes.

CHAIR:

The 2007 conference did raise that allowance to 1.5.

MS. WALKER:

So that will be the accepted standard for this regulation, because it will reference the PMO then?

CHAIR:

If I have it right, I think the objective is to be in step with the national standards. And if they increase from one million to 1.5 we want to be. And if you see in the proposed regulation where you think we don't accomplish that, please point that out in the from of a written comment. And as I said, we're going to look at that. But at the end of the day, we want a regulation that incorporates that standard, so we don't have to change the regulation every time the standard changes.

MR. HOGE:

This was one of our first experiences with an updated PMO. And actually, we don't have Chapter 59a in place yet, so it's hard to comment on that, how we're going to work with a new PMO. Those provisions will take place --- take effect in

Pennsylvania in October 2010. So we can't really comment on those being in effect until next fall. I will say that I saw in an e-mail recently, yesterday I think, that the manufacturing USDA standards, he indicated that they have also sent out for comment an elevated sheep milk standard for 1,500,000. So as --- my assumption is that as these standards are updated by federal standards, we will follow. But we can't say for sure until we are in a position to do so with the new Chapter 59a.

MS. WALKER:

Okay. When is this new proposed standard to take effect, if it does?

CHAIR:

Do you mean proposed regulation or ---?

MS. WALKER:

Chapter 59.

CHAIR:

I'd say the timetable is kind of difficult. A very rough guess would be February or March of 2010. And that's optimistic. Once we draft a proposed regulation, we kind of lose control of the process in that the Governor's Policy Office, the Office of the Budget, the Office of General Counsel get a look at it, the Independent Regulatory Review

Commission and then after them, the Office of Attorney General. So we do lose some control, but best guess would be March 2010. And please don't hold me to that.

MS. WALKER:

All right.

CHAIR:

Thank you. Questions? Sir. Please state your name, I'm sorry.

MR. KINZEL:

Lloyd Kinzel from FDA. In regard to pathogen testing for raw milk, proposed pathogen testing, the wording is at least --- would that mean that a sample in subsequent months like January and then again in February over a long period of time or every six months?

MR. HOGE:

As I mentioned, Mr. Kinzel, we would like to go to every six months, so in fact we produce a good snapshot of their milk from the pathogen standpoint at a more separated distance of six months and not back-to-back evaluations.

CHAIR:

And I would say in preparing for today's hearing and looking over the bacterial standards that

was --- that language immediately jumped off the page. We'd like to put a time interval between those two tests. And I can assure the audience that that will happen in the final form reg. But again, I invite your comments to remind us to do that, but we will do it. Questions? Very well --- oh yeah.

MS. WALKER:

Back to the raw milk for human consumption somatic cell testing, up until now it's been once a month. And with this new regulation it is being doubled to twice a month. And that adds expense to all of us who have to pay for that testing. What's the purpose of that?

MR. HOGE:

We felt that raw milk is such an important commodity and that the somatic cells would deserve to be evaluated at the same frequency as the bacterial scanning.

MS. WALKER:

I believe in your regulation somewhere you state that there will be no increase to the consumer in price, but whenever there's additional testing, of course that's passed to the consumer. I just want to make that known. You can't require us to do additional testing, at the same time make the

statement there will be no additional effect on the consumer.

CHAIR:

I just suggest, if you can quantify that, that would be helpful. If you could put it in a comment and --- I don't have a feel for whether that testing is done as part of the twice monthly bacterial count testing and the testing for drugs and growth inhibitors. So I don't have a feel for what that will add to your cost. But if it does, please submit that in a comment and we'll at least try to address it in the final regs somehow. We made a representation that there weren't costs. If there are, we'll straighten that out.

MR. HOGE:

May I ask a question? We have two --- at least two people here from various labs. A somatic cell count test, what is the cost of that? Janice, do you know the cost of that approximately?

MS. BAUERMASTER:

Ours is $3.

MR. HOGE:

How much?

MS. BAUERMASTER:

Ours is $3.

MR. HOGE:

$3? Jim, what's the cost?

MR. MILLER:

I can't really tell you, because I don't keep track of what they charge for testing, but I would say $3 is probably pretty close to it.

MR. HOGE:

So that would be actually $3 a month approximately. So you're more expensive.

CHAIR:

Are there more other questions from the audience? We'll have a chance for testimony and comments, but questions?

MR. HOGE:

The other comment I was going to make, the general public, I'm distinguishing general public from the permit holders.

CHAIR:

Now --- sir?

MR. MILLER:

I just wanted to clarify the frequency of testing. Currently if you had a raw milk permit, you're required to be tested two times a month. And if you have a milk manufacturing permit, that's one time a month. Is that changing or --- I'm trying to

read through this. It's a little unclear to me if you have a milk manufacturing permit, you're producing cheese or you're producing milk that's going to be made into cheese, are you going to be required to have a raw milk permit, two time a month testing?

MR. HOGE:

If you you're only doing milk for manufacturing, for manufacturing grade producers, then you're tested once per month as per the USDA recommended requirements.

MR. MILLER:

Okay, that's not going to change.

MR. HOGE:

That's not changing.

CHAIR:

Sir, yes?

MR. STOLFUS:

Lester Stolfus. If you take tests twice a year, every six months does that state pay for that then?

CHAIR:

Mr. Chirdon?

MR. CHIRDON:

The answer to the question is no. The state can't afford that, especially in these very

difficult financial times. We're not doing that.

MR. STRICKER:

Forrest Stricker, what will that cost us?

MR. CHIRDON:

Every lab is different, Forrest. We have some labs here that can actually comment on that. With my brief study on this, it's approximately $200 every six months, which Janice, you're closer to this than I am, and John, what would you fine folks say?

MR. PCSOLAR:

I would say it's a minimum of $150.

MR. CHIRDON:

$150.

MR. PCSOLAR:

Minimum.

MR. CHIRDON:

It could be more.

MS. BAUERMASTER:

I think it's $150 and $200. There are some charges --- personally I contact UC and silicer (phonetic) the campylobacter. So I have to send that sample back to Georgia and shipping charges are --- unless I can piggybank several down at the same time and slip between the farmers, it does get quite costly.

CHAIR:

That's for the four pathogens.

MS. BAUERMASTER:

UC --- yes, three of those. I get those testings, campylobacter goes to Georgia.

CHAIR:

Got it.

MR. STRICKER:

That will affect our cost then, which as this lady has pointed out will affect the cost of our consumers.

CHAIR:

Doctor Beal?

DR. BEAL:

Just to clarify, the quote that you're making is just for bacteriological testing, not any of the other testing that is bacteriology. Just for the bacteriological ---.

MS. BAUERMASTER:

No, just for the four pathogens.

CHAIR:

Now we can --- oh, yes.

MS. WALKER:

I'd like to mention in this list there was a note from manufacturing. There is no exception

made for the farms cheese maker. It looks like every batch of milk has to be tested for antibiotics in the new proposed rule. That's an extreme expense.

CHAIR:

As I indicated, we updated our regulations to the USDA recommended requirements. Actually that program mirrors the PMOs appendix in antibiotic residue monitoring testing. And in fact it does --- it is in there. It is a residue retention program and you would bring that same standard to the USDA work, into the manufacturing work.

MS. WALKER:

So every farm that produces any cheese has to test every batch that will be made into cheese, every batch of milk that will be made into cheese for antibiotics. And that will either require --- how are we supposed to accomplish that?

MR. HOGE:

We would provide you guidance on the appendix and approved test kits. And you would have to keep certification to operate those test kits with certified individuals. That's a program that Mr. Hydock administers throughout the State of Pennsylvania. And again, we've been doing that in the Grade A community since 1991.

MS. WALKER:

Well, could you have a lesser regulation for in-state sales, because I believe the test kit is somewhere between $3,000 and $4,000 to purchase. And then we're going to be licensed to operate it and trained and you're going to come out and watch us do it a couple times a year. And I don't think you have the staff for that. And we don't have the financial capability of doing that on the farm.

MR. HYDOCK:

The only thing that I would recommend is that based on the type of operation we have, we can recertify if you pull the sample and have a commercial laboratory come and pick it up and test it within 72 hours of you pulling the sample and keep that documentation on the farm. So therefore you would only be paying for an antibiotic test that is being done by your approved commercial laboratory. Therefore if you're only doing this once or twice a week, that's the cost you would incur, instead of that initial cost of over $3,000 to get involved in the appendix setting. It should be based on the type of operation, what is occurring and what will be required. Pulling the sample, keeping it in the refrigerator, dating it and waiting for --- it would

be like the haulers, as they pull the truck in, and they pull a sample for antibiotic testing. You would pull the sample of that milk, put it in the refrigerator and mark the date, time and temperature. You would be certified as a food sample, pull a sample for appendix setting. But upon doing that, you would notify your commercial laboratory and they would do the testing. And you would keep that documentation in your files. That would be one way of meeting compliance, but saving that initial investment for use.

CHAIR:

May I suggest that when we look at the proposed regulations, you want to formulate a written comment, and again we have to give it a look and we have to give a written response in a comment and response section of the final reg that would address that. So I think that's a good place to ---.

MS. WALKER:

Cheese makers in the state should be notified of that, because you've notified raw milk producers, but I don't believe you've notified all the cheese makers. So that's a huge change.

MR. HOGE:

Well, the list that I had, as long as ---

there was 118 letters that were sent out. That included all raw milk permit holders that manufacture aged cheese 60 days and also fluid raw milk permit holders. So anybody who was manufacturing aged cheese 60 days would have got a notification of this hearing. Did you get a notification?

MS. WALKER:

Yes, I did. Thank you.

CHAIR:

Sir.

MR. STRICKER:

Forrest Stricker. Would the PDA no longer be doing the testing, it would be all done by independent labs?

MR. HOGE:

Concerning what?

MR. STRICKER:

I'm sorry, concerning the pathogen testing or the somatic cell count testing.

MR. HYDOCK:

Pretty much that's --- most of the standards are being done by commercial laboratories that are doing routine testing right now. The pathogens will be now done by commercial laboratories also.

CHAIR:

Generally speaking, Mr. Stricker, once a year we do a survey. And once a year what we have is checking, just like now, we'll do it once a year. I know that in 2007 we had an 8.4 percent pathogen positive. In 2008 a 6.2 and in 2009 it was 2.2. You see how it's going down, which is a very positive thing. And we want to maintain that. And we feel that testing and the corrective actions taken to find that positives have been very instrumental in that.

MR. STRICKER:

I would ask that you make sure that those tests are accurate. Because a lot of times they did a retest and there was no pathogens found. And then the farmer's name got put in the paper and sales were suspended and there was no record of anyone being sick. And it was quite a hardship. But now can two be tests be taken just to make sure that it's proven before it goes to the meeting.

CHAIR:

We do a confirmation test. And what the confirmation test means is we will see the bacteria and the pathogenic bacteria present. So unless we have confirmation, which is a hundred percent accurate, we won't take those steps, Mr. Stricker.

Now if we have it absolutely we will let the people know that there is a problem here. Milk could change from day to day, what happens today changes tomorrow. If the price should fall off, suck something off the ground, that may not have to be performed. Milk today is not the same as it might be tomorrow. Things can change. So that's not unusual to have a positive pathogen today and negative tomorrow. That can happen. We see that.

MR. STRICKER:

And like for instance on the Trent Nendricks Farm it was actually taken from creek water. But his raw milk got blamed and ---.

CHAIR:

We're getting a little bit afield from the purpose of the hearing. We're concentrating on bacteriological standards, but I think what you have to say is a fair comment under our proposed regulation. I hope you'd put it in writing and address what specific changes you would like to see to try to avoid the problem you described. I'm aware of Mr. Chirdon's position that --- actually looking through the microscope or what have you and observing the pathogens. And it's a --- they're there or they're not. And I'm also aware that milk changes

from day to day as he indicates. If there's something we can put on paper that helps strike the balance between protecting the public and our duty to let folks know if we find something that's potentially problematic with our responsibility to the industry to see that it's strong and vital. If there's some words we can put on paper, I invite public comment. And like I said, our proposed regulation will certainly change as a result of comments. And it will certainly change for the better. So if there's a better idea out there, go entertain it. And if we don't implement it, we'll explain why in the comment and response time. Sir?

MR. MILLER:

One question. Could someone outline what the testing responsibilities will be for the producer versus what the stat's going to do? There's some references in here this might be beyond the purview of this hearing. There's some references in here to shelf life testing, milking and pesticides. And so it's a little unclear, as I was reading through it. I think the shelf life does say that the department can do it, but the pesticides it doesn't say specifically who's responsible for doing that testing, just what happens if you have pesticides in your milk. So I

didn't know if someone could outline who is responsible for what.

MR. HYDOCK:

Yeah, that's basically what the pesticides department may monitor, pesticides. So if there is a complaint concerning the misuse of pesticides we would get involved in it. Usually what we'd try to do is go to the Bureau of Planning. They regulate the pesticide controls and that. But if a farmer calls in there and says hey, we have a possibility of contamination, we would start the process of testing and work through it that way. But if it would come up that it's present, then we would end up notifying the industry it's their fault to the misuse of pesticides. The question would be, why was that pesticide misused to cause this problem? Concerning the shelf life, the department will monitor the shelf life of the products to determine if they fall into the 17 days. We will continue to do that. That's our responsibility and it's laid out. But if you see where it says about pesticides and chemicals, we may monitor it, we may not. But if there's a problem we're supposed to.

MR. MILLER:

I don't really see where it says

specifically who was going to do that.

MR. HOGE:

James, let me refer you to 59a.408(a), responsibility. The raw milk permit holder shall be responsible to arrange for the regular sampling and testing required with respect to the raw milk permit and pay for this testing. So that is pretty much meant to verify that, that in fact the onus is on the producer and the permit holder in this situation to validate twice monthly that their milk conforms to these standards. And I say that by way of bacterial count, the less than --- 20,000 or lower bacterial count, the cholaform count not to exceed ten per milliliter, the accompany antibiotic test which must be run with those bacterial tests. We used to say only one bacteria test month. Current methodology requires that an antibiotic test be run with any bacterial test that's run officially.

So now we obviously had to bump that up to the same frequency of twice per month for the antibiotics. And the somatic cell count, as I said we made that uniformly twice a month. And I mentioned the drugs. And then finally we're adding pathogenic bacteria. And again that would be the permit holder's responsibility, financial responsibility. You would

need to contract with an improved laboratory or laboratory certified by the department for doing these tests officially. And that way we have a better level of confidence in the laboratory results, because it's been certified for that testing.

MR. MILLER:

If you look just further down under 59a.409 to subparagraph 2 --- or (b), I'm sorry, that's where I read about the --- what happens if there's a presence of pesticide. But nowhere could I find where either the department or the permit holder are indeed testing for pesticides. So there's a violation requirement there, but there's no requirement for testing. I guess I was a little concerned, because if the producer is required to do pesticide testing, again that gets into a more advanced technology that most laboratories don't have, dairy laboratories.

MR. HOGE:

This is a good point, and I encourage you to put a comment in on this, but we didn't anticipate you --- the producer doing pesticide testing. We don't do that for our regular producers of milk for pasteurization and milk for manufacturing. But as Mike already eluded to if they're --- it's a recorded

accident, whereby a cow will get into a treated field crop or something, which that does happen and we do get those reports, then of course this would kick in. Additionally if we would do a survey, Mike had been doing some of those, to find that is to be the responsibility of that producer and caused by that producer's milk, then again --- it's not part of the table and the monthly testing. No, even the PMO doesn't require that pesticide testing.

CHAIR:

Question?

MS. WALKER:

Yes, Candace Walker. In that same area, 59a for '09, now we're using --- we're seeing using these new standards for the bacterial count and so forth. But then in a change, not only do you have to pass all the tests, but if you fail two out of four you're notified. But if you fail three out of five you're prosecuted. That's a big change. It used to be --- yeah.

CHAIR:

You're not --- I should make a point that you're not prosecuted. Your permit is suspended or revoked. There's no criminal prosecution. It's an administrative procedure until milk is in compliance

with standards, so ---.

MS. WALKER:

Okay, I'll read it to you and you can hear what you hear.

CHAIR:

Okay.

MS. WALKER:

Three of the last five tested raw milk samples and see the bacterial count, somatic cell count or chloroform count standards or cooling temperature requirements, the department will proceed to revoke or suspend the raw milk permit. And the raw milk permit holder shall be subject to summary criminal prosecution under the act.

CHAIR:

Apparently that's the current regulatory standard. I don't have a cross cite for you, but we'll double check that. And I'm immediately leery if I see a regulation that says we shall prosecute. I'd like to think that there's some discretion. So would you please put that in the comment as well. And I think you'll see that's how you got them in final form regulation or at least explain. Thank you. Let us now take comments or testimony from anyone who would like to come forth. I had a sign-in sheet where

people could indicate if they'd like to testify. And I think I failed miserably in that. We don't have anyone specific signed up. Can we just, by show of hands, see who would like to offer their own comments this afternoon? Show of hands? Seeing none ---. I'm sorry.

MS. BEAL:

I have a document from Brian Snyder you can put on record here, if you want to I'm prepared to read it into evidence. That document and your earlier actions today, we have a couple more comments.

CHAIR:

Okay. For the record, we've received a letter from the Pennsylvania Association for Sustainable Agriculture. It's a letter dated October 17, 2009 from Brian Snyder, who is executive director of that organization. It will be included in the record of these proceedings as Document Number Seven. And it will be available online for everyone to see. In essence it requests that the public comment period, which had been 30 days for this proposed regulation, he extended to a total of 90 days. And as I indicated at the beginning of today's hearing, we've extended it to 60 days. This letter will be part of the record. And Doctor Beal, you wanted to add to that?

DR. BEAL:

Well, without complaining about your extension, because I'm quite happy that that was decided, but the reality is we're still two-thirds of the way now through the 30 days of the first stop. And I just wondered if there might be some consideration about pushing that date out. And I would appreciate it, but that's without maybe asking for the cake and the ice cream all in one batch. The other comment that I would like to explore is the possibility of holding another public meeting within the comment period. I appreciate that this meeting had to be held because of the --- because the dictates of the process. But it would seem to me to be a good idea to hold at least one other public meeting within that period.

CHAIR:

I'll take that suggestion. It will be part of the record. And I have to present this record to Secretary Wolff, who will make some decisions based on that. Thank you. Are there any other people who would like to offer comment? All right. From here the documents I identified will be part of the record of this hearing. A transcript of every word that has been said will be part of the record of this hearing.

We'll put both on our website probably within two weeks or so. After that, the comment period on the proposed reg. runs through September 30th. I would encourage any interested persons, and we've heard a lot of good ideas today, to submit formal written comment. That is the first and best way to impact the regulation. If you have language that you think is better, suggest it.

I can tell you as a fact that people who have suggested language in the past, if it's well reasoned, have found their language in our regulations. I can tell you also that there is no perfect document. And the longer the regulation the more potential for things to be wrong with it. So I welcome people looking carefully at this, thinking things through and letting us know their thoughts. Even if your ideas don't make it into the final form regulation, you will know why. That's very helpful. With that, we're going to adjourn this meeting.

I'll be sitting here for 10 or 15 minutes if anyone wants to ask me any questions or has any questions about the regulatory promulgation process or where do we go as I pack up these papers. Thank you for coming. I think it was very helpful having such a cross section here. It was great to have laboratory

people in the room who could provide numbers, different questions or the audience members who kind of answered their own questions a bit. So thank you again. Have a safe drive home and please look at the proposed regulation and comment if you want to. I encourage you to. Thank you.

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MEETING CONCLUDED AT 2:15 P.M.

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CERTIFICATE

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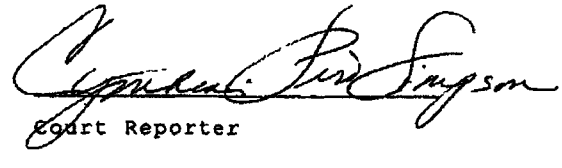

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