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INDEPENDENT REGULATORY REVIEW COMMISSION

333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

October 30, 2009

Honorable Dennis C. Wolff, Secretary
Department of Agriculture
211 Agriculture Building
2301 North Cameron Street
Harrisburg, PA 17110

Re: Regulation #2-160 (IRRC #2777)
Department of Agriculture
Milk Sanitation

Dear Secretary Wolff:

Enclosed are the Commission's comments for consideration when you prepare the final version of this regulation. These comments are not a formal approval or disapproval of the regulation. However, they specify the regulatory review criteria that have not been met.

The comments will be available on our website at www.irrc.state.pa.us. If you would like to discuss them, please contact me.

Sincerely,

Kim Kaufman
Executive Director
wbg
Enclosure
cc: Honorable Michael W. Brubaker, Majority Chairman, Senate Agriculture and Rural Affairs Committee
Honorable Michael A. O'Pake, Minority Chairman, Senate Agriculture and Rural Affairs Committee
Honorable Michael K. Hanna, Sr., Majority Chairman, House Agriculture and Rural Affairs Committee
Honorable John A. Maher, Minority Chairman, House Agriculture and Rural Affairs Committee
Robert A. Mulle, Esq., Office of Attorney General
Andrew Clark, Esq., Office of General Counsel

Comments of the Independent Regulatory Review Commission

Department of Agriculture Regulation #2-160 (IRRC #2777)

Milk Sanitation

October 30, 2009

We submit for your consideration the following comments on the proposed rulemaking published in the August 1, 2009 *Pennsylvania Bulletin.* Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the Department of Agriculture (Department) to respond to all comments received from us or any other source.

1. Determining whether the regulation is in the public interest.

Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b) directs the Independent Regulatory Review Commission (IRRC) to determine whether a regulation is in the public interest. When making this determination, IRRC considers criteria such as economic or fiscal impact and reasonableness. To make that determination, the Commission must analyze the text of the Preamble and proposed regulation and the reasons for the new or amended language. The Commission also considers the information a promulgating agency is required to provide under Section 5 of the Regulatory Review Act (§ 745.5(a)) in the Regulatory Analysis Form (RAF).

This proposed rulemaking is a comprehensive rewrite of the Department's milk sanitation regulation that includes seven subchapters. The Preamble included with the proposal only provides an "overview of the major provisions of the proposed rulemaking." This brief overview does not provide an adequate description of the numerous sections of the rulemaking and the rationale behind the language. Without this information, this Commission is unable to determine if the regulation is in the public interest. In the Preamble submitted with the final-form rulemaking, the Department should provide more detailed information, including a description of the language proposed for each section of the regulation and why the language is required.

2. Fiscal impact.

According to the RAF, some dairy producers may be required to incur new testing costs as a result of this rulemaking. The costs are estimated at $85,200 for fiscal year 2009-2010 and then at $55,200 per year after that. It is our understanding that raw milk producers will also incur additional costs related to testing of their products. However, those costs were not quantified in the RAF. We ask the Department to provide an analysis of the costs this rulemaking will impose on the raw milk producer community.

3. Need.

Subsection 59a.11, relating to the adoption of the Grade "A" PMO (Pasteurized Milk Ordinance), establishes the standards of the Grade "A" PMO as those of the Department. In addition, Subchapter C, relating to the production and processing of milk for manufacturing purposes, adopts the United States Department of Agriculture's document titled "*Milk for Manufacturing Purposes and its Production and Processing – Recommended Requirements*" as the Department's regulatory standards with respect to milk manufacturing. Given the detail contained in these two documents, what is the need for the various sections of this rulemaking which address the same topics?

Subchapter A. PRELIMINARY PROVISIONS

4. Section 59a.1. Scope. – Clarity.

A commentator has questioned if this regulation applies to other milk producing animals, such as goats or sheep. To the extent that the regulation does apply to these other animals, we recommend including appropriate language in this section.

In addition, this section does not make any reference to the regulation of raw milk. We recognize that raw milk may fall under the definition of milk. However, we believe that adding raw milk to this section would improve the clarity of the rulemaking.

5. Section 59a.2. Definitions. – Implementation procedures; Need; Clarity

3-A Sanitary Standards – This definition references the latest standards jointly promulgated by certain parties. It concludes with the following phrase, "...or as otherwise defined in the Grade "A" PMO." This would appear to create two sets of standards that may or may not be consistent. Since regulations create binding standards and have the full force and effect of law, the Department must clearly indicate which standards will take precedence. We have similar

concerns with the phrase as used in the definition of "*PMO – defined milk products.*"

Adulterated – Several definitions found in this section are either direct quotes or paraphrases of statutory definitions found in the Milk Sanitation Law (31 P.S. §§ 645—660g) (Act) or the Food Act (31 P.S. §§ 20.1—20.18) (Food Act). Why is this definition a cross-reference to a statutory definition when other definitions are a quote or paraphrase? We have a similar concern with the definition of "misbranded." We recommend that the Department be consistent with the way it defines terms.

Dairy farm – A commentator has asked if this definition is limited to farms with cows. This should be clarified in the final-form regulation.

Food Act – This definition simply states, "31 P.S. §§ 20.1—20.18." We recommend that it be amended to mirror the format used for the definition of "Act", which states "The act of July 2, 1935 (P.L. 589, No. 210) (31 P.S. §§ 645—660g), known as the Milk Sanitation Law."

Manufactured dairy products – This definition lists specific products and concludes with the phrase "...and other products for human consumption, as may be designated by the Secretary." We recognize that this definition is a verbatim quotation from the Act. However, it is vague and does not set a binding standard. How will the regulated community know if a product was designated as a manufactured dairy product? We recommend that the final-form regulation provide greater clarity as to what is or is not a manufactured dairy product.

Milk plant or *plant* – Most of the language in this definition is from the same definition found in the Act. However, the regulatory definition adds the phrase "milk for manufacturing purposes or milk for pasteurization." Why is the new language being added?

Milk products – What is the need for this definition and the definition of "*PMO-defined milk products*"?

Pennsylvania-approved dairy laboratory director – We have two concerns with this definition. First, it references "written examinations." What examinations are being referred to? Second, how would an individual "demonstrated the necessary experience" referenced?

Permitholder – Would producers of raw milk that hold permits be considered permitholders? If so, this definition should be amended to reflect that fact.

Raw milk – This definition references "relevant provisions of this chapter." We recommend that the specific relevant provisions be cross-referenced in this definition.

In addition, while the Act does explain what raw milk is, it only defines "milk." *See* 31 P.S. §§ 645 and 652 (a). However, where the Act references "milk, milk products or manufactured dairy products," it is unclear if this language encompasses raw milk. Clarification of this phrase is significant since several provisions of the proposed regulation pertaining to raw milk contain language that is similar to provisions of the Act that address "milk, milk products or manufactured dairy products."

The final-form regulation should explain how the definition for "raw milk" is properly aligned with the Act. Specifically, the Department should clarify whether raw milk is included as part of "milk, milk products or manufactured dairy products" under the Act.

6. Section 59a.4. Approved inspectors. – Statutory authority; fiscal impact; clarity.

We have two concerns with this section. First, Subsection (a) imposes an application fee of $50 and Subsection (d) imposes a renewal fee of $20. However, the statutory definition of "approved inspector" sets these fees at $15 and $5 respectively. What authority does the Department have to charge different fees?

Second, under Subsection (b) how will the Department determine that an applicant demonstrated that he or she is of good character? Other vague language in this subsection includes "adequate education or experience" and "capable and efficient manner." How will the Department and the regulated community know if these standards are being met?

7. Section 59a.5. Standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results. – Implementation procedures; Clarity.

We have two concerns with Subsection (a). First, what is the difference between a Pennsylvania-approved dairy laboratory, an official laboratory and other laboratories?

Second, these laboratories must conform to specific sampling and testing standards or "other methods approved by the Secretary." This phrase is vague and does not set a binding standard. What are these other methods? How would a laboratory seek and obtain approval of these other methods? The final-form regulation should either delete this phrase or provide the procedures that need to be followed to obtain approval by the Secretary.

Under Subsection (b), why are only Pennsylvania-approved dairy laboratories referenced? Why wouldn't laboratory directors from the other two types of laboratories be required to follow the same procedures of this subsection?

Subchapter B. PERMIT REQUIREMENTS

8. Section 59a.11. Adoption of Grade "A" PMO. – Statutory authority.

Subsection (a) states:

> The provisions, terms, procedures, appendices and standards of the Grade "A" PMO are adopted as the regulatory standards of the Department to the extent they do not conflict with one or more of the following:
>
> (1) The act.
> (2) The Food Act.
> (3) A provision of this chapter.

Is the Department required by federal law to adopt the Grade "A" PMO? If so, what is the Department's statutory authority for permitting state laws and regulations to supersede the federal requirement? A similar concern applies to Section 59a.405.

9. Section 59a.12. Permits. – Implementation procedures; Reasonableness; Clarity.

Subsection (g) pertains to the ownership of milk permits. It states the person in possession of a milk permit must immediately return or surrender the permit if the permit is suspended or revoked. How would this provision be administered if the permitholder requests an administrative hearing under Subsection (h)(2)? The Department should explain how this provision adequately protects a person's due process rights.

Under Subsection (h)(2), we question whether five days is long enough for a permitholder to decide if they want to request an administrative hearing on a proposed action involving refusal, revocation or suspension of a permit.

10. Section 59a.13. Adulterated or misbranded milk, milk products of manufactured dairy products. – Clarity.

We have three concerns with this section. First we note that the word "of" in the title of this section should be changed to "or." Second, the text of Subsection (b) only references milk and not milk products or manufactured dairy products. We recommend that all three types of milk be included in the

text of that subsection. Finally, we ask if raw milk and PMO-defined milk products should be included in this section.

11. Section 59a.14. Labeling: Bottles, containers and packages of milk, milk products or manufactured dairy products. – Clarity.

The title of this section includes milk, milk products or manufactured dairy products. However, various sections also include or make reference to PMO-defined milk products. We recommend that the title be amended to include PMO-defined milk products. Also, if this section applies to raw milk, it should be amended accordingly.

12. Section 59a.18. Sampling and examination. – Implementation procedures; Clarity.

Subsection (a) states that testing required under this section shall be conducted by a "Pennsylvania-approved dairy laboratory or the Department." However, Subsection (c) states that samples shall be analyzed in a "approved laboratory." These two provisions conflict. What type of laboratory must analyze the samples required under Subsection (c)?

Subsection (d) states that drug residue screening will be completed "at the direction of the Department and records of the testing shall be maintained on file by the permitholder." We have two concerns. First, the phrase "at the direction of the Department" is vague and provides no guidance to the regulated community. We suggest that the drug residue screening requirements be placed in the final-form regulation. Second, how long must the permitholder retain the records?

13. Subsection 59a.19. Standards for grade "A" raw milk for pasteurization, ultrapasteurization or aseptic processing. – Clarity.

The title of this section indicates that the section pertains to raw milk. However, Subsection (a) indicates that the section pertains to just milk. This discrepancy should be resolved in the final-form regulation.

14. Subsection 59a.20. Standards for grade "A" pasteurized, ultrapasteurized and aseptically processed milk and milk products. – Clarity.

To improve clarity and for consistency with the arrangement of the preceding section, we recommend that "applicability" be moved to Subsection (a) and "reference to applicable provisions of the Grade "A" PMO" be moved to Subsection (b).

15. Subsection 59a.26. Plans for construction and reconstruction. – Implementation procedures; Clarity.

This section requires the Secretary to approve construction and reconstruction projects. However, the processes and procedures associated with obtaining approval are not included in the regulation. To assist the regulated community in understanding the requirements of this section, the procedures that need to be followed to obtain approval, including timeframes, should be included in the final regulation.

16. Subsection 59a.27. Personnel health. – Conflict with other statutes; Reasonableness; Implementation procedures; Clarity.

Subsection (a) of this section reads as follows:

> *Specific requirements.* A person affected with any disease in a communicable form or while a carrier of the disease may not work at any dairy farm or milk plant in any capacity which brings the person into contact with the production, handling, storage or transportation of milk, milk products, containers, *equipment and utensils; and a dairy farm or milk plant operator* may not employ in any capacity a person suspected of having a disease in a communicable form, or a person suspected of being a carrier of the disease. A producer or distributor of milk or milk products upon whose dairy farm or in whose milk plant a communicable disease occurs or who suspects that an employee has contracted any disease in a communicable form or has become a carrier of the disease shall notify the Department immediately.

We have four concerns. First, inclusion of the phrase "any disease" makes the scope of this subsection very broad. Can this be narrowed in any way? Second, how would an employee or employer know if a disease is being carried if no symptoms are present? Third, we question the legality of requiring dairy farms or milk plant operators not to employ in any capacity a person *suspected* of having a disease in a communicable form. This could be a violation of federal and state civil rights and anti-discrimination laws. We also question the legality of the reporting requirements contained in the last sentence of the subsection, particularly with respect to reporting "suspected" carriers of diseases.

We suggest that this subsection be deleted and that the Department rely on the applicable provisions of the Grade "A" PMO referenced in Subsection (b).

Subchapter C. PRODUCTION AND PROCESSING OF MILK FOR MANUFACTURING PURPOSES

17. Section 59a.103. Plant inspection. – Need; Clarity.

This section states that plants receiving milk or dairy products for manufacturing or processing will be subject to inspection by the Secretary or an agent. Section 59a.17 pertains to inspection of dairy farms and milk plants and provides more detail on inspection requirements. Given the language found in Section 59a.17, what is the need for Section 59a.103?

18. Section 59a.104. Certification of bulk milk collectors – weigher/ samplers. – Clarity.

This section states: "Weighers/samplers will be evaluated and approved by the Department." The process the Department will use to evaluate and approve weighers/samplers should be included in the final-form regulation. Also, the word "weigher" in the title of this section should be made plural.

19. Section 59a.105. Approved milk graders. – Implementation procedures; Clarity.

Under this section, how will the Department be able to determine if the milk grader is capable of determining the quality classifications required for raw milk? The process for making this determination should be included in the final regulation.

20. Section 59a.107. Appearance and odor. – Clarity.

This section references an "acceptable test procedure" and "other test procedures." These references are vague. The final-form regulation should provide greater detail on what is considered an "acceptable test procedure" or include language that is similar to Section 59a.109(b)(10).

21. Section 59a.110. Somatic cell count. – Implementation procedures; Clarity.

Subsection (c)(1) requires laboratories to provide producers with a warning of excessive somatic cell counts. We recommend that this subsection include language similar to Section 59a.109 (c)(1), which states that the warning need not be in writing.

In addition, commentators have questioned what the acceptable somatic cell count will be for goat milk. If this regulation applies to goat milk, and if the standard is different, that standard should be included in the final-form regulation.

22. Section 59a.111. Drug residue level. – Implementation procedures; Clarity.

Subsection (a) pertains to "industry" responsibilities. What is meant by "industry"? The term should be defined or further explained in the final regulation. Similarly, Subsection (a)(5)(i) includes the undefined phrase, "industry personnel." What is meant by the phrase? We have a similar concern with Subsections (b)(1)(ii) and (iii).

Subsection (a)(4) pertains to sample and record retention requirements for load samples. Are there similar requirements for individual producer sampling under Subsection (a)(2)?

Under Subsection (b)(2)(v), a producer's milk shipping privileges could be suspended "according to State policy." This phrase is vague. What policies are being referred to? This should be included in the final-form regulation.

23. Subsection 59a.114. Inspection and quality testing of milk from producers. – Need; Reasonableness; Implementation procedures.

Subsection (d)(2)(i) requires new buyers to obtain certain records from previous buyers. Subsection (d)(5) also states that if a new buyer fails to receive required records from the previous buyer, that fact must be reported to the Department. We have three questions. First, what is the need for this transfer of information between a previous buyer and a new buyer? Second, what incentive would the previous buyer have for cooperating with the new buyer? Third, once the Department is notified of this situation, what can be done to require compliance?

24. Subsection 59a.115. Record of tests. – Implementation procedures; Clarity.

This section requires records to be kept "for at least 12 months." This language does not inform the regulated community of exactly how long the records must be kept. We recommend that the final-form regulation include a more specific timeframe for record retention.

25. Subsection 59a.117. Animal health. – Clarity.

This section refers to the following terms: "modified accredited area"; "accredited free state"; "accredited free herd as determined by the United States Department of Agriculture" (USDA); "Class B status" and "Certified-Free Herds." What do these terms mean? The final-form regulation should either define these terms or provide appropriate cross-references to definitions for these terms.

Subchapter D. FARMS PRODUCING MILK FOR MANUFACTURING

26. Section 59a.201. Farm inspection. – Implementation procedures; Clarity.

We have four questions and concerns with Paragraph (1). First, how is the passing score for inspections established? Second, inspections are required "at least once in each 6 month period." This requirement is vague. The final-form regulation should specify exactly how often inspections will occur. Third, how long must the required records be kept? Fourth, how would a permitholder know if a form for maintaining records is "acceptable" to the Secretary?

Under Paragraph (2), how will it be determined if milk is "of a wholesome sanitary quality"? In addition, the phrase "appropriate time for correction of deficiencies" is vague. Who will decide what is an appropriate amount of time?

Finally, under Paragraph (3), how would a permitholder know if a producer of milk has been instated, suspended or reinstated?

27. Section 59a.202. Milking facilities and housing. – Clarity.

This section includes vague phrases such as "adequate size", "sufficient distance" and "ample size." We recommend that more precise language be added to the final regulation.

28. Section 59a.207. Water supply. – Need; Implementation procedures; Clarity.

The first sentence of this section contains vague words or phrases such as "properly located," "easily accessible" and "ample." It would be difficult for the regulated community to determine if they meet the requirements of this provision. Furthermore, since the second sentence requires the water supply to be approved by the Department, what is the need for the first sentence? In addition, what procedures are required to obtain Department approval of a water supply? The procedures should be included in the final-form regulation.

Subchapter E. MANUFACTURING PLANTS

GENERAL REQUIREMENTS

29. Section 59a.302. Buildings. – Clarity.

Subsection (f)(5) requires laboratories to be properly equipped and maintained "to meet requirements established by the Department," yet the regulation does not set forth what these requirements are. The final-form regulation should

either list the requirements or, if available, provide a cross-reference to relevant code provisions relating to these conditions.

30. Section 59a.304. Equipment and utensils. – Clarity.

Subsection (a)(2) contains a typographical error. The final-form regulation should state that: "New or rearranged equipment shall be set away from any wall or spaced **in** a manner...." (Emphasis added.)

In Subsection (i)(2), what does the Department consider a record of temperature or time of cooling and of holding that is "of significant importance?" This phrase is vague and the final-form regulation should clarify this phrase.

31. Section 59a.305. Personnel cleanliness. – Clarity.

This section includes provisions for proper attire worn by all persons dealing with dairy products. A commentator suggests that "caps" be deleted as a form of clothing, and replaced with "hair nets," in order to be consistent with the current PMO standards. We agree and recommend this change to the final-form regulation. In addition, do "hair nets" encompass covering facial hair (for example, beards)? If the PMO doesn't provide this information, then it should be clarified and included in the final-form regulation.

32. Section 59a.308. Raw product storage. – Implementation procedures; Clarity.

Subsection (c) requires the Department or "a designated representative, from each plant" to conduct raw milk sampling. Who determines the designated representative, the Department or the plant? Under what circumstances would the designated representative and not the Department perform the sampling?

Under Subsection (e)(3), after a new sample is taken subsequent to a high bacteria count, what does the Department consider a "satisfactory" sample? The final-form regulation should explain this standard.

33. Section 59a.310. Composition and wholesomeness. – Implementation procedures.

This section refers to the "necessary precautions" to prevent contamination during manufacturing. However, this section never specifically provides what these precautions are. To improve clarity, the final-form regulation should include a list of requisite precautions. The same concern applies to Sections 59a.349, 59a.363(b), 59a.371(a), and 59a.373(c)(1).

34. Section 59a.311. Cleaning and sanitizing treatment. – Clarity.

Subsection (a)(1) refers to "other similar materials" which will not adversely affect the products used to clean and sanitize. This phrase is vague and should be deleted from the final-form regulation.

Subsection (c) discusses transport tanks. However, Subsections (c)(1)-(3) contain a list of information that does not appear to relate to this issue. The final-form regulation should include additional language to explain why these provisions are included in this subsection.

35. Section 59a.312. Insect and rodent control program. – Implementation procedures.

Who determines who is the "specially designated employee" from the commercial pest control service? In addition, Section 59a.353 refers to a "specifically" designated employee from the commercial pest control service. Is the use of "specially" in one section and "specifically" in another a typographical error? If so, it should be corrected in the final-form regulation. If not, the Department should explain the use of different terms.

36. Section 59a.314. Packaging and general identification. – Clarity.

Subsection (b) requires packaging and repackaging of dairy products to be conducted under "rigid sanitary conditions." Previous subsections, when discussing sanitation, refer to "adequate" sanitary conditions. The terms "adequate" and "rigid" are vague and should be clarified in the final-form regulation. Additionally, why is a higher standard used in this section? The same concern applies to Subsection 59a.373(d).

37. Section 59a.316. Permits. – Implementation procedures; Clarity.

This section states that plant permitting requires "satisfactory compliance." How is such compliance determined? Also, the version of the proposed regulation published in the *PA Bulletin* contains a typographical error within the parenthesis contained in this section. The final-form regulation should correct this error.

SUPPLEMENTAL REQUIREMENTS FOR PLANTS MANUFACTURING, PROCESSING AND PACKAGING INSTANT NONFAT DRY MILK, NONFAT DRY MILK, DRY WHOLE MILK, DRY BUTTERMILK, DRY WHEY AND OTHER DRY MILK PRODUCTS

38. Section 59a.343. Operations and operating procedures: Pasteurization. – Reasonableness; Need; Implementation procedures.

Subsection (b) requires buttermilk to be pasteurized at 185 degrees Fahrenheit, while Subsection (c) requires cheese whey to be pasteurized at 161 degrees Fahrenheit. A commentator questions why these products are pasteurized at different temperatures. The Preamble to the final-form regulation should explain the rationale for the difference.

39. Section 59a.348. Operations and operating procedures: Packaging, repackaging and storage. – Clarity.

In Subsection (a), what would be considered a package or container that protects the contents "without significant impairment of quality"? This phrase is vague and should be explained in the final-form regulation.

SUPPLEMENTAL REQUIREMENTS FOR PLANTS MANUFACTURING, PROCESSING AND PACKAGING BUTTER AND RELATED PRODUCTS

40. Section 59a.361. Rooms and compartments. – Clarity.

In Subsection (a), what are considered "good commercial practices?"

41. Section 59a.362. Equipment and utensils. – Clarity.

In Subsections (d) and (e), what is the difference between "easily cleanable" and "readily cleanable"? These terms are vague and the final-form regulation should clarify this distinction.

42. Section 59a.363. Operations and operating procedure. – Implementation procedures; Clarity.

Subsection(a)(1)(i) requires certain temperatures for pasteurization. As mentioned in this subsection, when would the Department approve "another equivalent time and temperature combination"?

Subsection (e) explains how commercial bulk shipping containers should be properly identified. When would "other identification" be required? The final-form regulation should list these circumstances.

Subsection (g)(2)(i) explains appropriate freezer storage. It includes the sentence: "Adequate air circulation is desirable." The terms "adequate" and "desirable" are vague and do not establish a binding standard that can be complied with or enforced. We recommend that the final regulation include a more measurable and definite standard.

SUPPLEMENTAL REQUIREMENTS FOR PLANTS MANUFACTURING AND PACKAGING CHEESE

43. Section 59a.371. Rooms and compartments. – Fiscal impact; Need; Clarity.

This section describes various types of manufacturing and packaging rooms for cheese. Subsection (g) refers to cutting and packaging rooms, and requires separate *rooms* for cleaning and preparation of cheese. A commentator is concerned that requiring numerous rooms would be cost prohibitive to a farmstead cheese maker. What is the need for separate rooms? Have these costs been quantified in the RAF?

44. Section 59a.372. Equipment and utensils. – Implementation procedures; Clarity.

This section describes various types of equipment and utensils. Subsection (e) includes the phrase "miscellaneous equipment," but it is unclear what this includes. The final-form regulation should define this term.

Subsection (i) discusses paraffin tanks. A commentator questions whether a food grade ceramic tank would be acceptable. The Department should explain why only "metal tanks" are considered paraffin tanks.

SUPPLEMENTAL REQUIREMENTS FOR PLANTS MANUFACTURING, PROCESSING AND PACKAGING PASTEURIZED PROCESS CHEESE AND RELATED PRODUCTS

45. Section 59a.382. Operations and operating procedures. – Implementation procedures; Clarity.

Subsection (c) states that filler crews shall handle forming containers "with extreme care." How does the Department intend for crews to meet the standard of "extreme care?" This term is vague and should be defined in the final-form regulation.

SUPPLEMENTAL REQUIREMENTS FOR PLANTS MANUFACTURING, PROCESSING AND PACKAGING EVAPORATED, CONDENSED OR STERILIZED MILK PRODUCTS

46. Section 59a.391. Equipment and utensils. – Clarity.

Subsection (a) states that: "...for certain other equipment, the requirements of this section shall be met." What does the Department consider the "other equipment" that would be subject to this section?

Subchapter F. RAW MILK FOR HUMAN CONSUMPTION

47. Section 59a.402. Raw milk; Prohibitions. – Statutory authority; Clarity.

Subsection (a) prohibits the sale of raw milk without the seller having a valid permit issued by the Department. Several commentators, including Representative Samuel E. Rohrer (128th Legislative District), suggest that this type of permit is unconstitutional, as the Department does not have jurisdiction to regulate direct farmer-to-consumer transactions. While the Act does permit the Secretary to require permits, it also includes a section that relates to portions of the Act being ineffective due to court holdings of unconstitutionality. *See* 31 P.S. § 660g. What is the Department's statutory authority for regulating these types of transactions? Are there any court holdings related to this issue?

Subsection (b) authorizes a raw milk permitholder to obtain a permit for the sale of aged cheese manufactured from raw milk. Commentators recommend that this additional permit be expanded to include other dairy products, such as yogurt, kefir, butter and cottage cheese. Has the Department considered expanding the scope of the second permit?

48. Section 59a.403. Raw milk permit. – Implementation procedures.

Subsection (b) states that "Each raw milk permit will expire as of September 1 each year...." This subsection also limits a permit's validity to no more than one year. However, if a person receives a permit in August, for example, how can the permit be valid for a year if it automatically expires in September? In order to fulfill the entire year for the permit, has the Department considered including in this subsection a deadline for when a person can *apply* and *receive* a valid permit?

49. Section 59a.404. Requirements for the issuance of a raw milk permit. – Protection of the public health, safety and welfare; Need; Implementation procedures; Clarity.

This section details the requirements for the issuance of a raw milk permit. However, while it does require that specific processes be followed from other sections, the majority of these requirements are included, almost verbatim, in subsequent sections of this subchapter. To improve clarity, the Department should consider only listing in this section the specific permit requirements and maintaining further details about them in other sections.

Subsection (a)(1)

This subsection states that: "The dairy farm must be **in passing condition** to be eligible for a raw milk permit." (Emphasis added.) What do Department inspectors consider "passing condition"? The final-form regulation should clarify this issue.

Subsection (c)

Subsections (c)(1) and (2) require applicants for both new and successor raw milk permits to provide the Department with a report from a licensed veterinarian that the herd is "...free from communicable disease." A commentator is concerned that an examination by a veterinarian may not have enough information to reach this conclusion, because the regulation is unclear as to what specific diseases this phrase encompasses. To improve clarity, this phrase should be deleted from the final-form regulation. The same concern applies to Section 59a.406(d).

Subsection (d)

This subsection provides that confirmation of a safe water supply must occur as a permit requirement. A commentator suggests that only the water supply is mentioned, and not the cooling water used in the cooling of the raw milk. Has the Department considered confirmation of the safety of cooling water as a permit requirement? The same concern applies to Section 59a.407.

Subsections (d)(1) and (2) require the water supply on the farm to be "bacteriologically safe," without further explanation. The final-form regulation should clarify what a "bacteriologically safe" water supply is. The same concern applies to Subsection 59a.407 (c).

Subsection (e)

Subsection (e)(1)(v) requires, as part of sampling and testing necessary for new raw milk permits, testing for the presence of "pathogenic bacteria."

Commentators argue that because all pathogenic bacteria do not cause illness in humans, it is unreasonable to test for them since they do not pose a threat to public health. Is it possible for testing to occur only for pathogens that can cause illness to humans? The same concern applies to Sections 59a.409(d), (d)(3) and (d)(4).

Subsection (f)

This subsection deals with different types of containers for packaging raw milk. A commentator suggests that not only are there containers owned by the consumer and the producer, but there are also containers *sold* by the farmer to the consumer along with the milk. The final-form regulation should include this third type of container. The same concern applies to Section 59a.410.

This subsection also discusses separate rooms for "bottling, single service container storage, and bottle washing." Section 59a.410(a) also requires use of a "mechanical means of filling and capping bottles." What is the need for both the separate rooms, as well as such mechanical equipment?

50. Section 59a.406. Animal health. – Clarity.

This section states in three places (Subsections (b)(1) and (2), and (c)) 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. The Act defines raw milk as "milk from a cow or cows...." *See* 31 P.S. §652 (a). However, Section 59a.404 (c) of the proposed regulation, which discusses animal health requirements for obtaining a permit for raw milk, only refers to "the herd." A commentator also notes that Section 59a.12(b)(5) states: "A person producing and selling milk from a single cow" is an "exception" for obtaining a permit. The Preamble to the final-form regulation should clarify whether Section 59a.12 (b)(5) applies to raw milk permits. In addition, given how raw milk is defined in the statute, the Preamble should also explain the discrepancy between the use of "animal or herd" and "herd" in Sections 59a.404 (c) and 59a.406.

51. Section 59a.407. Regular testing of water supply. – Implementation procedures.

In Subsection (d), how long must a raw milk permitholder retain water test records?

52. Section 59a.408. Regular testing of raw milk. – Protection of public health, safety and welfare; Implementation procedures.

Subsection (c) lists the raw milk testing schedule and standards. With respect to somatic cell count, a commentator questions why the testing has been

increased to twice a month. In addition, how did the Department determine that 750,000/milliliter is the appropriate limit for the count?

53. Section 59a.409. Violations of raw milk testing standards. – Implementation procedures; Clarity.

Subsection (b) lists various procedures to be followed if pesticides are detected in milk samples, but does not specify a required testing regimen. The final-form regulation should clarify if and when such testing is required.

54. Section 59a.411. Label content reviewed by the Department. – Implementation procedures; Clarity.

Subsection (a)(1) requires labels on raw milk containers to be submitted to and approved by the Department prior to use. The final-form regulation should include a timeframe for Department approval of the labels.

Subsections (a)(2)(ii) and (b)(2) include the following statement: "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." We raise two issues. First, why is this statement included in each of these subsections? Second, what is meant by "alternative written means?" The final-form regulation should address these concerns.

55. Section 59a.413. Enforcement: Suspension or revocation of a raw milk permit. – Implementation procedures; Clarity.

This section relates to the process for suspension or revocation of a raw milk permit. We raise three issues.

First, Subsection (b)(2) discusses the detection of pathogenic bacteria as the basis for suspension or revocation of a raw milk permit. Would this include detection of *all* pathogenic bacteria, or just those that would cause human illness? The final-form regulation should clarify this issue.

Second, under, Subsection (b)(2)(ii)(C), if a permitholder does not voluntarily cease raw milk sales, the Department will arrange for an administrative hearing upon the request of the permitholder. However, this subsection does not identify the process for arranging such a hearing. The final-form regulation should set forth the hearing procedures or include a cross-reference to any provisions in the regulation pertaining to the hearing process.

Finally, once a permit has been suspended, what will the process be for permit reinstatement? Would it be the same process as that included in Section 59a.12?

56. Section 59a.416. Enforcement: Seizure, condemnation, denaturing or destruction of raw milk; exclusion from sale. – Statutory authority; Implementation procedures; Clarity.

Subsection (a) permits the Secretary to "...seize, condemn, denature or destroy..." "raw milk or illegally-produced raw milk products...considered unsafe or a menace to public health...." Several commentators, including Representative Rohrer, consider such conduct to be unconstitutional, in particular for raw milk involved in direct farmer-to-consumer transactions. Representative Rohrer also expressed concerns related to Section 59a.415, which permits the Attorney General to "enjoin a person from selling raw milk without the required raw milk permit." Representative Rohrer states that "the attempt of this Section to label private contracts [direct farmer-to-consumer transactions] as "illegal" is a direct violation of both the state and federal Constitutions."

While similar language, pertaining to both seizures and injunctions, is included in the Act, these provisions refer to "milk, milk products, or manufactured dairy products" and it is unclear whether raw milk is included within these categories. *See* 31 P.S. §§660e and 660f. What is the Department's statutory authority for both of these types of raw milk enforcement?

Subsections (a) and (b)(1) refer to products that the Secretary "considers unsafe," and Subsection (a) also includes those products that are a "menace" to public health. How does the Secretary make these determinations? The final-form regulation should clarify what is considered "unsafe" as well as what would be a "menace" to public health.

Facsimile Cover Sheet

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INDEPENDENT REGULATORY REVIEW COMMISSION
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

To: April Orwig
Agency: Department of Agriculture
Phone: 2-2853
Fax: 5-8402
Date: October 30, 2009
Pages: 21

Comments: We are submitting the Independent Regulatory Review Commission's comments on the Department of Agriculture's regulation # 2-160 (IRRC #2777). Upon receipt, please sign below and return to me immediately at our fax number 783-2664. We have sent the original through interdepartmental mail. You should expect delivery in a few days. Thank you.

Accepted by: Nicole McCrone Nicole McCrone **Date:** 10/30/09

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