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

April 25, 2002

Honorable Samuel E. Hayes, Jr., Secretary
Department of Agriculture
211 Agriculture Building
2301 North Cameron Street
Harrisburg, PA 17110

Re: Regulation #2-137 (IRRC #2255)
Department of Agriculture
Food Code

Dear Secretary Hayes:

Enclosed are the Commission's Comments which list objections and suggestions for consideration when you prepare the final version of this regulation. These Comments are not a formal approval or disapproval; however, they specify the regulatory criteria which have not been met.

The Comments will soon be available on our website at www.irrc.state.pa.us. If you would like to discuss them, please contact my office at 783-5417.

Sincerely,

A handwritten signature in black ink that reads "Robert E. Nyce".

Robert E. Nyce
Executive Director

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Enclosure

cc: Honorable Raymond Bunt, Jr., Majority Chairman, House Agriculture and Rural Affairs Committee
Honorable Peter J. Daley, II, Democratic Chairman, House Agriculture and Rural Affairs Committee
Honorable Mike Waugh, Chairman, Senate Agriculture and Rural Affairs Committee
Honorable Michael A. O'Pake, Minority Chairman, Senate Agriculture and Rural Affairs Committee

Comments of the Independent Regulatory Review Commission

on

Department of Agriculture Regulation No. 2-137

Food Code

April 25, 2002

We submit for your consideration the following objections and recommendations regarding this regulation. Each objection or recommendation includes a reference to the criteria in the Regulatory Review Act (71 P.S. § 745.5a(h) and (i)) which have not been met. The Department of Agriculture (Department) must respond to these Comments when it submits the final-form regulation. If the final-form regulation is not delivered by March 25, 2004, the regulation will be deemed withdrawn.

1. Application of the statutes and proposed regulation to schools and nonprofit organizations. - Impact on public health; Consistency with other regulations; Clarity.

Two commentators, the Pennsylvania Catholic Conference and Pennsylvania School Boards Association, raised questions regarding the application of this regulation to different types of entities. There are two concerns.

First, it is unclear how the provisions and requirements of Chapter 46 will apply to cafeterias in private and public schools, and kitchens in camps, nonprofit agencies, religious organizations and private clubs, or similar establishments. For example, will school cafeterias or church kitchens need to obtain a permit, license or registration as required by Section 46.1141? The Department should clearly delineate how this regulation will apply to these types of facilities.

Second, this proposed regulation is repealing existing regulations that are referenced in the existing regulations of other state agencies. For example, a regulation of the Environmental Quality Board at 25 Pa. Code § 171.6, references 7 Pa. Code Chapter 78. Chapter 78 will be deleted by this regulation and replaced by Chapter 46. What steps is the Department taking to notify other agencies of these changes and the need to update their regulations?

Subchapter A. Purpose and Definitions.

2. Section 46.3. Definitions. - Consistency; Reasonableness; Readability; Clarity.

Adulterated

Paragraph (iii) is an extremely long sentence. For clarity and readability, it should be edited into shorter sentences.

Approved

The definition of this term includes the following phrase "Acceptable to the Department based on a determination of conformity with principles, practices and generally recognized standards." We have two concerns.

First, the regulation doesn't specify the process for making the determination of conformity. The Department should include these steps in the final-form regulation, perhaps in Subchapter H, relating to administrative procedures.

Second, the phrase "principles, practices and generally recognized standards" is unclear. The definition should include examples, cross-references or citations to these practices and standards.

Food employee

A hyphen should be added between the words "food" and "contact" to be consistent with the definition of "food-contact surface."

Hazard

This definition contains the phrase "that may cause an unacceptable consumer health risk." For clarity, the Department should include examples of what it considers an "unacceptable consumer health risk" in the definition.

Honestly presented

The words "honestly presented" are used in Sections 46.1, 46.201, 46.421, and in other sections in the proposed regulation. Section 46.421(b)(1) contains a straightforward description of this phrase. Since this phrase is used in different provisions in the regulation, a definition, similar to the provision in Section 46.421(b)(1), should be added to Section 46.3.

Packaged

The definition of this term is not similar to the definition of the term "package" as set forth in Section 20.2 of the Food Act (31 P.S. § 20.2). The Department should review the regulation, and determine whether it is more appropriate to use "packaged" or the statutorily defined term "package" in the final-form regulation.

Potentially hazardous food

There is a typographical error in Paragraph (i) of the definition of "potentially hazardous food" in the *Pennsylvania Bulletin*. The word "ingredient" is misspelled.

Private water system

This term is not used in the regulation. Therefore, the definition is unnecessary and should be deleted.

Public eating or drinking place

The word "not" is missing in Paragraph (ii) of this definition in the version printed in the *Pennsylvania Bulletin*. The word "not" should be placed between "does" and "apply" in this definition in the final-form regulation.

Substance

The definition of this term contains the word "substance." Section 1.7(e), relating to definitions, in the *Pennsylvania Code and Bulletin Style Manual* states, "the term being defined may not be included as part of the definition." The Department should either delete this term from the definition, or replace it with a word or phrase that conveys the same meaning.

Subchapter B. Employees

3. Section 46.112. Disease or medical conditions that must be reported. - Protection of public health; Reasonableness; Clarity.

There are two concerns.

First, the structure of this section differs from that of the 1999 Federal Recommended Food Code at Section 2-201.11. Specifically, Subparagraphs 1-4 of Section 46.112, list diseases or medical conditions. However, Subparagraphs 5-8 describe situations where someone is suspected of causing or being exposed to a disease, or is living with another person with a disease. The 1999 Federal Recommended Food Code clearly identifies the "someone" as the food employee or applicant. The proposed regulation does not clearly identify the subject of Paragraphs 5-8 as the employee or applicant. This section should be rewritten to more closely reflect the 1999 Federal Recommended Food Code at Section 2-201.11.

Second, the Chester County Health Department suggests the term "Esherichia coli O157:H7" in Section 46.112 should be replaced by the term "Shiga toxinproducing *E. coli*." This change would allow for the use of rapid nonculture assays, thereby avoiding delays in receiving results of culture-based subtyping procedures. The term "Esherichia coli O157:H7" is also used in Section 46.113(a)(2)(ii). This update should be made in the final-form regulation.

4. Section 46.132. Duty of food employees to wash. - Protection of public health; Consistency with other regulations; Clarity.

The Department used the 1999 Federal Recommended Food Code as a model for developing this regulation. The Federal Recommended Food Code is updated and revised periodically. One commentator suggested that this section should be updated to match the 2001 Federal Recommended Food Code by including a requirement that employees wash their hands before using gloves. The Department should include this requirement in the final-form regulation.

5. Section 46.133. Required washing locations. - Fiscal impact; Reasonableness; Clarity.

This section prohibits food employees from using a utility sink for required hand washing. There are two concerns.

First, the term "utility sink" should be defined.

Second, the prohibition against using a "utility sink" as a washing location for employees may not be feasible for small business food establishments with limited space. The Department should consider providing a variance that allows food employees to wash their hands in a utility sink not used for food preparation when a facility, such as a small business, does not have space for additional sinks or lavatories for hand washing.

6. Section 46.134. Hand sanitizers. - Clarity.

Subsection (a)(1)(ii)(A) refers to the "current FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash." OTC is not defined but only appears in Section 46.134. The final-form regulation should include the words "over-the-counter" in parentheses following "OTC" to insure that readers know the meaning of the acronym.

Subchapter C. Food

7. Section 46.213. Packaged food. - Duplication of other regulations; Clarity.

There are two concerns.

First, this section states that packaged food shall be labeled as specified in the Food Act, this chapter, 21 CFR 101, 9 CFR 317 and 9 CFR 381, Subpart N. Labeling requirements are set forth in greater detail in Section 46.422 with the same citations to federal regulations. Rather than referencing the Act and federal regulations, this section should cross-reference Section 46.422.

Second, if the reference to “the Food Act” is retained in this section, it should be changed to “the Act” to be consistent with the definition of “the Act” in Section 46.3.

8. Section 46.220. Wild mushrooms. - Reasonableness; Clarity.

This section refers to an “approved mushroom identification expert.” What are the qualifications of an approved mushroom identification expert? Who approves them?

9. Section 46.241. Receiving temperature of food. - Reasonableness; Clarity.

Subsection (d) states, “Upon receipt, potentially hazardous food shall be free of evidence of previous temperature abuse.” This subsection should include examples of “visible evidence of improper temperature.”

10. Section 46.261. Preventing contamination from food employees’ hands. - Reasonableness; Clarity.

Stakeholders have suggested new language to clarify the situations when employees may contact food, including ready-to-eat food, with their bare hands. The Department should review the new language and make changes to the final-form regulation to clarify when employees may touch food with their bare hands.

11. Section 46.303. Linens and napkins: use limitations. - Clarity.

A commentator suggested that this provision should also apply to the use of linens or napkins in a retail display. This section should allow, and provide for, the use of linens or napkins in contact with food in retail displays.

12. Section 46.321. Food storage. - Clarity.

Subsection (d)(9) states, “Food may not be stored under any source of contamination.” It is our understanding that the Department actually intends this provision to prohibit food storage in proximity of any source of contamination. The Department should clarify the language to indicate the minimum safe distance between food and a source of contamination.

13. Section 46.345. Miscellaneous sources of contamination. - Reasonableness; Clarity.

This section states, “Food shall be protected from contamination that may result from a factor not specified in §§ 46.261, 46.262, 46.281-46.286, 46.301-307, 46.321-323 and 46.341-344.” It is understandable that the Department wants to insure that public health authorities can react to sources of contamination not foreseen by this regulation. However, it is unclear how this provision will be implemented. How will the Department measure or observe compliance with this provision? How will regulated parties know when they are in compliance?

The Department should outline procedures that its staff or public health officials will follow when notifying regulated facilities of a previously unidentified contamination source. The Department and public health officials should then inform the regulated community of the steps necessary to protect food from the new type of contamination.

14. Section 46.362. Microwave cooking. - Clarity.

A word is missing in the first sentence of this section in the *Pennsylvania Bulletin*. It reads: "Raw animal foods cooked in a microwave oven meet all of the following." It should read: "Raw animal foods cooked in a microwave oven shall meet all of the following."

15. Section 46.385. Potentially hazardous food: hot and cold holding. - Impact on public health; Reasonableness; Clarity.

The proposed regulation does not contain the date marking provisions found at Section 3-501.17 of the 1999 Federal Recommended Food Code. One commentator contends that these provisions are necessary to insure proper refrigerated storage and to protect public health. If these provisions are not included in the final-form regulation, the Department should explain the reasons for not adopting this portion of the 1999 Federal Recommended Food Code.

Subchapter D. Equipment, Utensils and Linens.

16. Section 46.612. Manual warewashing: sink compartment requirements. - Reasonableness; Clarity.

Size of sink compartments

Subsection (b) requires sink compartments "shall be large enough to accommodate immersion of the largest equipment or utensils." The definition of "equipment" in Section 46.3 includes items that are not typically placed in a sink.

The Department should delete the word "equipment" in this subsection, or add a quantifying term such as "equipment that requires cleaning by immersion" to describe the equipment that should fit in a sink compartment.

Alternative warewashing equipment

Subsection (c) provides for the use of alternative warewashing equipment. Examples of alternative warewashing equipment include "other task-specific cleaning equipment" in Subsection (c)(3) and "brushes or other implements" in Subsection (c)(5). For clarity, the Department should provide examples of both "other task-specific cleaning equipment" and "other implements" in this section.

Subchapter E. Water, Plumbing and Waste

17. Section 46.802. Drinking water system flushing and disinfection. - Clarity.

This section is not clear about whether the water will be tested before placing the system back in service after construction, repair, modification or after an emergency situation. In what instances, if any, would the Department require check samples to be taken?

18. Section 46.804. Quality of water. - Clarity.

Paragraph (b)(1) states, "A nondrinking water supply shall be used only if approved by the Department." How does one get Department approval? This section should include a cross-reference or a citation to the procedure for requesting Department approval.

19. Section 46.805. Quantity and availability of water: capacity and pressure. - Clarity.

Paragraph (b) is one run-on sentence. For clarity, it should be redrafted.

20. Section 46.822. Design, construction and installation of plumbing systems. - Clarity.

Paragraph (a)(2) contains the phrase, "...such as a handwashing facility, toilet for urinal shall be...." This is a typographical error. This phrase should be revised to say "...toilet or urinal..." (Emphasis added.)

21. Section 46.823. Numbers and capacities of plumbing facilities. - Reasonableness; Clarity.

Paragraphs (a)(2) and (a)(3) both start with "If approved by the Department...." How does one obtain Department approval?

Paragraph (b) references requirements for the number of toilets and urinals required. In what instance will the Department's requirements be different than those of the Department of Labor and Industry? For clarity, the Department should remove the phrase "the Department or."

22. Section 46.841. Materials used in construction of mobile water tanks and mobile food facility water tanks.

Section 46.842. Design and construction of mobile water tanks and mobile food facility water tanks. - Clarity.

Paragraph (1) in Section 46.841 and Paragraph (f)(1) in Section 46.842 use the term "safe." However, the Department defines the term "safe materials" in Section 46.3. Consistent terms should be used throughout the regulation.

23. Section 46.843. Numbers and capacities of mobile water tanks and mobile food facility water tanks. - Reasonableness.

Paragraph (c)(2) states, "Provided with a hose connection of a size or type that will prevent its use for any other service." Is it necessary to require a hose connection that cannot possibly be used for another purpose?

Subchapter F. Physical Facilities

24. Section 46.922. Functionality of various physical facilities of a food facility. - Clarity.

Subparagraphs (e)(3)(ii) and (iii) appear to be different ways of stating the same thing. Therefore, one should be eliminated.

Paragraph (e)(4) states, "...protected against the entry of insects and rodents...." However, Paragraph (e)(5) states, "Paragraph (4) does not apply if flying insects and other pests...." These two paragraphs should use consistent language.

The Department should set forth and give examples of what constitutes "Other effective means," found in Subparagraph (e)(4)(iii), or the subparagraph should be deleted.

Subchapter G. Poisonous or Toxic Materials

25. Section 46.1022. Poisonous or toxic substances: limitations on presence and use. - Clarity.

The Department should set parameters for the “Additional conditions that may be established by the Department,” found in Paragraph (b)(3), or the paragraph should be deleted.

Subchapter H. Administrative Procedures

26. General. - Consistency with the statute.

This subchapter includes requirements for licensure, permitting and registration. In all instances, the Department appears to be responsible for these actions. However, the Department is not the only entity that is responsible for licensure, permitting and registration.

Under the definition of “licensor” in the Public Eating and Drinking Places Act (35 P.S. § 655.1) the other entities responsible for these administrative tasks are listed. For consistency with the statute, the Department should consider replacing the term “Department” in this subchapter with the defined term “licensor.”

27. Section 46.1101. Application for intended purpose: public health protection. - Unnecessary duplication.

This section repeats the regulation’s purpose, already noted in Section 46.1, relating to purpose. Section 46.1 amply covers the entire regulation; there is no need to repeat the purpose in this section. Therefore, the Department should delete Section 46.1101 in the final-form regulation.

28. Section 46.1102. Access to food facilities. - Clarity.

This section describes who will be able to gain access to food facilities to ensure regulatory compliance. We have two concerns.

Credentials

First, this section states, “After the Secretary presents *credentials*...” (Emphasis added.) The term “credentials” in this context is confusing. There could be many acceptable examples of credentials that would satisfy this requirement. For clarity, the Department should replace the word “credentials” with “identification,” or specify what type of identification is acceptable.

Reasonable times

Second, the regulations enable the Secretary to conduct these inspections “during the food facility’s hours of operation and other reasonable times.” The phrase “other reasonable times” is unclear. For example, does an inspection during “other reasonable times” require agreement by the owner or operator who may need to give up her or his day off to open a closed facility? The Department should either give examples of “other reasonable times” or delete the phrase.

29. Section 46.1121. Facility and operating plans. - Clarity.

Subsection (b)

Section 46.1121 requires food facility operators and applicants to submit plans and certifications to the Department in specific instances. We have two concerns.

First, Subsection (b) describes the contents of the plans and specifications. Subsection (b)(5) states that the plans and specifications shall include “Other information that may be required by

the Department.” This subsection should include a provision that the Department will issue written requests for “other information” to the operators.

Second, it is unclear how plans and specifications will be communicated to the Department. Will the information requested need to be in writing? Can it be filed electronically or by fax? The Department should explain the procedure and the format for delivery of this information in the final-form regulation.

30. General. - Clarity.

Incomplete references to statutes or other regulations

Several sections contain references to the Food Act or other statutes but do not identify the specific sections of the statutes that applied to the particular regulatory provision. Specific references should be used. The following sections are examples:

Section 46.3. Definitions.

In Paragraphs (iii), (iv), (viii), (ix) and (xiv) of the definition of “adulterated food,” there are references to “Federal acts” and “Federal acts and their regulations.” The Department should specifically cite the pertinent sections of Federal statutes and regulations.

Sections 46.213, 46.421 and 46.422

These three sections include references to the Food Act. The Department should cite the specific sections of the Food Act that apply.

In addition, Section 46.422(e)(1) states: “If required by law, consumer warnings shall be provided.” The final-form regulation should include citations to the appropriate statutes.

Sections 46.217 and 46.244

The references to the Milk Sanitation Law need specific citations to applicable sections.

Section 46.219. Molluscan shellfish.

Subsection (a) references the act and this chapter. The Department should provide the specific sections that apply.

Section 46.221. Game animals.

This section refers to the “laws governing meat and poultry, as determined by the Department or other food regulatory agency that has jurisdiction over the food establishment.” The regulation should identify the laws or regulations that apply to this section.

Section 46.243. Receiving shell eggs.

This section references Chapter 87 and the Egg Refrigeration Law. These references need to include the specific sections of the existing regulation that apply.

Section 46.821. Approved materials to be used in plumbing systems.

The reference to the Pennsylvania Construction Code Act needs a specific citation to applicable sections. This is also found in Sections 46.822(a)(1), 46.825(e), 46.862(b)(2), (b)(3) and (c)(1), 46.863(a)(2) and (b) and 46.902(b).

Section 46.1102. Access to food facilities.

This section allows the Secretary “to determine if the food facility is in compliance with this chapter by...providing information and records specified in this chapter and to which the Secretary is entitled under the Public Eating and Drinking Place Law, the act and any other relevant statutory or regulatory authority.” The phrase “any other relevant statutory or regulatory authority” is vague. The Department should delete this phrase, or replace it with citations to specific statutes and regulations that give the Secretary authority to obtain information from food facilities.

Non-existent and inaccurate CFR cites

The two citations to the CFR in Section 46.242 appear to be inaccurate. These citations, 9 CFR 318.7 and 40 CFR 185, are non-existent. The Department should use appropriate citations that are consistent with existing sections of the CFR.

Additionally, Section 46.1026(a)(1) contains an inaccurate cite to the United States Code Annotated.

Other regulatory agencies

There are a few sections in the rulemaking that reference other regulatory agencies. For example, Sections 46.220 and 46.221 contain the phrase “other food regulatory agency that has jurisdiction over the food establishment.” Additionally, Section 46.221 contains “laws governing meat and poultry, as determined by the Department or other food regulatory agency that has jurisdiction over the food establishment.” The Department should explain what other regulatory agencies would have jurisdiction over food and food establishments in the final-form regulation and under what circumstances.