

Regulatory Analysis Form

(Completed by Promulgating Agency)

**INDEPENDENT REGULATORY
REVIEW COMMISSION**

2012 AUG - 1 AM 11: 31

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(All Comments submitted on this regulation will appear on IRRC's website)

(1) Agency: Agriculture

(2) Agency Number: 02

Identification Number: 174

IRRC Number: 2962

(3) PA Code Cite: 7 Pa. Code Chapters 46 and 76

(4) Short Title: Food Code (7 Pa. Code Chapter 46); Food Employee Certification (7 Pa. Code Chapter 76)

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact: Sheri Morris, Telephone: (717) 787-4315, E-Mail: shmorris@pa.gov

Secondary Contact: Judy Martin: (717) 787-4315, E-Mail: judmartin@pa.gov

(6) Type of Rulemaking (check applicable box):

Proposed Regulation

Final Regulation

Final Omitted Regulation

Emergency Certification Regulation;

Certification by the Governor

Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The proposed regulation amends the current Food Code regulations at 7 Pa. Code Chapter 46 to: (1) adopt the terminology and implement the changes necessitated or authorized by Act 106 of 2010; (2) incorporate, to the extent practicable, the standards and requirements of the "Food Code" published by the United States Department of Health, Food and Drug Administration ("Model Food Code") as the food safety standards and requirements for Pennsylvania (Pennsylvania is among 49 States that have adopted this Model Food Code, in whole or in part, as its regulatory food safety standards); (3) establish retail food facility license intervals of greater than one year, using risk-based factors identified in the Model Food Code as a basis for determining the appropriate license interval. It also streamlines the Food Employee Certification regulations at 7 Pa. Code Chapter 76 to reflect changes wrought by Act 106 of 2010.

(8) State the statutory authority for the regulation. Include specific statutory citation.

The following statutes provide authority for the regulation:

- The Retail Food Facility Safety Act (3 Pa.C.S.A. §§ 5701 – 5714), at 3 Pa.C.S.A. § 5707(a);
- The Food Safety Act (3 Pa.C.S.A. §§ 5721 – 5737), at 3 Pa.C.S.A. § 5733(a);
- The Milk Sanitation Law (31 P.S. §§ 645 – 660e), at 31 P.S. §§ 660c;
- Section 1705(d) of the Administrative Code of 1929 (71 P.S. § 445(d)); and
- The Food Employee Certification Act (3 Pa.C.S.A. §§ 6501 – 6510), at 3 Pa.C.S.A. § 6505.

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

No, to both questions.

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The regulation is needed in order to implement changes to the statutes underlying the current regulation, to more-fully incorporate the Model Food Code's food safety standards as Pennsylvania's regulatory food safety standards, and to better protect public health with respect to food safety. The Model Food Code embodies the state-of-the-science with respect to food safety.

The regulation is expected to make food safer, and to lessen the number of incidents of foodborne illness in Pennsylvania. The beneficiaries will include consumers, owners/operators/employees of retail food facilities and food establishments and the public-in-general. Consumers will experience fewer incidents of foodborne illness and will realize the health and safety benefits from that (as well as reduced medical costs and losses resulting from foodborne illness). Fewer foodborne illness incidents will also benefit owners/operators/employees of retail food facilities and food establishments, who will be spared some costs associated with lawsuits, compensation or business disruption relating to foodborne illness.

(11) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

Although statutory revisions, rather than data, drive the regulation, the Pennsylvania Department of Agriculture (Department) is mindful that the 2011 *Estimates of Foodborne Illness in the United States* issued by The Centers for Disease Control and Prevention (CDC) report that that each year roughly 1 in 6 Americans (or 48 million people) gets sick, 128,000 are hospitalized, and 3,000 die because of foodborne diseases. This document provides the most accurate picture yet of which foodborne bacteria, viruses, microbes ("pathogens") are causing the most illnesses in the United States, as well as estimating the number of foodborne illnesses without a known cause.

The referenced 2011 *Estimates of Foodborne Illness in the United States* can be viewed at The Centers for Disease Control website (www.cdc.gov) at www.cdc.gov/foodborneburden.

(12) Describe who and how many people will be adversely affected by the regulation. How are they affected?

The regulation is not expected to have an adverse impact on people or businesses. The regulation will not change the current procedures or costs associated with food safety to the point where it would impose an adverse impact on any entity.

(13) List the persons, groups or entities that will be required to comply with the regulation. Approximate the number of people who will be required to comply.

Retail food facilities and food establishments will be required to comply with the regulation. There are approximately 70,000 to 75,000 of these in this Commonwealth, with the Department inspecting approximately 30,000, County health departments inspecting approximately 30,000 and local health departments inspecting between 10,000 and 15,000.

County health departments and local (city, borough, township) health department will also be required to comply with the regulation. This will impact approximately 6 county health departments and 156 local health departments.

(14) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

Regulated retail food establishments in general – and particularly those that operate retail food establishments in more than one State – should realize some small savings from operating in a regulatory environment where the food safety standards of the Model Food Code are the basis for regulations from one State or jurisdiction to the other.

To the extent any retail food facility or food establishment must pay a license or permit fee or a fee for a follow-up inspection, these fees are imposed by statute, rather than by the regulation.

(15) Provide a specific estimate of the costs and/or savings to **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

The regulation is not expected to impose new costs on local governments. Local governments that handle food safety inspections in their respective jurisdictions may realize some small savings from having a uniform Statewide approach to food safety, from consistency among local and State food safety standards and from adopting and using an electronic method for issuing and tracking retail food facility inspection reports (as referenced in the Retail Food Facility Safety Act, at 3 Pa.C.S.A. § 5703(f)).

(16) Provide a specific estimate of the costs and/or savings to **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

The Department expects to incur a one-time cost of approximately \$5,000 as it changes literature, websites, forms and its electronic licensing system to align with the regulation. Beyond that initial cost, the regulation is not expected to impose any new costs on State government. The regulation updates existing regulatory authority, and does not appreciably impact the resources, personnel, equipment needs or attendant costs associated with the Department's food safety efforts. The Department might realize some small savings from being able to more-efficiently direct its food safety inspection resources in accordance with the risk-based inspection intervals established in the regulation (at proposed § 46.1141(c)).

(17) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	\$	\$	\$	\$	\$	\$
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Savings	0	0	0	0	0	0
COSTS:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	\$5,000 labor to change printed material, web sites, etc.	0	0	0	0	0
Total Costs	\$5,000	0	0	0	0	0
REVENUE LOSSES:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Revenue Losses	0	0	0	0	0	0

(17a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3 2008-2009	FY -2 2009-2010	FY -1 2010-2011	Current FY 2011-2012
Bureau of Food Safety	1,088,400.00	1,341,812.00	1,835,780.00	1,894,250.00

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

The benefits of the regulation will outweigh any costs. The expected benefits include (a) uniform statewide and national regulations for retail food establishments and food establishments; (b) enhanced public health protection through adoption of the Model Food Code – which embodies the state-of-the-science with respect to food safety; and (c) more efficient use of inspection resources (those of the Department and those Counties and local governments that handle food safety inspections) by establishing risk-based licensing periods for retail food facilities.

As explained in Answer Nos. 14 – 17, above, there are not expected to be appreciable costs associated with the regulation (beyond a one-time cost of approximately \$5,000 to the Department, as described in Answer No. 16).

(19) Describe the communications with and input from the public and any advisory council/group in the development and drafting of the regulation. List the specific persons and/or groups who were involved.

The Department engaged food industry trade associations on the changes wrought by Act 106 of 2010, and circulated draft regulatory language. These trade associations included the Pennsylvania Restaurant Association, the Pennsylvania Convenience Store Council and the Pennsylvania Food Merchants Association.

The Department also conducted a series of regional outreach meetings with *local and county health authorities* after Act 106 of 2010 became law, letting these entities know of the statutory changes and providing a *general* picture of the regulatory changes that would be forthcoming. These meetings included: the Northwest region (on 1/18/11), the North Central region (on 1/11/11), the Northeast region (on 1/12/11), the Southwest region (on 1/13/11), the South Central region (on 1/14/11) the Harrisburg area (on 1/20/11), the Southeast region (on 1/21/11) and Delaware County (on 1/21/11).

The Department also conducted a similar series of regional outreach meetings with *County health authorities* after Act 106 of 2010 became law. These meeting included: Philadelphia (on 1/19/11), Montgomery & Bucks (on 1/25/11), Chester (on 2/9/11), Erie (on 2/11/11) and Allegheny (on 1/28/11).

The Department also sent mass mailing notices regarding Act 106 of 2010 and its impacts to all retail food facilities, health departments, and municipal and borough associations.

(20) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

The Department considered copying language directly from the current Model Food Code as the text of the regulation and revising it in response to subsequent revisions to the Model Food Code. Since the Model Food Code is revised every two years, the Department's food safety regulations would regularly lag behind the state-of-the-science Model Food Code standards as the Department sought to revise the text of the regulation through the process required by the Regulatory Review Act. The Department and local and county health organizations did not favor this idea and, instead, believe the better approach is to incorporate the standards of the current Model Food Code by reference as the food safety standards for this Commonwealth. In addition, changes to the Model Food Code are the product of a well-regarded collaborative process that allows for participation by food safety enforcement interests and the food industry.

(21) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

No.

(22) How does this regulation compare with those of other states? How will this affect Pennsylvania's ability to compete with other states?

The regulation will be consistent with food safety regulations of surrounding states, as well as with all other States in the continental United States. All have adopted the Model Food Code, in whole or in part, as their regulatory food safety standards.

The regulation should have no adverse impact on competition with other states. To the contrary, it should facilitate compliance by establishing greater inter-jurisdictional uniformity with respect to food safety standards.

(23) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No. Although the regulation relates to food safety, and food safety is considered by several other Commonwealth agencies such as the Department of Public Welfare (with respect to daycares and group homes), the Department of Health (with respect to hospitals and nursing homes) and the Department of Education (with respect to schools), the changes that will be wrought by the regulation are not expected to have an appreciable impact on any of these agencies.

(24) Submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

No additions recordkeeping or paperwork required. Inspection reports will remain the same, with some modification of the specific code citations on the report. Since retail food facility license intervals will vary based upon risk-based factors, the Department will need to modify electronic licensing system to provide for these various license terms.

The cost to modify the Department's electronic licensing system to accommodate varying license intervals and the specific section numbers of the regulation were planned for when the Department designed the *current* electronic licensing system. This should help minimize these costs (which are included within the \$5,000 figure provided in Answer No. 16, above).

(25) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

None.

(26) Include a schedule for review of the regulation including:

- | | |
|---|--------------------|
| A. The date by which the agency must receive public comments: | August 1, 2012 |
| B. The date or dates on which public meetings or hearings will be held: | None are planned |
| C. The expected date of promulgation of the proposed regulation as a final-form regulation: | September 15, 2012 |
| D. The expected effective date of the final-form regulation: | September 15, 2012 |
| E. The date by which compliance with the final-form regulation will be required: | October 15, 2012 |
| F. The date by which required permits, licenses or other approvals must be obtained: | Varies |

(27) Provide the schedule for continual review of the regulation.

The efficacy of the regulation will be considered on an ongoing basis.

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(Pursuant to Commonwealth Documents Law)

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality.
Attorney General



By: _____
(Deputy Attorney General)

JUL 20 2012
DATE OF APPROVAL

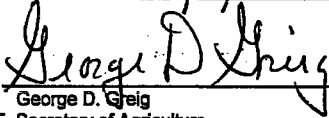
Check if applicable
Copy not approved. Objections attached.

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correct copy of a document issued, prescribed or
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Department of Agriculture

DOCUMENT/FISCAL NOTE NO. 2-174

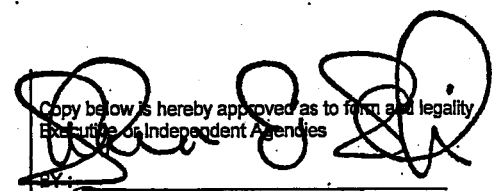
DATE OF ADOPTION 6/5/12

BY 
George D. Greig

TITLE Secretary of Agriculture

EXECUTIVE OFFICER CHAIRMAN OR SECRETARY

Copy below is hereby approved as to form and legality
Executive of Independent Agencies



Shawn E. Smith

JUN 22 2012
DATE OF APPROVAL

(Deputy General Counsel)
(Chief Counsel - Independent Agency)
(Strike inapplicable title)

Check if applicable. No Attorney General Approval or
objection within 30 days after submission.

NOTICE OF PROPOSED RULEMAKING

Department of Agriculture
Bureau of Food Safety and Laboratory Services

7 Pa. Code Chapters 46 and 76
Food Code; Food Employee Certification

PROPOSED RULEMAKING

DEPARTMENT OF AGRICULTURE

**THE FOOD CODE
[7 PA. CODE CH. 46]**

**FOOD EMPLOYEE CERTIFICATION
[7 PA.CODE CH. 76]**

The Department of Agriculture (Department) proposes to amend the regulations at 7 Pa. Code Chapter 46 (relating to Food Code) and 7 Pa. Code Chapter 76 (relating to food employee certification), to read as set forth in Annex A.

Statutory Authority

The Retail Food Facility Safety Act (3 Pa.C.S.A. §§ 5701 – 5714), the Food Safety Act (3 Pa.C.S.A. §§ 5721 – 5737), the Milk Sanitation Law (31 P.S. §§ 645 – 660e), Section 1705(d) of the Administrative Code of 1929 (71 P.S. § 445(d)) and the Food Employee Certification Act (3 Pa.C.S.A. §§ 6501 – 6510) provide the legal authority for this proposed rulemaking.

The Retail Food Facility Safety Act charges the Department with responsibilities relating to the licensure, inspection, cleanliness and sanitation of "retail food facilities" (such as restaurants) in the Commonwealth. This includes the responsibility to promulgate regulations necessary to implement that statute, and requires that – in promulgating these regulations – the Department “be guided by the most current edition of the Food Code, published by the United States Department of Health, Food and Drug Administration” (3 Pa.C.S.A. § 5707(a)) (Model Food Code). The Retail Food Facility Safety Act also affords the Department the discretion to establish retail food facility license intervals of greater than one year, but requires that these license intervals be established by regulation, and that the regulation use risk-based factors identified in the Model Food Code as a basis for determining the appropriate license interval.

The Food Safety Act charges the Department with the responsibility to: (1) regulate, register and inspect "food establishments" in the Commonwealth (3 Pa.C.S.A. § 5734(a)); (2) promulgate regulations and food safety standards necessary to the proper enforcement of the food safety requirements set forth in that statute (3 Pa.C.S.A. § 5733(a)); and (3) construe the statute and its attendant regulations in a manner that is as consistent with Federal statutory and regulatory authority as practicable (3 Pa.C.S.A. § 5736).

The Milk Sanitation Law requires that a person selling milk, milk products or manufactured dairy products have a Department-issued permit. It also charges the Department with responsibility to promulgate regulations necessary for the proper enforcement of that statute (31 P.S. § 660c).

Section 1705(d) of the Administrative Code of 1929 requires the Department to establish regulatory standards necessary to enforce food safety laws.

The Food Employee Certification Act requires that a retail food facility have at least one employee who holds a valid certificate evidencing successful completion of a Department–approved food safety training course (3 Pa.C.S.A. § 6504(a)), and authorizes the Department to promulgate regulations necessary for the proper enforcement of that statute (3 Pa.C.S.A. § 6505).

Purpose

Act 106 of 2010 accomplished a significant overhaul of the food-related statutes administered and enforced by the Department. It repealed the Public Eating or Drinking Places Law (35 P.S. §§ 655.1 – 655.13) and the Food Act (31 P.S. §§ 20.1 – 20.18), and supplanted these with the Retail Food Facility Safety Act and the Food Safety Act, respectively. It also made substantive changes to the Food Employee Certification Act. Although many of the provisions of these new or revised food-related statutes are similar to provisions of the statutes they replaced, there are also a number of changes that necessitate the regulatory revisions described in this document.

The proposed rulemaking seeks to: (1) adopt the terminology and implement the changes necessitated or authorized by Act 106 of 2010; (2) incorporate, to the extent practicable, the standards and requirements of the Model Food Code as the food safety standards and requirements for Pennsylvania; (3) establish retail food facility license intervals of greater than one year, using risk-based factors identified in the Model Food Code as a basis for determining the appropriate license interval; and (4) streamline the Food Employee Certification regulations at 7 Pa. Code Chapter 76 to reflect changes wrought by Act 106 of 2010.

Background

The Model Food Code is the product of a collaborative effort among the Department, the Food and Drug Administration, the Food Safety Inspection Service, the Centers for Disease Control, various state and local public health and food control agencies, food industry representatives, academia and consumers. It represents the state-of-the-science with respect to food handling and food safety. It is adopted by reference in portions of the current regulation at 7 Pa. Code Chapter 46. It is also a basis for food safety training courses nationwide. In addition, the Retail Food Facility Safety Act specifically *requires* that the Department be guided by the Model Food Code in promulgating regulations (3 Pa.C.S.A. § 5707(a)). Against this backdrop, the Department is satisfied that the regulated community is familiar with the Model Food Code and that the expansive adoption of Model Food Code standards and requirements in the proposed rulemaking will not have an adverse impact on that regulated community.

The other provisions of the proposed rulemaking implement new or revised statutory requirements established by Act 106 of 2010 – which revised or replaced a number of the food-related statutes, as described above.

Need for the Proposed Rulemaking

The proposed rulemaking is driven by the substantial changes to underlying food-safety-related statutes accomplished by Act 106 of 2010.

The proposed rulemaking is also needed to reduce foodborne illness to the fullest extent possible. This public health and safety objective is the primary reason for the proposed rulemaking.

The food safety standards set forth in the proposed regulation should also serve the regulated community by helping to lower the number of claims and lawsuits related to foodborne illness.

The provisions of the proposed rulemaking that prescribe the appropriate license intervals for various types of retail food facilities (based on risk-based factors identified in the Model Food Code) are needed in order for the Department and other licensors of these facilities to make better use of limited manpower resources involved in accomplishing inspections and processing license paperwork.

Act 106 of 2010 also made significant revisions to the Food Employee Certification Act; and the proposed rulemaking is needed in order to implement these changes.

The Department is satisfied there are no reasonable alternatives to proceeding with the proposed rulemaking. The Department is also satisfied the proposed rulemaking meets the requirements of Executive Order No. 1996-1, "Regulatory Review and Promulgation."

Overview of the Major Provisions of the Proposed Rulemaking

Proposed § 46.3 (relating to definitions) would delete a number of terms that are defined in the Model Food Code, to maintain a common vocabulary of food-safety terminology. Where an underlying statute uses a term that is not used in the Model Food Code, but that is synonymous with another term in the Model Food Code, the proposed regulation identifies that synonymous Model Food Code term. This occurs in the definitions of "licensee," "proprietor" and "retail food facility."

Proposed § 46.4 (relating to adoption of Model Food Code) would adopt the standards of the Model Food Code as the regulatory standards of the Department, to the extent they do not conflict with an underlying statute or a specific provision of the regulation at 7 Pa. Code Chapter 46.

The proposed rulemaking would delete current regulatory provisions where the subject matter of those provisions is adequately addressed in the underlying statutes or the Model Food Code, or where the provisions are no longer necessary. These deletions are throughout the proposed rulemaking, and address a wide range of food-safety-related subjects.

Proposed § 46.212 (relating to food prepared in a private home) would add language to track with the provision of the Retail Food Facility Safety Act (at 3 Pa.C.S.A. § 5712) that generally exempts food that is prepared in private homes and then sold at events such as church suppers and fund-raisers for charitable organizations from the requirements of that statute.

The list of the types of retail food facilities that are exempt from licensure under the Retail Food Facility Safety Act would be revised in proposed § 46.1141 (relating to license requirement) to reflect that the Retail Food Facility Safety Act (at 3 Pa.C.S.A. § 5703(b)) affords a licensor (whether the Department or a local government unit) the *discretion* to issue an Order establishing which types of retail food facilities will be exempt. The Department has exercised this discretion, and has published an Order at 41 *Pennsylvania Bulletin* 524 (January 22, 2011) designating the types of retail food facilities that are exempt. A reference to this Order or its date or place of publication is not included in the proposed rulemaking because the Order might change, and because it might cause confusion in those jurisdictions where the licensor is an entity other than the Department.

Proposed § 46.1141(c) would establish retail food facility license intervals based on risk-based factors identified in the Model Food Code, as authorized under the Retail Food Facility Safety Act (at 3 Pa.C.S.A. § 5703(g)).

Proposed § 76.20 (relating to definitions) would establish definitions either included or authorized in the Food Employee Certification Act.

Proposed § 76.21 (relating to certification programs) would implement the requirement of the Food Employee Certification Act (at 3 Pa.C.S.A. § 6503(c)) definitions) that the Department recognize certain certification programs as adequate for purposes of meeting the requirements of that statute. It would also require the Department to maintain, post on its agency website, and readily provide copies of that list of acceptable certification programs.

Affected Individuals and Organizations

The proposed regulation would impact upon the public by reducing the number of foodborne illness outbreaks originating from retail food facilities and food establishments.

Retail food facilities and food establishments would also be affected by the regulation. Fewer foodborne illness incidents will benefit owners/operators/employees of these

businesses, who will be spared some costs associated with lawsuits, compensation or business disruption relating to foodborne illness. Also, since the proposed regulation would bring Pennsylvania's food safety standards into greater alignment with the Model Food Code, and the Model Food Code is the basis for food safety standards in all of the continental United States, there may be some savings associated with operating in a regulatory environment where there is a greater degree of consistency and uniformity in regulatory food safety standards.

Fiscal Impact

Commonwealth: Aside from an initial expected outlay of approximately \$5,000 to revise literature, websites, forms and its electronic licensing system, the proposed rulemaking would impose no costs and have no fiscal impact on the Commonwealth. The Department currently registers and inspects food establishments under the Food Safety Act and licenses and inspects retail food facilities under the Retail-Food Facility Safety Act. The proposed regulation would not appreciably expand or alter the Department's role in administering and enforcing these underlying statutes.

Political Subdivisions: The proposed rulemaking would impose no costs and have no fiscal impact upon political subdivisions. Although a local government unit may act as the "licensor" of retail food facilities within its borders, the proposed rulemaking would not impose any requirement on a local government unit licensor that is not imposed by one or more of the underlying statutes.

Private Sector: The proposed rulemaking is not expected to impose costs on the private sector. Owners of restaurants, food processing operations, other retail food facilities and other food establishments are already familiar with the food safety standards and procedures prescribed under the Model Food Code. The current regulation at 7 Pa. Code Chapter 46 embodies many of the provisions of the Model Food Code; and the Model Food Code is the basis for much of the food-safety-related training that is available to these persons and that has been obtained for purposes of compliance with the Food Employee Certification Act.

General Public: The proposed rulemaking would enhance public health and safety. It is expected to reduce the number of cases of foodborne illness attributable to food originating from food facilities in the Commonwealth. This should result in some indeterminate cost savings to the general public.

Paperwork Requirements

The proposed regulation is not likely to appreciably impact upon the paperwork generated by the Department or other retail food facility licensors, or upon retail food facilities or food establishments.

Effective Date

The proposed rulemaking will be effective one month following publication in the *Pennsylvania Bulletin* as final-form rulemaking.

Sunset Date

There is no sunset date for the proposed rulemaking. The Department will review the efficacy of this regulation on an ongoing basis.

Public Comment Period/Contact Person

Interested persons are invited to submit written comments regarding the proposed regulations within 30 days following publication in the *Pennsylvania Bulletin*. Comments are to be submitted to the Department of Agriculture, Bureau of Food Safety and Laboratory Services, 2301 North Cameron Street, Harrisburg, PA 17110-9408, Attention: Sheri Morris.

Regulatory Review

The Department submitted a copy of the proposed regulation to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House and Senate Standing Committees on Agriculture and Rural Affairs on August 1, 2012, in accordance with section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)). The Department also provided IRRC and the Committees a detailed Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If IRRC has an objection to any portion of the proposed regulation, it must so notify the Department within 30 days of the close of the public comment period.

The notification shall specify the regulatory criteria that have not been met by that portion. The Regulatory Review Act sets forth detailed procedures for review of these objections by the Department, the General Assembly and the Governor prior to the final publication of the proposed regulation.

GEORGE D. GREIG, *Secretary*

Annex A

TITLE 7. AGRICULTURE.

PART III. BUREAU OF FOOD SAFETY AND LABORATORY SERVICES

CHAPTER 46. FOOD CODE

**Subchapter A. [PURPOSE AND DEFINITIONS] PURPOSE; DEFINITIONS;
ADOPTION OF MODEL FOOD CODE**

Sec.

46.1 Purpose.

46.2. Scope.

46.3. Definitions.

46.4. Adoption of Model Food Code.

§ 46.1. Purpose.

The purpose of this chapter is to safeguard public health and ensure that consumers are provided food that is safe, unadulterated and honestly presented.

§ 46.2. Scope.

This chapter establishes definitions; sets standards for management and personnel, food operations and equipment and facilities; and provides for retail food facility plan review, licensing, [registration,] inspection and employee restriction.

§ 46.3. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

[*Additive*--A food additive or a color additive.]

[*Adulterated*--Food with respect to which one or more of the following is accurate:

(i) The food bears or contains any poisonous or deleterious substance, which may render it injurious to health. However, if the substance is not an added substance, the food will not be considered adulterated if the quantity of the substance in the food does not ordinarily render it injurious to health.

(ii) The food bears or contains any added poisonous or added deleterious substance, which is unsafe within the meaning of section 11 of the Food Act (31 P. S. § 20.11). This subparagraph does not apply to a pesticide chemical in or on a raw agricultural commodity, a food additive or a color additive.

(iii) The food is a raw agricultural commodity and bears or contains a pesticide chemical which is unsafe within the meaning of section 11 of the Food Act, except that, when a pesticide chemical has been used in or on a raw agricultural commodity with an exception granted or tolerance prescribed under section 11 of the Food Act or under any of the Federal acts and the raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating or milling, the residue of the pesticide remaining in or on the processed food will, notwithstanding section 11 of the Food Act and this subparagraph, not be deemed unsafe if the residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of the

residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity.

(iv) The food bears or contains any food additive, which is unsafe within the meaning of section 11 of the Food Act or any of the Federal acts.

(v) The food consists in whole or in part of any diseased, contaminated, filthy, putrid or decomposed substance or is otherwise unfit for food.

(vi) The food has been produced, prepared, packed or held under unsanitary conditions so that it may have become contaminated with filth or may have been rendered diseased, unwholesome or injurious to health.

(vii) The food is, in whole or part, the product of a diseased animal or of an animal which has died otherwise than by slaughter.

(viii) The food is in a container composed, in whole or part, of any poisonous or deleterious substance which may render the contents injurious to health, unless the container is fabricated or manufactured with good manufacturing practices as that standard is defined and delineated by any of the Federal acts and their regulations.

(ix) The food has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption under section 11 of the Food Act or under one of the Federal acts.

(x) The food has had any valuable constituent, in whole or part, omitted or abstracted therefrom.

(xi) The food has had any substance substituted wholly or in part.

(xii) Damage or inferiority of the food is concealed in any manner.

(xiii) A substance has been added to the food and it is mixed or packed so as to increase its bulk or weight or reduce its quality or strength or make it appear better or of greater value than it is.

(xiv) The food bears or contains any color additive which is unsafe within the meaning of section 11 of the Food Act, or under one of the Federal acts.

(xv) The food bears or contains eggs processed by or egg products derived from a manufacturing, processing or preparing method wherein whole eggs are broken using a centrifuge-type egg breaking machine that separates the egg's liquid interior from the shell.]

[*Approved*—Acceptable to the Department based on a determination of conformity with principles, practices and generally recognized standards proven to be scientifically sound that protect public health.]

Bed and breakfast homestead or inn--A private residence which contains ten or fewer bedrooms used for providing overnight accommodations to the public, and in which breakfast is the only meal served and is included in the charge for the room.

[*Beverage*--A liquid for drinking, including water.]

[*Bottled drinking water*—Water that is sealed in bottles, packages or other containers and offered for sale for human consumption. The term includes bottled mineral water.]

[*CFR*--The most-recently published edition or revision of the *Code of Federal Regulations*, a compilation of the general and permanent rules published in the *Federal Register* by the executive departments and agencies of the Federal government.]

[*CIP*--*Cleaned in place*--

(i) Cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse and sanitizing solution onto or over equipment surfaces that require cleaning, such as the method used, in part, to clean and sanitize a frozen dessert machine.

(ii) The term does not include the cleaning of equipment such as band saws, slicers or mixers that are subjected to in-place manual cleaning without the use of a CIP system.]

[*Casing*—A tubular container for sausage products made of either natural or artificial (synthetic) material.]

[*Certification number*—A unique combination of letters and numbers assigned by the Department or other shellfish control authority having jurisdiction to a molluscan shellfish dealer according to the provisions of the National Shellfish Sanitation Program.]

[*Color additive*--A material which is a dye, pigment or other substance made by a process of synthesis or similar artifice or extracted, isolated or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral or other source and when added or applied to a food is capable, alone or through reaction with other substances, of imparting color thereto.

(i) The term includes black, white and intermediate grays.

(ii) The term does not include [materials] material, which the Secretary, by regulation, determines [are] is used, or [are] is intended to be used, solely for a purpose or purposes other than coloring.

(iii) The term does not include any pesticide chemical, soil or plant nutrient or other agricultural chemical solely because of its effect in aiding, retarding or

otherwise affecting, directly or indirectly, the growth or [otherwise] other natural physiological process of produce of the soil and thereby affecting its color, whether before or after harvest.]

[*Commingle*—To combine shellstock harvested on different days or from different growing areas as identified on the tag or label or to combine shucked shellfish from containers with different container codes or different shucking dates.]

[*Comminuted*—A food that is reduced in size by methods including chopping, flaking, grinding or mincing. The term includes fish or meat products that are reduced in size and restructured or reformulated such as gefilte fish, gyros, ground beef and sausage; and a mixture of two or more types of meat that have been reduced in size and combined, such as sausages made from two or more meats.]

[*Confirmed disease outbreak*—A foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiological analysis implicates the food as the source of the illness.]

[*Consumer*—A person, who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food facility or food processing plant, and does not offer the food for resale.]

[*Controlled atmosphere packaging*--A type of reduced oxygen packaging in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring food and impermeable packaging material.]

[*Corrosion-resistant material*—A material that maintains acceptable surface cleanability characteristics under prolonged influence of the food to be contacted, the normal use of cleaning compounds and sanitizing solutions and other conditions of the use environment.]

[*Critical control point*—A point or procedure in a specific food system where loss of control may result in an unacceptable health risk.]

[*Critical limit*—The maximum or minimum value to which a physical, biological or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur.]

Department--The Department of Agriculture of the Commonwealth. The term is synonymous with the term “regulatory authority” in the Model Food Code.

Drinking water, potable water or water--Safe drinking water as defined in the Pennsylvania Safe Drinking Water Act (35 P. S. §§ 721.1--721.17). The term does not include water such as boiler water, mop water, rainwater, wastewater and "nondrinking" water.

[*Dry storage area*—A room or area designated for the storage of packaged or containerized bulk food that is not potentially hazardous and dry goods such as single service items.]

[*EPA*--The United States Environmental Protection Agency.]

[*Easily cleanable*--

(i) A characteristic of a surface that:

(A) Allows effective removal of soil by normal cleaning methods.

(B) Is dependent on the material, design, construction and installation of the surface.

(C) Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose and use.

(ii) The term includes a tiered application of the criteria that qualify the surface as easily cleanable as specified in subparagraph (i) to different situations in which varying degrees of cleanability are required, such as one of the following:

(A) The appropriateness of stainless steel for a food preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for consumer dining.

(B) The need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the consumer dining area.]

[Easily movable---A unit of equipment that is both of the following:

(i) Portable; mounted on casters, gliders or rollers; or provided with a mechanical means to safely tilt the unit of equipment for cleaning.

(ii) Has no utility connection, a utility connection that disconnects quickly or a flexible utility connection line of sufficient length to allow the equipment to be moved for cleaning of the equipment and adjacent area.]

[Egg—The shell egg of the domesticated chicken, turkey, duck, goose or guinea.]

Employee--The license [or registration] holder, person in charge, person having supervisory or management duties, person on the payroll, family member, volunteer,

person performing work under contractual agreement or other person working in a retail food facility.

[Equipment--

(i) An article that is used in the operation of a food facility such as a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, temperature measuring device for ambient air, vending machine or warewashing machine.

(ii) The term does not include items used for handling or storing large quantities of packaged foods that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks and skids.]

*[Exclude—*To prevent a person from working as a food employee or entering a food facility except for those areas open to the general public.]

*FDA--*The United States Food and Drug Administration.

*[Federal acts--*The Wholesome Meat Act (21 U.S.C.A. §§ 601--641), the Federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 301--399), the Poultry Products Inspection Act (21 U.S.C.A. §§ 451--471), the Fair Packaging and Labeling Act (15 U.S.C.A. §§ 1451--1461), the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C.A. § 136--136y) and the Nutrition Labeling and Education Act of 1990 (21 U.S.C.A. § 343-1).]

*[Fish—*The term includes:

(i) Fresh or saltwater finfish, crustaceans, all mollusks and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of those animals), other than birds or mammals, if the animal life is intended for human consumption.

(ii) The term includes an edible human food product derived in whole or in part from fish, including fish that have been processed in any manner.]

Food--An article used for food or drink by humans, including chewing gum and articles used for components of any article. The term does not include medicines and drugs.

[*Food Act*--The Food Act (31 P. S. §§ 20.1--20.18).]

[*Food additive*--

(i) A substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, with respect to which one or more of the following is correct:

(A) The substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures to be safe under the conditions of its intended use.

(B) The substance has been used in food prior to January 1, 1958, and is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures or experience based on common use in food, to be safe under the conditions of its intended use.

(ii) The term does not include the following:

(A) A pesticide chemical in or on a raw agricultural commodity.

(B) A pesticide chemical to the extent that it is intended for use or is used in the production, storage or transportation of any raw agricultural commodity.

(C) A color additive.

(D) A substance used in accordance with a sanction or approval granted prior to the enactment of this subparagraph under a statute repealed by the Food Act, under the Poultry Products Inspection Act or under the Wholesome Meat Act.

(E) A new animal drug.]

[*Foodborne disease outbreak*—The occurrence of two or more cases of a similar illness after ingestion of a common food.]

[*Food-contact surface*—One of the following:

(i) A surface of equipment or a utensil with which food normally comes into contact.

(ii) A surface of equipment or a utensil from which food may drain, drip or splash into a food, or onto a surface normally in contact with food.]

[*Food employee*--An individual working with unpackaged food, food equipment or utensils, or food-contact surfaces.]

Food establishment--

(i) A [retail food store and a] room, building or place or portion thereof or vehicle maintained, used or operated for the purpose of commercially storing, packaging, making, cooking, mixing, processing, bottling, baking, canning, freezing, packing or otherwise preparing or transporting or handling food.

(ii) The term [includes those portions of public eating and drinking licensees which offer food for sale for off-premises consumption, except] excludes retail food facilities, retail food establishments, public eating and drinking places and those portions of establishments operating exclusively under milk or milk products permits.

(iii) The term is synonymous with the term “food processing plant” in the Model Food Code.

[*Food facility*--A public eating or drinking place or a retail food establishment. The term does not include the following:

- (i) A food service facility provided by or at an organized camp or campground.
- (ii) A food service facility provided by or at a school.
- (iii) A food service facility at an institution such as a nursing home or hospital.
- (iv) Any other food service facility that is not a public eating or drinking place.
- (v) Food processing plants, warehousing establishments and other food

establishments that comply with the following:

- (A) Are not retail food establishments.
- (B) Do not provide food to the consumer either directly or indirectly (such as through the home delivery of groceries).
- (C) Applicable Federal regulations.]

[*Food facility operator*--The entity that is legally responsible for the operation of the food facility, such as the owner, owner's agent or other person.]

[*Food facility premises*--The food facility, its contents and the contiguous land or property under the control of the food facility operator. If a food facility is a component

of a larger operation, such as a hotel, motel, shopping mall or public campground, and that larger operation is also under the control of the food facility operator, that larger operation is part of the food facility premises to the extent it may impact the food facility, its personnel or its operations.]

*[Food processing plant—*A commercial operation that manufactures, packages, labels or stores food for human consumption and does not provide food directly to a consumer. The term does not include a food facility.]

*Food Safety Act—*The Food Safety Act (3 Pa.C.S.A. §§ 5721 – 5737).

[Game animal--

(i) An animal, the products of which are food, that is not classified as any of the following:

(A) Fish, as that term is defined in this chapter.

(B) Cattle, sheep, swine, goat, horse, mule or other equine, as those terms are used in 9 CFR Chapter III, Subchapter A (relating to agency organization and terminology; mandatory meat and poultry products inspection and voluntary inspection and certification).

(C) Poultry, as that term is used in 9 CFR Chapter III, Subchapter A.

(D) Ratites, such as ostriches, emus or rheas.

(ii) The term includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria or muskrat, and nonaquatic reptiles such as land snakes.]

*[General use pesticide—*A pesticide that is not classified by the EPA for restricted use as specified in 40 CFR 152.175 (relating to pesticides classified for restricted use).]

HACCP--Hazard Analysis Critical Control Point--A system developed by the National Advisory Committee on Microbiological Criteria for Foods that identifies and monitors specific foodborne hazards that can adversely affect the safety of the food products.

[*HACCP plan*—A written document that delineates the formal procedures for following the HACCP principles developed by the National Advisory Committee on Microbiological Criteria for Foods.]

[*Hazard*—A biological, chemical or physical property (such as the presence of pathogens, pesticides, natural toxins, rodent contamination or foreign materials) that may cause an unacceptable consumer health risk.]

[*Hermetically sealed container*—A container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned foods, to maintain the commercial sterility of its contents after processing.]

[*High humidity cooking*--Cooking in an oven that attains relative humidity of greater than 90% for at least 1 hour as measured in the cooking chamber or exit of the oven, or cooking in a moisture-impermeable bag that provides 100% humidity.]

[*Highly susceptible population*—A group of persons who are more likely than other people in the general population to experience foodborne disease because both of the following conditions exist:

- (i) The group is comprised of immunocompromised persons, preschool-age children or older adults.
- (ii) The group obtains food at a facility that provides services such as custodial care, health care, assisted living services, nutritional services or socialization services. Examples of facilities providing these services include child or adult day

care centers, health care centers, assisted living facilities, hospitals, nursing homes, kidney dialysis centers and senior centers.]

[*Honestly presented*--Food offered for human consumption in a way that does not mislead or misinform the consumer, and without misrepresenting the true appearance, color or quality of the food through the use of food or color additives, colored overwraps, lighting or other means.]

[*Imminent health hazard*—A significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on one or more of the following:

- (i) The number of potential injuries.
- (ii) The nature, severity and duration of the anticipated injury.]

[*Injected*—Manipulating a meat so that infectious or toxigenic microorganisms may be introduced from its surface to its interior through tenderizing with deep penetration or injecting the meat such as with juices which may be referred to as "injecting," "pinning" or "stitch pumping."]

[*Juice*----When used in the context of food safety, the term refers to the aqueous liquid expressed or extracted from one or more fruits or vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrate of the liquid or purée. The term includes juice as a whole beverage, an ingredient of a beverage, and a puree as an ingredient of a beverage. This definition does not apply to standards of identity established by the FDA or USDA.]

[*Kitchenware*--Food preparation and storage utensils.]

License—A grant to a [licensee to operate a public eating or drinking place, as defined in the Public Eating and Drinking Places Law] proprietor to operate a retail food facility. The term is synonymous with the term “permit” in the Model Food Code.

Licensee—The person (such as a retail food facility operator) that is directly responsible for the operation of a retail food facility and that holds a current license. The term is synonymous with the term “permit holder” in the Model Food Code.

Licensor--Includes the following:

(i) The county department of health or joint-county department of health, whenever the [public eating or drinking place] retail food facility is located in a political subdivision which is under the jurisdiction of a county department of health or joint-county department of health.

(ii) The health authorities of cities, boroughs, incorporated towns and first-class townships, whenever the [public eating or drinking place] retail food facility is located in a city, borough, incorporated town or first-class township not under the jurisdiction of a county department of health or joint-county department of health.

(iii) The health authorities of second class townships and second class townships which have adopted a home rule charter which elect to issue licenses under the [Public Eating and Drinking Places Law] Retail Food Facility Safety Act whenever [the public eating and drinking place] a retail food facility is located in [the] a second class township or second class township which has adopted a home rule charter not under the jurisdiction of a county department of health or joint-county department of health.

(iv) The Department, whenever the [public eating and drinking place] retail food facility is located in any other area of this Commonwealth.

[*Linens*—Fabric items such as cloth hampers, cloth napkins, tablecloths, wiping cloths and work garments, including cloth gloves.]

[*mg/L*—Milligrams per liter, which is the metric equivalent of parts per million.]

[*Meat*--The flesh of animals used as food including the dressed flesh of cattle, swine, sheep or goats and other edible animals. The term does not include fish, poultry and wild game animals as specified under § 46.221(b) and (c) (relating to game animals).]

Milk Sanitation Law--The act of July 2, 1935 (P. L. 589, No. 210) (31 P. S. §§ 645--660e).

[*Mobile food facility*--Any stationary, movable or temporary food facility--such as a stand, vehicle, cart, basket, box or similar structure from which food is stored, prepared, processed, distributed or sold--which physically locates at one site or location for no more than 14 consecutive days, whether operating continuously or not during this time. The term does not include a food facility that is physically located at one site for more than 14 consecutive days.]

Model Food Code—The most current edition of the Food Code published by the Department of Health and Human Services, Food and Drug Administration.

[*Modified atmosphere packaging*--

(i) A type of reduced oxygen packaging in which the atmosphere of a package of food is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food.

(ii) The term includes: reduction in the proportion of oxygen, total replacement of oxygen or an increase in the proportion of other gases such as carbon dioxide or nitrogen.]

[*Molluscan shellfish*—An edible species of fresh or frozen oysters, clams, mussels and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle.]

[*Nonpublic water supply*--A system for the provision of piped water for human consumption that is not a public water system.]

[*Other food regulatory agency*--Local bodies, State bodies other than the Commonwealth or Federal enforcement bodies having jurisdiction over a food establishment or food processing plant. Examples include the USDA with respect to most meat processing plants within this Commonwealth and the FDA having jurisdiction over food products imported from other countries.]

Organized camp-- A combination of programs and facilities established for the primary purpose of providing an outdoor group living experience for children, youth and adults, with social, recreational and educational objectives, and operated and used for five or more consecutive days during one or more seasons of the year.

[*pH*--The symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution. Values between 0 and 7 indicate acidity and values between 7 and 14 indicate alkalinity. The value for pure distilled water is 7, which is considered neutral.]

[*Packaged*--

(i) Bottled, canned, cartoned, securely bagged or securely wrapped in a food facility or a food processing plant.

(ii) The term does not include a wrapper, carryout box or other nondurable container used to containerize food with the purpose of facilitating food protection during service and receipt of the food by the consumer.]

[*Pennsylvania Construction Code Act*--35 P. S. §§ 7210.101--7210.1103.]

[*Pennsylvania Sewage Facilities Act*--35 P. S. §§ 750.1--750.20a.]

[*Permanent food facility*--A food facility--whether stationary or mobile--that is not a temporary food facility operating more than 14 days in a single calendar year--whether these days are consecutive or not.]

[*Person*--A corporation, partnership, limited liability company, business trust, other association, government entity (other than the Commonwealth), estate, trust, foundation or natural person.]

[*Personal care items*--

(i) Items or substances that may be poisonous, toxic or a source of contamination and are used to maintain or enhance a person's health, hygiene or appearance.

(ii) The term includes items such as medicines, first aid supplies, cosmetics, toiletries (such as toothpaste and mouthwash) and similar items.]

Person in charge—[The individual present at a food facility responsible for the operation at the time of inspection] A person designated by a retail food facility operator to be present at a retail food facility and responsible for the operation of the retail food facility at the time of inspection.

[*Physical facilities*—The structure and interior surfaces of a food facility, including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.]

[*Plumbing fixture*—A receptacle or device that is one or more of the following:

(i) Permanently or temporarily connected to the water distribution system of the premises and demands a supply of water from the system.

(ii) Discharges used water, waste materials or sewage directly or indirectly to the drainage system of the premises.]

[*Plumbing system*—The water supply and distribution pipes; plumbing fixtures and traps; soil, waste and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices and appurtenances within the premises; and water-treating equipment.]

[*Poisonous or toxic material*—A substance that is not intended for ingestion and that fits within one or more of the following categories:

(i) Cleaners and sanitizers, including cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes and other chemicals.

(ii) Pesticides.

(iii) Substances necessary for the operation and maintenance of the establishment, such as nonfood grade lubricants, solvents and personal care items that may be deleterious to health.

(iv) Substances that are not necessary for the operation and maintenance of the establishment and are on the premises for retail sale, such as petroleum products and paints.]

[Potentially hazardous food--

(i) A food which consists, in whole or part, of milk or milk products, eggs, meat, poultry, fish, shellfish, edible crustacea or other ingredients, including synthetic ingredients, which is in a form capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms.

(ii) The term does not include foods that have a pH level of 4.6 or below or a water activity of 0.85 or less under standard conditions or food products in hermetically sealed containers processed to maintain commercial sterility.]

[Poultry—One or more of the following:

(i) A domesticated bird (chickens, turkeys, ducks, geese or guineas), whether live or dead, as defined in 9 CFR Chapter III, Subchapter A, Part 381 (relating to poultry products inspection regulations).

(ii) A migratory waterfowl or game bird, such as pheasant, partridge, quail, grouse, guineas, pigeon or squab, whether live or dead, as defined in the USDA regulations in 9 CFR Part 362 (relating to voluntary poultry inspection regulations).

(iii) The term does not include ratites.]

[Primal cut—A basic major cut into which carcasses and sides of meat are separated, such as a beef round, pork loin, lamb flank or veal breast.]

Proprietor-- A person, partnership, association or corporation conducting or operating a retail food facility within this Commonwealth. The term is synonymous with the term “person” in the Model Food Code.

Public eating or drinking place--A place within this Commonwealth where food or drink is served to or provided for the public, with or without charge. The term does not include dining cars operated by a railroad company in interstate commerce or a bed and breakfast homestead or inn.

[*Public Eating and Drinking Places Law*--The act of May 23, 1945 (P. L. 926, No. 369) (35 P. S. §§ 655.1--655.13).]

[*Public water system*—A system which provides water to the public for human consumption, and which has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year, or as otherwise specified in 25 Pa. Code Chapter 109 (relating to safe drinking water).

(i) The term includes collection, treatment, storage and distribution facilities under control of the operator of the system and used in connection with the system.

(ii) The term also includes a system which provides water for bottling or bulk hauling for human consumption.]

[*Ratite*—An animal belonging to the same family as ostriches, emus and rheas.]

Raw agricultural commodity--A food in its raw or natural state, including all fruits which are washed, colored or otherwise treated in their unpeeled, natural form prior to marketing, or as otherwise defined in the Food Safety Act, at 3 Pa.C.S.A. § 5722 (relating to definitions).

[*Ready-to-eat food*—Any of the following types of food:

(i) Food in a form that is edible without additional preparation to achieve food safety, such as raw animal-derived foods that have been cooked in accordance

with § 46.361 or § 46.362 (relating to cooking raw animal-derived foods; and microwave cooking), or fish that have been frozen in accordance with § 46.364 (relating to parasite destruction in fish other than molluscan shellfish by freezing), although additional preparation may occur for palatability or aesthetic, epicurean, gastronomic or culinary purposes.

(ii) Food that is raw or partially-undercooked animal-derived food, where the food facility offering the food has complied with § 46.361(d)(1) and the consumer notification requirements of § 46.423 (relating to consumer advisory required with respect to animal-derived foods that are raw, undercooked or not otherwise processed to eliminate pathogens), although additional preparation may occur for palatability or aesthetic, epicurean, gastronomic or culinary purposes.

(iii) Food that is prepared in accordance with a variance issued by the Department under § 46.361(d)(2) and § 46.1103 (relating to variances), although additional preparation may occur for palatability or aesthetic, epicurean, gastronomic or culinary purposes.

(iv) Raw fruits and vegetables that are washed in accordance with § 46.285 (relating to washing raw fruits and vegetables).

(v) Fruits and vegetables that are cooked for hot holding in accordance with § 46.363 (relating to plant food cooking for hot holding).

(vi) Potentially hazardous food that is cooked in accordance with the time and temperature requirements for that specific food in §§ 46.361--46.363, and that is cooled as specified in § 46.384 (relating to potentially hazardous food: cooling).

(vii) Plant food with respect to which further washing, cooking or other processing is not required for food safety, and from which rinds, peels, husks or shells (if naturally present) are removed.]

[*Reduced oxygen packaging--*

(i) The reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the surrounding 21% oxygen atmosphere.

(ii) A process as specified in subparagraph (i) that involves a food for which *Clostridium botulinum* is identified as a microbiological hazard in the final packaged form.

(iii) The term includes vacuum packaging, modified atmosphere packaging and controlled atmosphere packaging.]

[*Refuse*—Solid waste not carried by water through the sewage system.]

[*Registration--*A grant to a person to operate a food establishment within this Commonwealth as required by section 14 of the Food Act (31 P. S. § 20.14).]

[*Reg. Penna. Dept. Agr.--*An abbreviation connoting that a food bearing that abbreviation on its package label has been processed by a food establishment that is "registered with the Pennsylvania Department of Agriculture" in accordance with section 14(a) of the Food Act.]

[*Restrict*—To limit the activities of a food employee so that there is no risk of transmitting a disease that is transmissible through food and the food employee does not

work with exposed food, clean equipment, utensils, linens and unwrapped single-service or single-use articles.]

[*Restricted egg*—Any check, dirty egg, incubator reject, inedible, leaker or loss as defined in Chapter 87 (relating to standards for grading and marketing eggs).]

[*Restricted use pesticide*—A pesticide classified for restricted use under section 3(d) of the Federal Insecticide, Fungicide and Rodenticide Act of 1947 (7 U.S.C.A. § 136(d)), or a pesticide designated by the Secretary for restricted use under section 7(b)(6) of the Pennsylvania Pesticide Control Act of 1973 (3 P. S. § 111.27(b)(6)).]

Retail food establishment—[A food] An establishment which stores, prepares, packages, vends, offers for sale or otherwise provides food for human consumption and which relinquishes possession of food to a consumer directly, or indirectly, through a delivery service such as home delivery of grocery orders or delivery service provided by common carriers. The term does not include dining cars operated by a railroad company in interstate commerce or a bed and breakfast homestead or inn.

Retail food facility-- A public eating or drinking place or a retail food establishment. The term is synonymous with the term “food establishment” in the Model Food Code.

Retail food facility operator--The entity that is legally responsible for the operation of the retail food facility, such as the owner, owner's agent or other person.

Retail Food Facility Safety Act—The Retail Food Facility Safety Act (3 Pa.C.S.A. §§ 5701 – 5714).

[*Risk*—The likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.]

[*Safe material*—One or more of the following:

(i) An article manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any food.

(ii) An additive that is used as specified in section 409 or section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. §§ 301 and 376).

(iii) A material that is not an additive and that is used in conformity with applicable regulations of the FDA.]

[*Sanitization*—The application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of five logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.]

[*Sealed*—Free of cracks or other openings that allow the entry or passage of moisture.]

Secretary--The Secretary of the Department or an authorized representative, employee or agent of the Department.

[*Service animal*—An animal such as a guide dog, signal dog or other animal individually trained to provide assistance to an individual with a disability.]

[*Servicing area*—An operating base location to which a mobile food facility or transportation vehicle returns regularly for things such as discharging liquid or solid wastes, refilling water tanks and ice bins and boarding food.]

[*Sewage*—A substance, which contains waste products or excrements or other discharges from the bodies of human beings or animals and any noxious or deleterious substance being harmful or inimical to the public health, or to animal or aquatic life, or to the use of water for domestic water supply or for recreation.]

[*Shellfish control authority*—A State, Federal, foreign, tribal or other government entity legally responsible for administering a program that includes certification of molluscan shellfish harvesters and dealers for interstate commerce.]

[*Shellfish permit*--A permit issued by the Department in accordance with Chapter 49 (relating to shellfish) and the National Shellfish Sanitation Program, that authorizes a person to operate a food establishment for shellfish.]

[*Shellfish permit holder*--The entity that meets the following conditions:

(i) Is legally responsible for the operation of the food establishment such as the owner, owner's agent or other person.

(ii) Possesses a valid shellfish permit to operate a shellfish food establishment.]

[*Shellstock*--Raw, in-shell molluscan shellfish.]

[*Shiga toxin-producing Escherichia coli*—Any E. coli capable of producing Shiga toxins, also called Verocytotoxins or Shiga-like toxins. This includes, but is not limited to, E. coli serotypes O157:H7, O157:NM and O157:H.]

[*Shucked shellfish*—Molluscan shellfish that have one or both shells removed.]

[*Single-service articles*—Tableware, carry-out utensils and other items such as bags, containers, place mats, stirrers, straws, toothpicks and wrappers that are designed and constructed for one time, one person consumer use after which they are intended for discard.]

[*Single-use articles*--

(i) Utensils and bulk food containers designed and constructed to be used once and discarded.

(ii) The term includes items such as wax paper, butcher paper, plastic wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles and number 10 cans which do not meet the materials, durability, strength and cleanability specifications in §§ 46.521(a), 46.541(a) and 46.542(a) and (b) (relating to materials in multiuse utensils and food-contact surfaces; durability and strength; and cleanability of multiuse food-contact surfaces and CIP equipment) for multiuse utensils.

(iii) The term does not include formed aluminum containers used in conjunction with pan liners that may be reused to cook nonpotentially hazardous baked goods.]

[*Slacking*—The process of moderating the temperature of a food such as allowing a food to gradually increase from a temperature of -23°C (-10°F) to -4° C (25°F) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen food such as spinach.]

[*Smooth*—One or more of the following:

(i) A food-contact surface having a surface free of pits and inclusions with cleanability equal to or exceeding that of (100 grit) number-3 stainless steel.

(ii) A nonfood-contact surface of equipment having a surface equal to that of commercial grade hot-rolled steel free of visible scale.

(iii) A floor, wall or ceiling having an even or level surface with no roughness or projections that renders it difficult to clean.]

[*Substance*--A material intended for use in producing, manufacturing, packaging, processing, preparing, treating, transporting or holding food and any source of radiation intended for any use.]

[*Sulfiting agent*--A substance which imparts a residual of sulfur dioxide.]

[*Table-mounted equipment*--Equipment that is not portable and is designed to be mounted off the floor on a table, counter or shelf.]

[*Tableware*—Eating, drinking and serving utensils for table use such as plates, flatware (including forks, knives and spoons) and hollowware (including bowls, cups, serving dishes and tumblers).]

[*Temperature measuring device*—A thermometer, thermocouple, thermistor or other device that indicates the temperature of food, air or water.]

[*Temporary food facility*--A food facility that operates for a period of no more than 14 consecutive days in a fixed location and in conjunction with a single event or celebration (such as a fair, festival, carnival or other transitory gathering).]

[*Temporary license*--Either of the following:

(i) A license that is the following:

- (A) Issued to the operator of a temporary food facility.
- (B) Valid for the duration of a particular event or celebration (such as a fair or carnival) of no more than 14 days duration (whether these days are consecutive or nonconsecutive).
- (C) Issued to the operator with respect to no more than three events or celebrations in a particular calendar year.

(ii) A license that is the following:

(A) Issued to a food facility operator operating a food facility, whether stationary or mobile.

(B) In operation for a total of no more than 14 days within a particular calendar year.

(C) Not in conjunction with an event or celebration.]

[*USDA*--The United States Department of Agriculture.]

[*Utensil*—A food-contact implement or container used in the storage, preparation, transportation, dispensing, sale or service of food. The term includes the following:

- (i) Kitchenware or tableware that is multiuse, single-service or single-use.
- (ii) Gloves used in contact with food.
- (iii) The temperature sensing probes of food temperature measuring devices.
- (iv) Probe-type price or identification tags used in contact with food.]

[*Utility sink*--A sink used for the disposal of mop water or other similar liquid waste.]

[*Vacuum packaging*--A type of reduced oxygen packaging in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package, such as sous vide.]

[*Variance*—A written document issued by the Department that authorizes a modification or waiver of one or more requirements of this chapter if, in the opinion of the Department, a health hazard or nuisance will not result from the modification or waiver.]

[*Vending machine*—A self-service device that, upon insertion of a coin, paper currency, token, card or key, dispenses unit servings of food in bulk or in packages without the necessity of replenishing the device between each vending operation.]

[*Vending machine location*—The room, enclosure, space or area where one or more vending machines are installed and operated. The term includes the storage areas and areas on the premises that are used to service and maintain the vending machines.]

[*Warewashing*—The cleaning and sanitizing of food-contact surfaces of equipment and utensils.]

[*Water activity or a_w* --A measure of the free moisture in a food, obtained by dividing the water vapor pressure of the substance by the vapor pressure of pure water at the same temperature. Water activity is typically indicated by the symbol a_w .]

[*Water for human consumption*--The term includes water that is used for drinking, bathing and showering, cooking, dishwashing or maintaining oral hygiene.]

[*Whole-muscle, intact beef*—Whole muscle beef that is not injected, mechanically tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.]

§ 46.4. Adoption of Model Food Code.

The provisions, terms, procedures, appendices and standards set forth in the current edition of the Model Food Code are adopted to the extent they do not conflict with one or more of the following:

- (1) The Retail Food Facility Safety Act.
- (2) The Food Safety Act.
- (3) A provision of this chapter.

Subchapter B. MANAGEMENT AND PERSONNEL

[SUPERVISION]

§ 46.101. - § 46.102. [Reserved.]

[EMPLOYEE HEALTH]

§ 46.111. - § 46.115. [Reserved.]

[PERSONAL CLEANLINESS]

§ 46.131. - § 46.137. [Reserved.]

[HYGIENIC PRACTICES]

§ 46.151. - § 46.153. [Reserved.]

Subchapter C. FOOD CHARACTERISTICS

[CHARACTERISTICS]

§ 46.201. [Reserved.]

FOOD SOURCES

§ 46.211. [Food sources.] [Reserved.]

§ 46.212. Food prepared in a private home.

(a) General. Food prepared in a private home[, not approved by the Department, may not] may be used or offered for human consumption in a retail food facility if all of the following are accurate:

(1) The food is not potentially hazardous food.

(2) The food is used or offered for human consumption by any of the following organizations:

(i) A tax-exempt organization under section 501(c)(3) of the Internal Revenue Code of 1986 (Public Law 99-514, 26 U.S.C. § 501(c)(3)).

(ii) A volunteer fire company or ambulance, religious, charitable, fraternal, veterans, civic, sportsmen, agricultural fair or agricultural association or any separately chartered auxiliary of any of these associations, on a not-for-profit basis.

(iii) An organization that is established to promote and encourage participation and support for extracurricular recreational activities for youth of primary and secondary public, private and parochial school systems on a not-for-profit basis.

(3) The organization that uses or offers the food for human consumption informs consumers that the organization uses or offers food that has been prepared in private homes that are not licensed or inspected.

(4) The food is donated to an organization described under paragraph (2).

(b) Private homes that are registered food establishments under the Food Safety Act.

Food prepared in a private home may be offered for human consumption in a retail food facility if the private home is registered with the Department as a food establishment under the Food Safety Act.

§ 46.213. - § 46.216. [Reserved.]

§ 46.217. Milk and milk products.

Milk and milk products [shall be obtained from sources that comply] may be offered for human consumption in a retail food facility if the facility complies with section 2 of the Milk Sanitation Law (31 P. S. § 646).

§ 46.218. - § 46.222. [Reserved.]

[SPECIFICATIONS FOR RECEIVING, ORIGINAL CONTAINERS AND RECORDS]

§ 46.241. - § 46.251. [Reserved.]

[PREVENTING CONTAMINATION BY EMPLOYEES]

§ 46.261. - § 46.262. [Reserved.]

[PREVENTING FOOD AND INGREDIENT CONTAMINATION]

§ 46.281. - § 46.286. [Reserved.]

[PREVENTING CONTAMINATION FROM EQUIPMENT, UTENSILS AND LINENS]

§ 46.301. - § 46.307. [Reserved.]

[PREVENTING CONTAMINATION FROM THE PREMISES]

§ 46.321. - § 46.323. [Reserved.]

[PREVENTING CONTAMINATION BY CONSUMERS]

§ 46.341. - § 46.344. [Reserved.]

[DESTRUCTION OF ORGANISMS OF PUBLIC HEALTH CONCERN]

§ 46.361. - § 46.366. [Reserved.]

[TEMPERATURE AND TIME CONTROL FOR LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN]

§ 46.381. - § 46.385. [Reserved.]

[SPECIALIZED PROCESSING METHODS]

§ 46.401. - § 46.402. [Reserved.]

[FOOD IDENTITY, PRESENTATION AND ON-PREMISES LABELING]

§ 46.421. - § 46.423. [Reserved.]

[UNSAFE, ADULTERATED OR CONTAMINATED FOOD]

§ 46.441. [Reserved.]

[SPECIAL REQUIREMENTS FOR HIGHLY SUSCEPTIBLE POPULATIONS]

§ 46.461. [Reserved.]

Subchapter D. EQUIPMENT, UTENSILS AND LINENS

[GENERAL STANDARD]

§ 46.501. [Reserved.]

[MATERIALS FOR USE IN CONSTRUCTION AND REPAIR]

§ 46.521. - § 46.523. [Reserved.]

[DESIGN AND CONSTRUCTION]

§ 46.541. - § 46.544. [Reserved.]

[ACCURACY]

§ 46.561. - § 46.563. **[Reserved.]**

[FUNCTIONALITY]

§ 46.581. - § 46.595. **[Reserved.]**

[NUMBERS AND CAPACITIES OF EQUIPMENT]

§ 46.611. - § 46.615. **[Reserved.]**

**[NUMBERS AND CAPACITIES OF UTENSILS, TEMPERATURE MEASURING
DEVICES AND TESTING DEVICES]**

§ 46.631. - § 46.634. **[Reserved.]**

[LOCATION AND INSTALLATION OF EQUIPMENT]

§ 46.651. - § 46.652. **[Reserved.]**

[MAINTENANCE AND OPERATION OF EQUIPMENT]

§ 46.671. - § 46.676. **[Reserved.]**

**[MAINTENANCE AND OPERATION OF UTENSILS AND TEMPERATURE
AND PRESSURE MEASURING DEVICES]**

§ 46.691. - § 46.693. **[Reserved.]**

[CLEANING OF EQUIPMENT AND UTENSILS]

§ 46.711. - § 46.719. **[Reserved.]**

[SANITIZATION OF EQUIPMENT AND UTENSILS]

§ 46.731. **[Reserved.]**

[LAUNDERING]

§ 46.751. - § 46.753. [Reserved.]

[PROTECTION OF CLEAN ITEMS]

§ 46.771. - § 46.775. [Reserved.]

**Subchapter E. WATER, PLUMBING AND WASTE
WATER**

[WATER]

§ 46.801. - § 46.806. [Reserved.]

[PLUMBING SYSTEM]

§ 46.821. - § 46.825. [Reserved.]

[WATER TANK AND MOBILE FOOD FACILITY WATER TANK]

§ 46.841. - § 46.844. [Reserved.]

[SEWAGE, OTHER LIQUID WASTE AND RAINWATER]

§ 46.861. - § 46.863. [Reserved.]

[REFUSE, RECYCLABLES AND RETURNABLES]

§ 46.881. - § 46.886. [Reserved.]

Subchapter F. PHYSICAL FACILITIES

[MATERIALS FOR CONSTRUCTION AND REPAIR]

§ 46.901. - § 46.902. [Reserved.]

[DESIGN, CONSTRUCTION AND INSTALLATION]

§ 46.921. - § 46.922. [Reserved.]

[NUMBERS AND CAPACITIES]

§ 46.941. - § 46.946. [Reserved.]

[LOCATION AND PLACEMENT]

§ 46.961. - § 46.965. [Reserved.]

[MAINTENANCE AND OPERATION]

§ 46.981. - § 46.982. [Reserved.]

Subchapter G. POISONOUS OR TOXIC MATERIALS

[LABELING AND IDENTIFICATION]

§ 46.1001. - § 46.1002. [Reserved.]

[OPERATIONAL SUPPLIES AND APPLICATIONS]

§ 46.1021. - § 46.1029. [Reserved.]

[STOCK AND RETAIL SALE]

§ 46.1041. - [Reserved.]

Subchapter H. ADMINISTRATIVE PROCEDURES

ACCESS, APPROVALS AND VARIANCES

§ 46.1101. Access to retail food facilities.

After the Department or licensor presents identification, the person in charge shall allow the Department or licensor to determine if the retail food facility is in compliance with this chapter by allowing access to the facility, allowing inspection and providing information and records specified in this chapter and to which the Department or licensor is entitled under the [Public Eating and Drinking Places Law, the Food Act] Retail Food Facility Safety Act and any other relevant statutory or food regulatory authority during the retail food facility's hours of operation and other reasonable times if the facility is not open during normal business hours.

§ 46.1102. Obtaining Department or licensor approval.

(a) *General.* This section describes the process by which a person may obtain an approval from the Department or a licensor required by any other provision of this chapter.

(b) *Written request.* A person seeking an approval from the Department or a licensor under this chapter shall submit a written request for approval to the entity from which approval is sought. If approval is sought from the Department, the written request shall be mailed or delivered to the following address:

Pennsylvania Department of Agriculture
Bureau of Food Safety and Laboratory Services
[Attn: Chief, Division of Food Safety]
2301 North Cameron Street
Harrisburg, Pennsylvania 17110-9408

(c) *Contents of request.* The written request for approval described in subsection (b) shall specify the provision of this chapter under which approval is sought, the reason approval is sought and relevant documentation in support of the request.

(d) *Processing a request.* The Department or licensor will, within 30 days of receipt of a written request for approval under this section, mail or otherwise provide the requester with a written grant or denial of the request, or a specific request for additional information. If a written request for additional information is made, the Department or licensor shall have an additional 30 days from the date it receives the additional information within which to mail or otherwise provide the requester with a written grant or denial of the request.

(e) *Standard for approval.* The Department or licensor shall grant approval if it determines the approval would not constitute or cause a violation of the [Food Act, the Public Eating and Drinking Places Law] Retail Food Facility Safety Act or this chapter, and that no health hazard would result from the approval.

§ 46.1103. Variances.

(a) *Modifications and waivers.* The Department may grant a variance by modifying or waiving the requirements of this chapter if--in the opinion of the Department--a health hazard will not result from the variance. If a variance is granted, the Department will retain the information specified in subsection (b) in its records for the retail food facility and provide a copy of the approved variance to the licensor if the licensor is an entity other than the Department.

(b) *Documentation of proposed variance and justification.* Before a variance from a requirement of this chapter is approved, the information that shall be provided by the person requesting the variance and retained in the Department's file on the retail food facility includes the following:

(1) A statement of the proposed variance of the chapter requirement citing relevant chapter section numbers.

(2) An analysis of the rationale for how the potential public health hazards addressed by the relevant chapter sections will be alternatively addressed by the proposal.

(3) An HACCP plan--if required as specified in § 46.1122(a)(1) (relating to HACCP plans)--that includes the information specified in § 46.1122(b) as it is relevant to the variance requested.

(c) *Conformance with approved procedures.* If the Department grants a variance as specified in subsection (a), or an HACCP plan is otherwise required as specified in § 46.1122(a), the retail food facility operator shall do the following:

(1) Comply with the HACCP plans and procedures that are submitted as specified in § 46.1122(b) and approved as a basis for the modification or waiver.

(2) Maintain and provide to the Department or licensor, upon request, records specified in § 46.1122(b)(4) and (5) that demonstrate that the following are routinely employed:

(i) Procedures for monitoring critical control points.

(ii) Monitoring of the critical control points.

(iii) Verification of the effectiveness of an operation or process.

(iv) Necessary corrective actions if there is failure at a critical control point.

PLAN SUBMISSION AND APPROVAL

§ 46.1121. Facility and operating plans.

(a) *When plans are required.* A retail food facility licensing applicant or retail food facility operator shall have plans and specifications reviewed by the Department or licensor and will submit these properly prepared plans and specifications (as described in subsection (b)) to the Department or licensor for review and approval (using the procedure described in § 46.1142 (relating to application procedure for appropriate license [or registration])) before any of the following:

- (1) The construction of a retail food facility.
- (2) The conversion of an existing structure for use as a retail food facility.
- (3) The remodeling of a retail food facility (including installation and use of any new major food equipment for heating, cooling and hot and cold holding food) or a change of type of retail food facility or food operation if the Department or licensor determines that plans and specifications are necessary to ensure compliance with this chapter.
- (4) A change of ownership of a retail food facility.

(b) *Contents of the plans and specifications.* The plans and specifications for a retail food facility shall include (as required by the Department or licensor based on the type of operation, type of food preparation and foods prepared) the following information to demonstrate conformance with this chapter:

- (1) Intended menu and consumer advisory intentions, if a consumer advisory is required under [§ 46.423 (relating to consumer advisory required with respect to animal-

derived] the Model Food Code for animal foods that are raw, undercooked or not otherwise processed to eliminate pathogens).

(2) Anticipated volume of food to be stored, prepared and sold or served.

(3) Proposed layout, mechanical schematics, construction materials and finish schedules.

(4) Proposed equipment types, manufacturers, model numbers, locations, dimensions, performance capacities and installation specifications.

(5) Source of water supply, means of sewage disposal and refuse disposal.

(6) An HACCP plan, if required under § 46.1122 (relating to HACCP plans).

(7) Other information that may be required by the Department or licensor for the proper review of the proposed construction, conversion or modification of a retail food facility, and requested by the Department or licensor in writing.

§ 46.1122. HACCP plans.

(a) *When an HACCP plan is required.*

(1) Before engaging in an activity that requires an HACCP plan, a retail food facility applicant or retail food facility operator shall submit to the Department or licensor for approval a properly prepared HACCP plan as specified in subsection (b) and the relevant provisions of this chapter if any of the following occurs:

(i) Submission of an HACCP plan is required according to applicable Federal or State laws.

(ii) A variance is required as specified in [§ 46.250(b)(2)(ii), § 46.361(d)(2), § 46.401 or § 46.589(b)] the Model Food Code.

(iii) The Department or licensor determines that a food preparation or processing method requires a variance based on a plan submittal specified in § 46.1121(b) (relating to facility and operating plans), an inspectional finding or a variance request.

(2) A retail food facility applicant or retail food facility operator shall have a properly prepared HACCP plan as specified in [§ 46.402 (relating to reduced oxygen packaging)] the Model Food Code for reduced oxygen packaging.

(b) *Contents of an HACCP plan.* For a retail food facility that is required in subsection (a) to have an HACCP plan, the plan and specifications shall indicate the following:

(1) A categorization of the types of potentially hazardous foods that are specified in the menu such as soups and sauces, salads, and bulk, solid foods such as meat roasts, or of other foods that are specified by the Department or licensor.

(2) A flow diagram by specific food or category type identifying critical control points and providing information on the following:

(i) Ingredients, materials and equipment used in the preparation of that food.

(ii) Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved.

(3) Food employee and supervisory training plan that addresses the food safety issues of concern.

(4) A statement of standard operating procedures for the plan under consideration including clearly identifying the following:

(i) Each critical control point.

(ii) The critical limits for each critical control point.

(iii) The method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge.

(iv) The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring critical control points.

(v) Action to be taken by the person in charge if the critical limits for each critical control point are not met.

(vi) Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed.

(5) Additional scientific data or other information, as required by the Department or licensor, supporting the determination that food safety is not compromised by the proposal.

§ 46.1123. Confidentiality of trade secrets.

The Department or licensor will treat as confidential information that meets the criteria specified in law for a trade secret and is contained on inspection report forms and in the plans and specifications submitted as specified in §§ 46.1121(b) and 46.1122(b) (relating to facility and operating plans; and HACCP plans).

§ 46.1124. Preoperational inspection of construction.

The Department or licensor will conduct one or more preoperational inspections to verify that the retail food facility is constructed and equipped in accordance with the approved plans and approved modifications of those plans, and variances granted under

§ 46.1103 (relating to variances). The Department or licensor will also verify the retail food facility is otherwise in compliance with this chapter[, the Food Act and the Public Eating and Drinking Places Law] and the Retail Food Facility Safety Act.

REQUIREMENTS FOR OPERATION

§ 46.1141. [Requirement: license or registration] License requirement.

(a) *General requirement.* A person may not operate a retail food facility without a valid [registration issued by the Department, or] license issued by the Department or licensor, unless otherwise provided in subsection (b).

(b) [*Exceptions*] Exemptions.

[(1) A building, structure or place owned, leased or otherwise in possession of a person or municipal corporation or public or private organization, used or intended to be used by two or more farmers or an association of farmers for the purpose of selling food directly to consumers--otherwise known as a farmer's market--shall be considered to be a single retail food establishment for purposes of registration under section 14 of the Food Act (31 P. S. § 20.3).

(2)] The following [food establishments] retail food facilities are exempt from [registration] licensure requirements under [section 14 of the Food Act] the Retail Food Facility Safety Act, but remain subject to the inspection provisions and all other provisions of that statute:

[(i) Vehicles used primarily for the transportation of a consumer commodity in bulk or quantity to manufacturers, packers, processors or wholesale or retail distributors.

(ii) A food establishment in which at least 50% of the commodities sold were produced on the farm on which the food establishment is located.

(iii) A food establishment in which food or beverages are sold only through a vending machine.

(iv) A food establishment in which only prepackaged, nonpotentially hazardous food or beverages are sold]

(i) A retail food facility in which only prepackaged, nonpotentially hazardous food or beverages are sold.

(ii) A retail food facility that sells only raw agricultural commodities.

(iii) If the licensor is the Department, a retail food facility that is exempt from licensure by an Order of the Secretary that has been published in the *Pennsylvania Bulletin* in accordance with the provision of the Retail Food Facility Safety Act at 3 Pa.C.S.A. § 5703(b)(1).

(iv) If the licensor is an entity other than the Department, a retail food facility that is exempt from licensure by an Order of the local government unit or units having licensing authority in accordance with the provision of the Retail Food Facility Safety Act at 3 Pa.C.S.A. § 5703(b)(1).

(c) License interval. A license certificate issued by the Department under this chapter shall set forth the license expiration date. The license interval shall vary, in accordance with the risk-based factors identified in the Model Food Code, as follows:

(1) 24-month license interval (typical of convenience store operations, hot dog carts and coffee shops).

(i) The license interval shall be 24 months with a respect to a retail food facility that:

(A) serves or sells only pre-packaged, nonpotentially hazardous foods (non time/temperature control for safety foods);

(B) prepares only nonpotentially hazardous foods (non time/temperature control for safety foods);

(C) heats only commercially processed, potentially hazardous foods (TCS foods) for hot holding; and

(D) does not cool potentially hazardous foods (TCS foods) for hot holding.

(ii) Examples of the type of retail food facility that would typically be subject to the 24-month license interval described in subparagraph (i) are convenience store operations, hot dog carts, and coffee shops.

(iii) The license interval for a retail food facility shall be 24 months if the retail food facility would otherwise be subject to the 18-month license interval described in Paragraph (2) but demonstrates to the Department, through historical documentation, that it has achieved and documented active managerial control of foodborne illness risk factors identified in the Model Food Code. These risk factors include:

(A) A history of non-compliance with provisions related to foodborne illness risk factors or critical items.

(B) Specialized processes conducted.

(C) Food preparation a day in advance of service.

(D) Large numbers of people served.

(E) A history of foodborne illnesses or complaints, or both.

(F) Highly susceptible population served.

(2) 18-month license interval (typical of some retail food store operations, institutional facilities that do not serve highly susceptible populations, and quick food service operations).

(i) The license interval shall be 18 months with respect to a retail food facility that:

(A) has a limited menu;

(B) prepares/cooks and serves most products immediately;

(C) may involve hot and cold holding of potentially hazardous foods (TCS foods) after preparation or cooking; and

(D) limits complex preparation of potentially hazardous foods (TCS foods) requiring cooking, cooling, and reheating for hot holding to only a few potentially hazardous foods (TCS foods).

(ii) Examples of the type of retail food facility that would typically be subject to the 18-month license interval described in subparagraph (i) are retail food store operations that have only a limited number of separate departments (such as deli, bakery, produce, seafood or meat areas), institutional facilities that do not serve a highly susceptible population, and quick food service operations.

(iii) The license interval for a retail food facility shall be 18 months if the retail food facility would otherwise be subject to the 12-month license interval described in Paragraph (3) but demonstrates to the Department, through historical documentation, that it has achieved and documented active managerial control of foodborne illness risk factors described in Paragraph (1).

(iv) The license interval for a retail food facility shall be 18 months if the retail food facility would otherwise be subject to the 24-month license interval described in Paragraph (1), but the retail food facility is newly-licensed or has not yet demonstrated to the Department, through historical documentation, that it has achieved and documented active managerial control of foodborne illness risk factors described in Paragraph (1).

(3) 12-month license interval (typical of full service restaurants).

(i) The license interval shall be 12 months with respect to a retail food facility that:

(A) has an extensive menu and entails handling of raw ingredients;

(B) has complex preparation including cooking, cooling, and reheating for hot holding involves many potentially hazardous foods (TCS foods);
and

(C) uses a variety of processes that require hot and cold holding of potentially hazardous food (TCS food).

(ii) Examples of the type of retail food facility that would typically be subject to the 12-month license interval described in subparagraph (i) are full service restaurants or retail food stores with a full range of separate departments (such as

deli, bakery, produce, seafood or meat areas) that includes ready-to-eat foods from a café, salad bar or hot food bar.

(iii) The license interval for a retail food facility shall be 12 months if the retail food facility would otherwise be subject to the 6-month license interval described in Paragraph (4) but demonstrates to the Department, through historical documentation, that it has achieved and documented active managerial control of foodborne illness risk factors described in Paragraph (1).

(iv) The license interval for a retail food facility shall be 12 months if the retail food facility would otherwise be subject to the 18-month license interval described in Paragraph (2), but the retail food facility is newly-licensed or has not yet demonstrated to the Department, through historical documentation, that it has achieved and documented active managerial control of foodborne illness risk factors described in Paragraph (1).

(4) 6-month license interval (typical of retail food facilities that serve highly susceptible populations, and specialized processors).

(i) The license interval shall be 6 months with respect to a retail food facility that serves a highly susceptible population or that conducts specialized processes such as smoking, curing, or reduced oxygen packaging to extend shelf life.

(ii) Examples of the type of retail food facility that would typically be subject to the 6-month license interval described in subparagraph (i) are preschools, hospitals, nursing homes, and establishments conducting processing at retail.

(iii) The license interval for a retail food facility shall be 6 months if the retail food facility would otherwise be subject to the 12-month license interval

described in Paragraph (3), but the retail food facility is newly-licensed or has not yet demonstrated to the Department, through historical documentation, that it has achieved and documented active managerial control of foodborne illness risk factors described in Paragraph (1).

§ 46.1142. Application procedure for appropriate license [or registration].

Prior to the opening of a retail food facility, the operator shall contact the Department or licensor to obtain the appropriate application form for the required license [or registration]. The Department or licensor will supply the applicant the appropriate form, based upon the type of retail food facility involved. [If the food facility is a public eating and drinking place, the applicant shall obtain a license. If the food facility is a retail food establishment, the applicant must obtain a registration. A single location (such as a grocery store that also serves hot ready-to-eat foods) might require both a license and a registration.]

§ 46.1143. Issuance.

(a) *New, converted or remodeled retail food facilities.* For retail food facilities that are required to submit plans as specified in § 46.1121(a) (relating to facility and operating plans), the Department [will issue a registration, or the Department] or licensor will issue a license to the applicant after the following occur:

- (1) The required plans, specifications and information are reviewed and approved.
- (2) A preoperational inspection, as described in § 46.1124 (relating to preoperational inspection of construction) shows that the facility is built or remodeled in accordance

with the approved plans and specifications and that the facility is in compliance with this chapter.

(3) A properly completed application is submitted.

(4) The required fee is submitted.

(b) *License [or registration] renewal.* The retail food facility operator of an existing retail food facility shall submit an application, the required fee and be in compliance with this chapter prior to issuance [by the Department of a renewed registration or license, or the issuance] of a renewed license by the Department or a licensor.

(c) *Change of ownership.* Licenses [and registrations] are nontransferable. New owners shall apply to the Department or licensor in accordance with § 46.1142 (relating to application procedure for appropriate license [or registration]).

§ 46.1144. Conditions of retention: responsibilities of the retail food facility operator.

To retain a license [or registration] issued by the Department or licensor under this chapter, a retail food facility operator shall do the following:

(1) Post the license [or registration] in a location in the retail food facility that is conspicuous to consumers and the Department or licensor.

(2) Comply with this chapter--including the conditions of a granted variance as specified in § 46.1103(c) (relating to variances)--and approved plans as specified in § 46.1121(b) (relating to facility and operating plans).

(3) If a retail food facility is required in § 46.1122(a) (relating to HACCP plans) to operate under an HACCP plan, comply with the plan as specified in § 46.1103(c).

(4) Immediately contact the Department or licensor to report an illness of a food employee as specified in [§ 46.111(b) (relating to duty to report disease or medical condition)] Subpart 2-201 of the Model Food Code.

(5) Immediately discontinue operations and notify the Department or licensor if an imminent health hazard may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, gross unsanitary occurrence or condition or other circumstance that may endanger public health. A retail food facility operator need not discontinue operations in an area of a facility that is unaffected by the imminent health hazard.

(6) Not resume operations discontinued in accordance with paragraph (5) or otherwise according to the [Public Eating and Drinking Places Law or the Food Act] Retail Food Facility Safety Act until approval is obtained from the Department or licensor.

(7) Allow representatives of the Department or licensor access to the retail food facility as specified in § 46.1101 (relating to access to retail food facilities).

(8) Except as specified in paragraph (9), replace existing facilities and equipment with facilities and equipment that comply with this chapter if either of the following occurs:

(i) The Department or licensor directs the replacement because the facilities and equipment constitute a public health hazard or no longer comply with the criteria upon which the facilities and equipment were accepted.

(ii) The facilities and equipment are replaced in the normal course of operation.

(9) [Upgrade or replace refrigeration equipment as specified in § 46.385(a)(3) (relating to potentially hazardous food: hot and cold holding), by December 13, 2008, if the

circumstances specified in paragraph (8)(i) and (ii) do not occur first, and unless a variance has been approved as specified in § 46.1103] **[Reserved.]**

(10) Comply with directives of the Department or licensor including time frames for corrective actions specified in inspection reports, notices, orders, warnings and other directives issued by the Department or licensor in regard to the operator's retail food facility or in response to community emergencies.

(11) Accept notices issued and served by the Department or licensor according to the [Public Eating and Drinking Places Law or the Food Act] Retail Food Facility Safety Act.

(12) Remit any fee owed the Department under the Retail Food Facility Safety Act (at 3 P.S. § 5703(j)) within the time prescribed by the Department.

(13) Remit any civil penalty assessed against the retail food facility operator under the Retail Food Facility Safety Act or this Chapter within 30 days of the later of:

(i) the effective date of the final adjudication assessing the civil penalty; or

(ii) the expiration of the applicable deadline by which the final adjudication could be appealed to an appellate court of the Commonwealth of Pennsylvania.

Chapter 76. Food Employee Certification

§ 76.1. - § 76.19. [Reserved.]

§ 76.20. Definitions.

The following words and terms, when used in this chapter, have the following meanings unless otherwise defined in Chapter 46 (relating to food code):

Act—3 Pa.C.S. Chapter 65 (relating to the Food Employee Certification Act).

Certificate--A certificate of completion issued by a certification program that has been evaluated and listed by an accrediting agency that has been recognized by the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Program.

Conference for Food Protection--An independent, national voluntary nonprofit organization to promote food safety and consumer protection. Participants in this organization include Federal, State and local regulatory agencies, universities, test providers, certifying organizations, consumer groups, food service and retail store trade associations and retail food facility operators. The objectives of the organization include identifying and addressing food safety problems and promoting uniformity of regulations in food protection.

Department—The Department of Agriculture of the Commonwealth.

Employee—As defined in the Retail Food Facility Safety Act, at 3 Pa.C.S.A. § 5702.

§ 76.21. Certification programs.

(a) General recognition of certification programs. For purposes of compliance with the Act, the Department recognizes certification programs (including examinations developed under those programs) that are evaluated and listed by an accrediting agency that has been recognized by the Conference for Food Protection as conforming to the

Conference for Food Protection Standards for Accreditation of Food Protection

Manager Certification Program.

(b) List of acceptable certification programs. The Department will maintain a current list of Department-recognized certification programs. The Department will:

(1) publish the current list in the *Pennsylvania Bulletin* annually, and whenever the list is revised;

(2) post the current list on its agency website: www.agriculture.state.pa.us; and

(3) provide a copy of the current list upon request directed to the Department's Bureau of Food Safety and Laboratory Services, at (717) 787-4315 or the following mailing address:

Pennsylvania Department of Agriculture

Bureau of Food Safety and Laboratory Services

ATTN: Food Employee Certification

2301 North Cameron Street

Harrisburg, Pennsylvania 17110-9408



COMMONWEALTH OF PENNSYLVANIA
GOVERNOR'S OFFICE OF GENERAL COUNSEL

August 1, 2012

Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

RE: NOTICE OF PROPOSED RULEMAKING
Department of Agriculture
Bureau of Food Safety and Laboratory Services
7 Pa. Code Chapters 46 and 76
Food Code; Food Employee Certification
I.D. No. 2-174

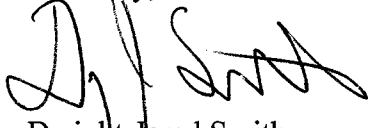
Dear Sir or Madam:

Please find enclosed copies of the Face Sheet, Preamble, Annex "A" and Regulatory Analysis Form with respect to the above proposed regulation.

Copies of these documents have been submitted to the majority and minority chairpersons of the House and Senate Agriculture and Rural Affairs Committees and to the Legislative Reference Bureau on this date.

The proposed regulation will be published in the August 11, 2012 edition of the *Pennsylvania Bulletin*. If I may be of further information, please advise.

Sincerely,



Dwight-Jared Smith
Assistant Counsel

Enclosures

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE
REGULATORY REVIEW ACT**

I.D. NUMBER: 2-174
 SUBJECT: FOOD CODE; FOOD EMPLOYEE CERTIFICATION
 AGENCY: DEPARTMENT OF AGRICULTURE


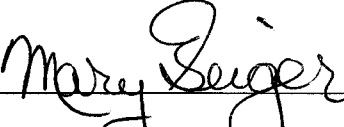
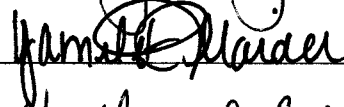
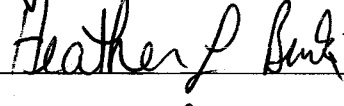


TYPE OF REGULATION

- X Proposed Regulation
- Final Regulation
- Final Regulation with Notice of Proposed Rulemaking Omitted
- 120-day Emergency Certification of the Attorney General
- 120-day Emergency Certification of the Governor
- Delivery of Tolled Regulation
 - a. With Revisions
 - b. Without Revisions

2012 AUG -1 AM 11:31

**RECEIVED
IRRC**

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
8-1-12		Petrarca HOUSE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS
8-1-12	 Maher	MAJORITY CHAIRMAN <u> Maher </u>
8-1-12	 Schwanck	SENATE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS
8-1-12	 Vogel	MAJORITY CHAIRMAN <u> Vogel </u>
8-1-12	 <u> Kathy Cooper </u> IRRC	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
8-1-12	 <u> Samatha Hussen </u> LRB	LEGISLATIVE REFERENCE BUREAU (for Proposed only)

July 24, 2012