

Regulatory Analysis Form

(Completed by Promulgating Agency)

INDEPENDENT REGULATORY
REVIEW COMMISSION

(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

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(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):

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

Proposed Regulation

XX 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 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 United States Department of Health, Food and Drug Administration's Model Food Code ("Model Food Code") as the food safety standards and requirements for Pennsylvania (Pennsylvania is among 50 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; and (4) revise and incorporate the Food Employee Certification regulations at 7 Pa. Code Chapter 76 into 7 Pa. Code Chapter 46.

(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 and 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 CDC 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 departments 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 2010-2011	FY -2 2011-2012	FY -1 2012-2013	Current FY 2013-2014
Bureau of Food Safety	1,835,780	1,894,250	1,954,245	2,074,250

(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 is 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: | September 10, 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: | February 1, 2014 |
| D. The expected effective date of the final-form regulation: | March 1, 2014 |
| E. The date by which compliance with the final-form regulation will be required: | March 1, 2014 |
| 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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By: _____
(Deputy Attorney General)

Department of Agriculture
(AGENCY)

BY 
SHAWN E. SMITH

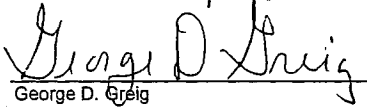
JAN 08 2014
DATE OF APPROVAL

DATE OF APPROVAL

DOCUMENT/FISCAL NOTE NO. 2-174

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

DATE OF ADOPTION 11/6/13

BY 
George D. Craig

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

Check if applicable
Copy not approved. Objections attached.

TITLE
SECRETARY
Pennsylvania Department of Agriculture

Notice of Final Rulemaking

**Department of Agriculture
Bureau of Food Safety and Laboratory Services**

**7 Pa. Code Subchapters 46 and 76
Food Code; Food Employee Certification**

FINAL RULEMAKING

Title 7 – AGRICULTURE DEPARTMENT OF AGRICULTURE

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

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

The Department of Agriculture (Department) hereby amends 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 regulation.

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 (at 3 Pa.C.S.A. § 5707(a)) 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" (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 of the Final-Form Regulation

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 regulation: (1) adopts the terminology and implements the changes necessitated or authorized by Act 106 of 2010; (2) incorporates, to the extent practicable, the standards and requirements of the Model Food Code as the food safety standards and requirements for Pennsylvania; (3) establishes 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) streamlines the substance of the Food Employee Certification regulations at 7 Pa. Code Chapter 76 and incorporates that into 7 Pa. Code Chapter 46 as described below.

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. The format, layout, section headings and subject matter of much of 7 Pa. Code Chapter 46 track with the Model Food Code. The Model Food Code 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 regulation will not have an adverse impact on that regulated community.

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

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

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 regulation 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 regulation is needed in order to implement these changes.

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

Comments and Responses

A notice of proposed rulemaking was published at 42 *Pennsylvania Bulletin* 5218 (August 11, 2012), affording the public, the Legislature and the Independent Regulatory Review Commission (IRRC) the opportunity to offer comments.

Comments were received from IRRC, the Pennsylvania Catholic Conference (PCC) and the Pennsylvania Association for Sustainable Agriculture (PASA). These comments and the Department's responses follow:

Comment 1: PASA reviewed proposed § 46.3 (relating to definitions) and raised a question regarding the definition of "commingle." PASA observed that the definition refers to the commingling of shellstock (raw, in-shell oyster, clams, mussels and scallops), and not the commingling of other foods.

Response: The proposed rulemaking reflects that the term "commingle" is proposed for deletion. The final-form regulation deletes that defined term, and the term itself is not used elsewhere in the regulation.

The Model Food Code defines "commingle" (at § 1-201.10, relating to statement of applicability and listing of terms) only with respect to the commingling of shellstock and shucked shellfish. In the context of the Model Food Code, the term is only used with respect to these foods. The Department does not believe there is a

need to adopt a definition of this term that varies from the Model Food Code's definition.

Comment 2: PASA reviewed proposed § 46.3 and offered a revision to the definition of the phrase "foodborne disease outbreak." PASA suggested the word "case" be replaced with word "occurrence" in that definition, but acknowledged that the use of the word "occurrence" is not the typical language of epidemiological discipline.

Response: The proposed rulemaking reflects that the term "foodborne disease outbreak" is proposed for deletion. The final-form regulation deletes that defined term and the single use of that phrase which appeared in the definition of the term "confirmed disease outbreak" in § 46.3.

The Model Food Code (at § 1-201.10) defines "foodborne disease outbreak" and includes the same "occurrence of two or more cases" language the commentator references. The Department declines to vary from the Model Food Code on this definition, given that the language is clear and has not been the source of any known confusion in the many years it has been in effect.

Comment 3: PASA reviewed proposed § 46.3 and noted that the definition of the term "food facility" exempts certain food establishments that do not: "... provide food to the consumer either directly or indirectly (such as through the home delivery of groceries)." The commentator asked "how the Department might view a CSA (community shared agriculture) making deliveries to homes, markets or collective drop off points."

Response: The proposed rulemaking reflects that the term "food facility" is proposed for deletion. The final-form regulation deletes that defined term. The only reference to home delivery of groceries in the final-form regulation is in the definition of a "retail food establishment." That definition is *verbatim* from the Retail Food Facility Safety Act (at 3 Pa.C.S.A. § 5702).

The Retail Food Facility Safety Act provides for the licensure of retail food facilities. The determination of whether a particular facility is a retail food facility is a fact-driven determination. In the examples provided by the commentator, if a community-shared agriculture business has a market or collective drop-off point, that market or drop-off point would fit within the definition of a retail food facility. If the market or drop-off point provides only raw agricultural commodities, it would be exempt (under 3 Pa.C.S.A. § 5703(b)(2)(i)) from having to acquire a retail food facility license and pay the attendant license fee, but would remain subject to inspection and would have to comply with all other applicable provisions of the Retail Food Facility Safety Act.

If a community-shared agriculture business has a home delivery service, that service would not fit within the definition of a retail food facility.

If a community-shared agriculture business consists of a farm that makes deliveries to its customers or shareholders, those direct deliveries would not make the farm a retail food facility. If the farm has a retail storefront from which food for human

consumption is sold, it would be a retail food facility. In addition, if a farm conducted on-farm food processing, it would likely be a “food establishment” subject to the registration requirements of the Food Safety Act.

Comment 4: PASA asked that the final-form regulation clarify that rabbits (whether captive bred or wild) are considered game in Pennsylvania. PASA also asked that the Department “offer some clarity about the requirements for slaughter and market of such animals.”

Response: Although the final-form regulation does not specifically reference game animals or rabbits, the Model Food Code (at § 1-201.10, relating to statement of application and listing of terms) defines “game animal” as including rabbits and (at § 3-201.17, relating to game animals) presents the legal requirements for the slaughter and legal sale of these animals. These include a requirement that game animals that are commercially raised for food be slaughtered and processed under a USDA-administered or State-administered regulatory inspection program.

Rabbit processors may choose to operate under a voluntary USDA-administered inspection program or be registered and inspected by PDA in accordance with the Food Safety Act.

Comment 5: PASA reviewed the definition of “licensor” at proposed § 46.3, and asked whether the regulations will supersede: “... those of the county (and other) departments of health.”

Response: The Retail Food Facility Safety Act (at 3 Pa.C.S.A. § 5703(e)(2)) requires that rules and regulations adopted by a licensor other than the Department meet and not exceed the requirements of that statute and its attendant regulations. This means that although a licensor other than the Department may enforce its own standards, they may not exceed standards set forth in the Retail Food Facility Safety Act or the final-form regulation.

Comment 6: PASA noted the defined term “mobile food facility” at proposed § 46.3 and asked:

Where does the definition of a mobile food facility – particularly that part that states cart, basket, box or similar structure – leave a CSA and that “basket, box or similar structure” in which the CSA person might deliver the food directly to the buyer and/or to a drop off location?

Response: The proposed rulemaking reflects that the term “mobile food facility” is proposed for deletion. The final-form regulation deletes that defined term.

A delivery truck or other conveyance or container used for delivering food from a farm, retail food facility or food establishment is not, itself, a mobile retail food facility. These vehicles or containers would be subject to the standards that are applicable to the retail food facility or food establishment from which the food originates.

In general, a vehicle that is being used for food preparation and sale of food directly to consumers (such as a lunch truck) *would* be considered a retail food facility or a food establishment and would be subject to the applicable legal licensure/registration requirements.

A basket, box or similar structure that is used by a community-shared agriculture business to deliver food to its customers or shareholders is not, itself, a mobile food facility.

Comment 7: PASA reviewed the defined term “person in charge” at proposed § 46.3 and asked:

What if there is an unannounced inspection? Is the most “senior” “responsible” person on site at that moment deemed the person in charge? Can the employee/owner ask that the inspector return at another time?

Response: The Model Food Code requires (at § 2-101.11, relating to assignment) that the retail food facility operator be the person in charge or that he/she designate a person in charge and ensure that a person in charge is present at all hours of operation.

Inspections of retail food facilities and food establishments are (with few exceptions) *unannounced*. The inspecting entity does not designate who the person in charge is. It is the affirmative obligation of the licensee or operator of the facility to make this designation and to have a person in charge present at the establishment at all hours of operation.

The regulation requires that the person in charge allow access to the retail food facility and provide information and records to facilitate the inspection. This is tempered by the language in § 46.1101 (relating to access to retail food facilities), which requires that this cooperation be provided “... during the retail food facility’s hours of operation and other reasonable times if the facility is not open during normal business hours.”

In general, a refusal to allow an inspection would constitute a violation of § 46.1101 and would subject the facility to enforcement action such as a civil penalty, a criminal prosecution, an action for injunctive relief or some other action. There might be specific circumstances (such as a medical emergency or death) that might justify a licensor in refraining from such enforcement actions, though.

Comment 8: PASA offered comments with respect to the definition of the term “public water system” at proposed § 46.3. The commentator sought:

... clarification around such situations in which individuals or families might need to have water hauled in situations, be they temporary or permanent, where, for example, their water is not good because of other actions (contaminated wells come to mind).

Response: The proposed rulemaking reflects that the term “public water system” is proposed for deletion, as are all provisions that made use of that term. The regulatory standard at § 46.801 (relating to sources of drinking water) requires that water be from: (1) a public water system; or (2) a nonpublic water system that meets the Department of

Environmental Protection's (DEP's) regulatory standards for safe drinking water. Although the final-form regulation deletes this provision, it supplants it with § 5-101.11 (relating to approved system) of the Model Food Code, which imposes an identical requirement. In practice, the Department works with DEP on issues relating to the adequacy of water at retail food facilities and – in particular – defers to that agency on questions relating to whether a nonpublic water source is in compliance with applicable DEP regulatory safe water drinking standards.

Comment 9: IRRC noted that the definition of “raw agricultural commodity” at proposed § 46.3 repeats the definition of that term from the Food Safety Act (at 3 Pa.C.S.A. § 5722) but adds the phrase “or as otherwise defined in Section 5722 of the Food Safety Act.” IRRC asked the Department to either explain the reason why this phrase was included or delete it from the final-form regulation.

Response: The Department has deleted the referenced phrase from the final-form regulation.

Comment 10: PASA reviewed the defined term “ready-to-eat food” at proposed § 46.3 and noted:

... there is so much potential for odd interpretations here. One could read this with greens and such in mind – and, in some peoples' minds, the ... (*definition of “ready-to-eat food”*) ... could make washed veggies ready to eat as opposed to having undergone the basics of field dressing. That potentially opens up a whole bunch of interpretive options (like the difference between field processing including washing and those greens {and other products, be they vegetable or meat/raw animal foods} that are actually sold as ready to eat.....).
(*Clarification added*).

Response: The proposed rulemaking reflects that the term “ready-to-eat food” is proposed for deletion. The only use of that term in the final-form regulation is at § 46.4144(c)(3)(ii) (relating to license requirement). In context, the provision references a retail food facility that includes “ready-to-eat foods from a café, salad bar or hot food bar.” The Department believes that the context in which the term is used adds sufficient clarity.

In addition, the Model Food Code provides a more detailed definition of the term (at § 1-201.10).

The Department is satisfied it can differentiate among raw agricultural commodities, ready-to-eat foods and other types of foods. In general, if a raw fruit or vegetable is washed so that no further washing is needed before it is eaten by the consumer, it is a ready-to-eat food. An example of such a food might be bagged lettuce or bagged greens.

A raw fruit or vegetable is not a ready-to-eat food if it is field-washed and the consumer must wash the fruit or vegetable before eating it. An example of such a food might be a head of iceberg lettuce.

If a raw fruit or vegetable is processed by chopping, cutting or some similar treatment it is no longer a raw agricultural commodity. If such a processed food is not to be washed by the consumer before eating, it is a ready-to-eat food.

Comment 11: PASA reviewed proposed § 46.3 and offered several questions and comments relating to the definition of the term “sanitization.” The comment is as follows:

Please clarify the need for the different types of operations to actually do this testing in said operation. Consider in the response the situation in which individuals actually need to test surfaces before and after cleaning (as opposed to using the recommended cleaning and sanitizing procedures provided by, for example, the product label or another professional).

Is the five log reduction in bacterial load predicated on the type (genus, species or serotype, for example) of organism? Is there any leeway in the log reduction based on the relative risk of the particular/specific organism?

Is the department prepared to be more specific with respect to identifying those organisms which are defined below as “representative disease microorganisms of public health importance?”

Response: The proposed rulemaking reflects that the term “sanitization” is proposed for deletion. The final-form regulation deletes that definition and any use of the term throughout the final-form regulation.

The Model Food Code (at § 1-201.10) defines “sanitization” as it was defined in § 46.3. That definition has long been the standard in the food industry and is well known and widely accepted. Manufacturers of commercially-available sanitizers are aware of this long-standing sanitization definition, and sanitizing agents that are formulated for food safety applications are, when used in accordance with manufacturer’s instructions, capable of cleaning food contact surfaces to meet the standard of sanitization. Chemical sanitizers are evaluated and approved by the United States Environmental Protection Agency for efficacy and - when so approved - meet the referenced standard of sanitization.

The Department declines to prescribe different sanitization standards for different types of food production operations. Sanitized food contact surfaces help lower the risk of foodborne illness.

The Department’s answer to each of the questions posed in the last two paragraphs of the comment quoted above is “no.”

Comment 12: PASA reviewed proposed § 46.3 and asked for clarification with respect to the definition of the term “sewage.” Specifically, the commentator asked whether substances that are not currently considered “sewage” – such as spray wash off, wash water from floors and milk houses – will be deemed “sewage.”

Response: The proposed rulemaking reflects that the term “sewage” is proposed for deletion. The final-form regulation references the term at §§ 46.1121(b)(5) (relating to facility and operating plans) and 46.1144(5) (relating to conditions of

retention: responsibilities of the retail food facility operator). In context, these provisions require that a facility's operating plan describe how it will dispose of sewage and that a facility report a sewage backup or other unsanitary condition.

The Model Food Code (at § 1-201.10) defines "sewage" in rather broad terms, as consisting of "liquid waste containing animal or vegetable matter in suspension or solution" and as including "liquids containing chemicals in solution." The substances referenced by the commentator *are*, under this broad definition, "sewage."

Comment 13: PASA noted that the proposed regulation would rescind §§ 46.101 (relating to designation of person in charge) through 46.153 (relating to animals), and asked:

What will be put in the place of this material, in the sections labeled reserved?
Once those blanks have been filled, will there be a second comment period?

Response: No material will be put in the place of this material. There will be no second comment period, as that is not required under the Regulatory Review Act.

The rescinded provisions comprise Subchapter B of the regulation. That subchapter, which is titled *Management and Personnel*, addressed topics relating to supervision, employee health, personal cleanliness and hygienic practices. These same subjects are addressed in Chapter 2 of the Model Food Code, which is also titled *Management and Personnel* and which also addresses supervision, employee health, personal cleanliness and hygienic practices. Proposed § 46.4 (relating to adoption of Model Food Code) effectively makes these Model Food Code standards those of the Department. As related in more detail in the Response to Comment No. 30, though, the Department has revised the final-form regulation by incorporating the substance of proposed § 76.21 (relating to certification programs) into a new section - § 46.1201 (relating to Food Employee Certification Act compliance).

Comment 14: IRRC reviewed proposed Subsection 46.212(a) (relating to food prepared in a private home) and noted that it establishes general requirements for food prepared in private homes that is used or offered for human consumption in a retail food facility. IRRC also noted that Paragraph (a)(3) of that provision requires an organization that uses this home-prepared food to inform the consumer that the food was prepared in an unlicensed and uninspected private home. IRRC recommended the Department specify what kind of notice is necessary to properly inform consumers that the food was prepared in an unlicensed and uninspected private home.

Response: The Department has implemented IRRC's recommendation in the final-form regulation.

The new language that was proposed for Subsection 46.212(a) essentially restated statutory language from the Retail Food Facility Safety Act (at 3 Pa.C.S.A. § 5712). The Department has added language to the final-form regulation to require that consumers be informed through written means at the point of sale. This can be accomplished by a menu, a menu board, a separate sign or through labeling of individual products. In

addition, the final-form regulation provides examples of language that is adequate to meet the referenced statutory requirement.

Comment 15: Both IRRC and the PCC expressed concern that proposed subsection 46.212(b) might cause confusion among those who prepare food in their homes and seek to donate it to the various charitable organizations identified in Subsection (a). Both commentators offered essentially the same solution, recommending that the final-form regulation include language to clarify that Subsection (b) relates to foods prepared in private homes "except as otherwise permitted under Subsection (a)," or explain why such clarification is not necessary.

Response: The Department agrees with the commentators, and has added the recommended clarifying language in the final-form regulation.

Comment 16: PASA noted that the proposed regulation would rescind §§ 46.218 (relating to fish) through 46.1041 (relating to storage and display: separation of poisonous or toxic materials from food), and asked:

What will be put in the place of this material, in the sections labeled reserved? Once those blanks have been filled, will there be a second comment period?

Response: No material will be put in the place of this material. There will be no second comment period, as that is not required under the Regulatory Review Act. In summary, the subject matter of the rescinded provisions is addressed in the Model Food Code.

The rescinded provisions include portions of Subchapter C of the regulation. That subchapter, which is titled *Food*, addressed topics that are essentially the same as are addressed in Chapter 3 of the Model Food Code (which is also titled *Food*). Proposed § 46.4 effectively makes these Model Food Code standards those of the Department.

The rescinded provisions include Subchapter D of the regulation. That subchapter, which is titled *Equipment, Utensils and Linens*, addressed topics that are essentially the same as are addressed in Chapter 4 of the Model Food Code (which is also titled *Equipment, Utensils and Linens*). Proposed § 46.4 effectively makes these Model Food Code standards those of the Department.

The rescinded provisions include Subchapter E of the regulation. That subchapter, which is titled *Water, Plumbing and Waste Water*, addressed topics that are essentially the same as are addressed in Chapter 5 of the Model Food Code (which is titled *Water, Plumbing and Waste*). Proposed § 46.4 effectively makes these Model Food Code standards those of the Department.

The rescinded provisions include Subchapter F of the regulation. That subchapter, which is titled *Physical Facilities*, addressed topics that are essentially the same as are addressed in Chapter 6 of the Model Food Code (which is also titled *Physical Facilities*). Proposed § 46.4 effectively makes these Model Food Code standards those of the Department.

The rescinded provisions include Subchapter G of the regulation. That subchapter, which is titled *Poisonous or Toxic Materials*, addressed topics that are essentially the

same as are addressed in Chapter 7 of the Model Food Code (which is also titled *Poisonous or Toxic Materials*). Proposed § 46.4 effectively makes these Model Food Code standards those of the Department.

Comment 17: PASA reviewed proposed § 46.1101 (relating to access to retail food facilities) and asked what the rights of a farm owner, business owner or employee are in the event a licensor conducts an unannounced inspection of a retail food facility.

Response: If a business entity applies for and obtains a retail food facility license under the Retail Food Facility Safety Act, it has consented to the provisions of that statute that require and allow inspection, sampling and analysis by the licensor. The Retail Food Facility Safety Act requires an inspection before a license is issued (at 3 Pa.C.S.A. § 5703(e)(1)) and an inspection as a condition of license renewal (at 3 Pa.C.S.A. § 5703(g)(1)). It also requires that an inspector present credentials and inspect “at reasonable times, within reasonable limits and in a reasonable manner” (at 3 Pa.C.S.A. § 5704(a)).

Proposed § 46.1101 essentially restates the inspection language of the statute, and suggests that a retail food facility’s normal hours of operation are generally a reasonable time for inspections to be conducted.

Section 46.1101 has been in place for many years, and the proposed changes to that provision are not substantive. The Department has applied this provision consistently with respect to those retail food facilities it licenses. The Department believes licensees understand their obligation to allow inspections, and that the Department’s inspection staff makes an effort to inspect at reasonable times.

Comment 18: PASA reviewed proposed § 46.1103 (relating to variances), noted that certain portions of that section were not included in the proposed regulation as published (at 42 *Pennsylvania Bulletin* 5218, August 11, 2012), and asked that the Department “clarify and enhance the continuity” of that provision.

Response: The missing material was deleted after the Department submitted the proposed regulation for publication. The Department does not propose any changes to this material. The entire current regulation can be viewed on-line, at: <http://www.pacode.com/secure/data/007/chapter46/chap46toc.html>. The material that was not included under Subsection 46.1103(b) reads as follows:

- (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.

The material that was not included under Subsection 46.1103(c) reads as follows:

(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.

Comment 19: PASA asked several questions with respect to proposed § 46.1121 (relating to facility and operating plans):

What are the implications and responsibilities for review of plans if the ownership is changing, for example, within a family unit? What are the implications and responsibilities if the type/structure of ownership changes, for example, from a private holding to an LLC or other business model?

Response: Retail food facility licenses are location-specific and proprietor-specific. If either of these changes, a new license is required. Licenses are not transferrable.

If the *location* of a licensed retail food facility changes, the licensee (or license applicant) may file a new retail food facility license application with the Department.

If the *ownership* of a licensed retail food facility changes and there are no substantial changes to the physical layout of the facility, itself, a license application is required but the application review process is generally faster, since the Department does not need to conduct the same plan review it would conduct with respect to licensing a *new* or *remodeled* retail food facility.

In practice, it is not uncommon for a licensee who is a sole proprietor to incorporate his or her business, or to establish a partnership and bring in business partners, to transfer ownership to a family member or to sell the facility to a third party. Each of these events would trigger the need for a new license.

Comment 20: PASA asked the Department to clarify what proposed Paragraphs 46.1121(b)(2) through (b)(6) say.

Response: The missing material was deleted after the Department submitted the proposed regulation for publication. The Department does not propose any changes to this material. The entire current regulation can be viewed on-line, at: <http://www.pacode.com/secure/data/007/chapter46/chap46toc.html>. The referenced material reads as follows:

- (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).

Comment 21: PASA offered several comments with respect to proposed § 46.1122 (relating to HACCP plans). Initially, it presented the following:

There are large sections quoted below in which the material is proposed rescinded. What will be put in the place of this material, in the sections labeled reserved? Once those blanks have been filled, will there be a second comment period?

Response: The Department believes the commentator is referring to the proposed replacement of several references to sections of the proposed regulation (that the Department proposes to delete) with references to the Model Food Code. To that extent, the blanks in this provision are filled with references to the Model Food Code.

The Department's response to Comment No. 16, above, sets forth some general references to the subject matter addressed in the Model Food Code.

There will not be a second comment period with respect to the proposed regulation, as that is not required under the Regulatory Review Act.

Comment 22: With respect to proposed § 46.1122, PASA also asked whether "any and all situations require HACCP plans."

Response: HACCP plans are not required in any and all situations. HACCP plans are required if they are also required under Federal or State law or in order to obtain a variance as described in § 3-502.11 of the Model Food Code (relating to Variance requirement). That provision of the Model Food Code requires a variance in order for a food establishment to conduct any of a number of specialized processing methods. These specialized processing methods include smoking food, curing food, using food additives for certain purposes, packaging food using reduced oxygen packaging, operating a life-support tank to display molluscan shellfish, certain custom processing practices, sprouting seeds or beans, and more.

Comment 23: With respect to proposed § 46.1122, PASA also offered that: "... for some educators, consultants and providers, the language of the discipline has changed/is changing from HACCP to Hazard Analysis Preventive Controls" and asked: "What is the longer term (and short term) implication/s of this change in nomenclature?"

Response: The term "HACCP" or "Hazard Analysis Critical Control Point" is defined in § 1-201.10 of the Model Food Code and is used throughout that document. If there is ever a movement to change that terminology in the Model Food Code the Department would have ample notice and a chance to participate in the amendment process, and can consider whether the change to the Model Food Code warrants a change to the Department's regulation, as well.

The phrase "Hazard Analysis Preventive Controls" used by the commentator suggests that the phrase may have originated from separate FDA rules or proposed rules on "... Hazard Analysis and Risk-Based Preventive Controls for Human Food..." These rules would apply to food manufacturing plants and distributing establishments, and would not be applicable to retail food facilities.

Comment 24: PASA reviewed proposed § 46.1124 (relating to preoperational inspection of construction) and asked whether the preoperational inspections described in

that provision are "in addition to the building permit/local inspections." The commentator also asked whether there are fees associated with these inspections.

Response: The referenced preoperational inspections are separate and distinct from any inspection that a local government unit might require as a condition of the issuance of a building permit or conduct under some other local authority.

Where the licensor is *the Department*, there will be no fee for this type of inspection because the Retail Food Facility Safety Act does not authorize such a fee. The provision at 3 Pa.C.S.A. § 5703(j) addresses the Department's authority to impose fees.

Where the licensor is *an entity other than the Department*, that type of licensor has the authority to establish its own fee schedule, and might establish a fee schedule that imposes a fee for the type of preoperational inspection of construction described above.

Comment 25: IRRC raised several concerns regarding the clarity of proposed Subsection 46.1141(c) (relating to license requirement). It noted that proposed § 46.1141 establishes the license requirements necessary to operate as a retail food facility and that Subsection (c) establishes the intervals for license expiration for various types of retail food facilities.

With respect to Subsection (c), IRRC notes the 24 month, 18 month, 12 month and 6 month license intervals and asked the Department to explain how it determined that each of these timeframes represent the appropriate license expiration date for a retail food facility that meets these criteria.

With respect to Subsection (c), IRRC noted that subparagraph (1)(iii) provides that the intervals between license expirations can increase should a retail food facility demonstrate that it has achieved "active managerial control of foodborne illness risk factors ... " IRRC asked that the final-form regulation clarify what the Department considers appropriate "historical documentation" to validate that a retail food facility has achieved this level of control. IRRC noted that this same terminology is used in Subparagraphs (c)(2)(iii), (c)(3)(iii), and (c)(4)(iii).

Response: With respect to IRRC's inquiry as to the origin of the various license intervals and categories described in Subsection 46.1141(c) of the proposed regulation, the Department notes that the Retail Food Facility Safety Act (at 3 Pa.C.S.A. § 5703(g)(1)) allows the Department to establish retail food facility license intervals using risk-based factors identified in the Model Food Code.

The Department consulted Annex 5 (titled *Conducting Risk-Based Inspections*) of the Model Food Code in developing the risk-based license intervals presented in proposed § 46.1141. That Annex contains a table identified as Annex 5, Table 1 (titled *Risk Categorization of Food Establishments*). That table establishes four separate risk categories for retail food facilities. The proposed regulation essentially incorporates each of these four risk categories and establishes a different (and risk-based) license interval for each. The referenced table also recommends inspection frequency intervals of from one to four inspections each year, based upon the risk category involved. Although the Department does not have the resources to inspect on this frequent an inspection schedule, the proposed regulation uses the same inspection interval ratios presented in that table: namely, that those retail food facilities that present the *highest* risk of

spreading foodborne illness should be inspected four times as often as those retail food facilities that present the *lowest* risk of spreading foodborne illness.

Annex 5 of the Model Food Code also recommends the Voluntary National Retail Food Regulatory Program (“VNRFRP”) Standards established by the United States Food and Drug Administration as a source of additional recommendations with respect to establishing risk-based inspection programs for retail food facilities. The VNRFRP Standards are part of a national initiative to promote application of effective food safety strategies that are based on risk factors and to promote uniformity among retail food facility regulatory programs. These standards were developed with input from federal, State and local regulatory officials, the food industry, food-related trade associations, academia and consumers, and provide common standards by which participating retail food facility regulatory programs can assess their programs. The Department has been a participating jurisdiction with respect to the VNRFRP Standards since 2004 and, as part of that participation, has completed a self-assessment of its retail food facility regulatory program.

The VNRFRP Standards consist of nine separate standards. Of these, Standard No. 3, titled *Inspection Based on HACCP Principles*, recommends that inspection frequency be based on the relative risk posed by a retail food facility and recommends the establishment of at least three categories of retail food facilities based on potential and inherent food safety risks. This allows inspection staff to spend more time in those higher-risk establishments that pose the greatest potential of causing foodborne illness. Standard No. 3 also allows regulatory jurisdictions to consider available resources (such as personnel and funding) in establishing inspection frequencies.

The Department considered its existing staffing levels and its experience in allocating manpower to meet the current annual inspection requirement for retail food facilities. Under the proposed regulation most retail food facilities will continue to be subject to this yearly inspection requirement, but the Department’s inspection resources can be better-focused on those retail food facilities that present the greatest risk of spreading foodborne illness.

In summary, the *categories* of retail food facilities described in proposed paragraphs 46.1141(c)(1) – (4) are essentially as recommended in Annex 5 of the Model Food Code and are consistent with the VNRFRP Standards. The *license intervals* establish an inspection timetable that can be met with current Department and/or local licensor inspection staff and that directs inspection resources toward those retail food facilities that present the greatest risk of causing foodborne illness.

With respect to the second portion of IRRC’s comment the Department has revised the referenced provisions to make clear that the “historical documentation” that is necessary to demonstrate the active managerial control of foodborne illness risk factors justifying a longer license interval shall consist of: (1) at least three regular inspections at the established risk-based interval that reflect the retail food facility is “in compliance” overall; (2) an absence of consumer complaints that prove valid; and (3) an absence of reported foodborne illnesses associated with the facility.

Comment 26: With respect to proposed § 46.1141, PASA asked for clarification of whether a farmers’ market *and* all individual farmers selling from that market must be licensed. PASA also adds:

Here – as well as in other portions of this (and other documents) - it seems appropriate and clear to substitute the phrase "compliant at a scale and risk appropriate level" rather than using the word "exemption." Please comment.

Response: Proposed Subsection 46.1141(b) repeats the full range of circumstances under which a retail food facility might be exempt from licensure under the Retail Food Facility Safety Act (at 3 Pa.C.S.A. § 5703(b)).

A typical farmers' market is not a *single* "retail food facility" in that it does not have a single proprietor that owns and operates all of the retail food facilities located in the market. It is usually a centralized gathering of *multiple* retail food facilities – each with its own proprietor (similar to a gathering of food vendors at a fair or other event). In this case each farmers' market stand is a discrete retail food facility. Depending on the type of food operation conducted in the facility, the facility may-or-may-not be exempt from the licensure requirement imposed by the Retail Food Facility Safety Act. This type of determination will be fact-driven.

With respect to the commentator's suggestion that the regulation should reference that a facility is compliant "at a scale and risk appropriate level," the Department maintains it is appropriate to continue to use the terms "exempt" and "exemptions" in proposed § 46.1141. The Retail Food Facility Safety Act describes the circumstances under which a retail food facility is "exempt" from the license requirements (but not the inspection requirements) of that statute. These are set forth at 3 Pa.C.S.A. § 5703(b), which describes them as exemptions. Although the Retail Food Facility Safety Act affords a licensor some leeway to determine appropriate maximum license intervals based upon certain risk-based factors (see 3 Pa.C.S.A. § 5703(g)(1)), it does not allow the scale of a retail food facility's operation or the risk level posed by that facility to determine whether a facility is exempt from licensure.

Comment 27: PASA reviewed proposed § 46.1143 (relating to issuance) and noted that certain portions of that section were not included in the proposed regulation as published (at 42 *Pennsylvania Bulletin* 5218, August 11, 2012), and asked that the Department "clarify and enhance the continuity" of that provision.

PASA also asked for clarification of the need for a new license when there is a change in ownership of the license retail food facility. PASA specifically asked that the response include consideration of such events as "changes within the family, changes in business structure and category."

Response: The missing material was deleted after the Department submitted the proposed regulation for publication. The Department does not propose any changes to this material. The entire current regulation can be viewed on-line, at: <http://www.pacode.com/secure/data/007/chapter46/chap46toc.html>. The material that was not included under Subsection 46.1143(a) reads as follows:

- (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.

With respect to the commentator’s request for clarification of the circumstances under which a new license would be required, the Department’s response to Comment No. 19, above, is responsive.

Comment 28: IRRC noted that proposed § 46.1144(4) (relating to conditions of retention: responsibilities of the retail food facility operator) references a specific subpart of the Model Food Code, but that other provisions in the proposed regulation contain more general references to the Model Food Code. IRRC referenced proposed §§ 46.3, 46.1121(b)(1), 46.1122, 46.1122(a)(2), 46.1141(c) and 46.1141(c)(iii) as examples. IRRC recommends that the final-form regulation include specific cross-references to the Model Food Code, or that the Department explain why such references are not appropriate.

Response: IRRC’s recommendation has been implemented in the final-form regulation.

Throughout the final-form regulation the Department has – where appropriate – changed *general* references to the Model Food Code to *specific* references to the applicable subpart of the Model Food Code. Specifically, the sections of the final-form regulation that have been revised, and the references to the appropriate subparts of the Model Food Code, are as follows:

<i>Section</i>	<i>New Model Food Code Reference</i>
46.3	Subpart 1-201 (titled <i>Applicability and Terms Defined</i>)
46.1121(b)(1)	Subpart 3-603 (titled <i>Consumer Advisory</i>)
46.1122(a)(1)(ii)	Subpart 8-201 (titled <i>Facility and Operating Plans</i>)
46.1122(a)(2)	Subpart 3-502 (titled <i>Specialized Processing Methods</i>)
46.1141(c)	Subpart 8-401 (titled <i>Frequency</i>) and Annex 5 (titled <i>Conducting Risk-Based Inspections</i>)
46.1122(c)(1)(iii)	Subpart 8-401 (titled <i>Frequency</i>)

Although the basic subject matter of a subpart of the Model Food Code does not change, individual sections or subsections are occasionally revised by the United States Food and Drug Administration. For this reason the final-form regulation does not reference exact sections of the Model Food Code but, instead, the subpart in which that section is located.

Comment 29: With respect to proposed § 76.20 (relating to definitions), IRRC recommended that: (1) the phrase “unless otherwise defined in Chapter 46 (relating to food code)” be deleted; and (2) the definition of the term “Department” in that section

“include the same language pertaining to the Model Food Code as that contained in Section 46.3.”

Response: The Department agrees with the commentator and has made the recommended changes in the final-form regulation, or has revised the final-form regulation to effectively accomplish IRRC’s recommendations. As explained in response to Comment No. 30, below, these changes appear in § 46.1201 (relating to Food Employee Certification Act compliance).

Comment 30: PASA noted that the proposed regulation would rescind §§ 76.1 (relating to compliance) through 76.19 (relating to civil penalties), and asked:

What will be put in the place of this material, in the sections labeled reserved? Once those blanks have been filled, will there be a second comment period? Please explain why the collection of these “odd definitions” are presented in this portion of the document rather than in the prodromal section with the remainder of the definitions.

Response: No material will be put in the place of the rescinded material. There will be no second comment period, as that is not required under the Regulatory Review Act.

The Food Employee Certification Act is the underlying statutory authority for Chapter 76 (relating to food employee certification). Act 106 of 2010 accomplished a significant and substantive revision of that statute, and had the effect of simplifying and streamlining the process by which a retail food facility shall have at least one employee who holds a current certificate evidencing successful completion of an accredited food safety training course. Much of the statute is self-executing, without the need for detailed supporting regulations. The proposed regulation does nothing more than implement the changes to the Food Employee Certification Act wrought by Act 106 of 2010.

With respect to the comment regarding the placement of proposed § 76.20 (relating to definitions) as a separate section, the Department agrees that the requirements of the Food Employee Certification Act are so intertwined with the subject matter of Chapter 46 (relating to food code) that the regulation will be more user-friendly if the substance of proposed Chapter 76 is incorporated into Chapter 46. The Department has revised the final-form regulation by: (1) incorporating the relevant definitions that appeared in proposed § 76.20 into § 46.3; and (2) incorporating the substance of proposed § 76.21 (relating to certification programs) into a new section - § 46.1201 (relating to Food Employee Certification Act compliance).

Affected Individuals and Organizations

The final-form regulation will 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 final-form 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 regulation will 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 regulation will 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 regulation will 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 regulation 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 regulation will 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 final-form 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 final-form regulation will be effective one month following the date of publication in the *Pennsylvania Bulletin*.

Contact Person

Individuals who need information about the final-form regulation should contact the Pennsylvania Department of Agriculture, Bureau of Food Safety and Laboratory Services, 2301 North Cameron Street, Harrisburg, PA 17110-9408, Attention: Sheri Morris.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on August 1, 2012, the Department submitted a copy of the notice of proposed rulemaking, published at 42 Pa.B. 5218, to the IRRC and the Chairpersons of the House and Senate Standing Committees on Agriculture and Rural Affairs for review and comment.

Under section 5(c) of the Regulatory Review Act, the Department provided IRRC and the referenced Committees with copies of all comments received during the public comment period.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on _____, 2010, the final-form regulation was _____ approved by the House Committee and on _____, 2010, the final-form regulation was _____ approved by the Senate Committee. Under section 5.1(g) of the Regulatory Review Act, the final-form regulation was approved by IRRC on November 6, 2008.

Findings

The Department finds that:

- (1) Public notice of intention to adopt this final-form regulation has been given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.
- (2) A public comment period was provided as required by law; and all comments that were received were considered.
- (3) The modifications that were made to this regulation in response to comments received do not enlarge the purpose of the proposed regulation published at 42 *Pennsylvania Bulletin* 5218 (August 11, 2012).
- (4) The adoption of the final-form regulation in the manner provided in this order is necessary and appropriate for the administration of the authorizing statute.

Order

The Department, acting under the authorizing statute, orders the following:

(1) The current regulations of the Department of Agriculture at 7 Pa. Code Chapter 46 (relating to Food Code) and 7 Pa. Code Chapter 76 (relating to food employee certification) are hereby amended to read as set forth in Annex "A."

(2) The Secretary of Agriculture shall submit this order, 42 Pa.B. 5218 and Annex "A" to the Office of General Counsel and the Office of Attorney General for approval as required by law.

(3) The Secretary of Agriculture shall certify and deposit this order, 42 Pa.B. 5218 and Annex "A" with the Legislative Reference Bureau as required by law.

(4) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

GEORGE D. GREIG, *Secretary*

Annex A

TITLE 7. AGRICULTURE.

PART III. BUREAU OF FOOD SAFETY AND LABORATORY SERVICES

Subpart A. SOLID FOODS

CHAPTER 46. FOOD CODE

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

§ 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, which the Secretary, by regulation, determines are used, or are intended to be used, solely for a purpose 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 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.]

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.

[*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 SUBPART 1-201 OF the Model Food Code (RELATING TO APPLICABILITY AND TERMS DEFINED).

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 EMPLOYEE CERTIFICATION ACT – THE FOOD EMPLOYEE
CERTIFICATION ACT (3 PA.C.S. §§ 6501 – 6510).

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
SUBPART 1-201 OF 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. §§ 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 SUBPART 1-201 OF 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 SUBPART 1-201 OF the Model Food Code.

Licensors--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] 660g).

*[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 that is 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 in this Commonwealth. The term is synonymous with the term "person" in SUBPART 1-201 OF 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 fruits which are washed, colored or otherwise treated in their unpeeled, natural form prior to

marketing, or as otherwise defined in section 5722 of the Food Safety Act (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]

(i) 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.

(ii) 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 SUBPART 1-201 OF 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 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) This chapter.

Subchapter B. [MANAGEMENT AND PERSONNEL] (Reserved)

Subchapter C. FOOD

[CHARACTERISTICS]

§ 46.201. [Food shall be safe, unadulterated and honestly presented.] (Reserved).

[Food shall be safe, unadulterated and - in accordance with § 46.421(b) (relating to accurate representation) – honestly presented.]

FOOD SOURCES

§ 46.211. [Food sources.] (Reserved).

[Food shall be obtained from sources that comply with the Food Act, the Public Eating and Drinking Places Law and this chapter. Records of food sources shall be maintained and made available for review upon request by the Department.]

§ 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 the following apply:~~

~~(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 (26 U.S.C.A. § 501(c)(3)).~~

~~(ii) A volunteer fire company or ambulance, religious, charitable, fraternal, veterans, civic, sportsmen, agricultural fair or agricultural association or a separately chartered auxiliary of an association on a nonprofit 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 nonprofit 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. FOOD PREPARED IN A PRIVATE HOME MAY NOT BE~~

~~USED OR OFFERED FOR HUMAN CONSUMPTION IN A RETAIL FOOD~~

FACILITY UNLESS THAT PRIVATE HOME MEETS THE REQUIREMENTS OF SUBSECTION (B) OR (C).

(B) *PRIVATE HOME THAT IS A REGISTERED FOOD ESTABLISHMENT.* FOOD PREPARED IN A PRIVATE HOME MAY BE USED OR OFFERED FOR HUMAN CONSUMPTION IN A RETAIL FOOD FACILITY IF THE PRIVATE HOME FROM WHICH THE FOOD ORIGINATES IS REGISTERED WITH THE DEPARTMENT AS A FOOD ESTABLISHMENT UNDER THE FOOD SAFETY ACT.

(C) *PRIVATE HOME THAT IS EXEMPT FROM LICENSURE OR INSPECTION UNDER THE RETAIL FOOD FACILITY SAFETY ACT.* FOOD PREPARED IN A PRIVATE HOME MAY BE USED OR OFFERED FOR HUMAN CONSUMPTION IN A RETAIL FOOD FACILITY IF THE FOLLOWING APPLY:

(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 (26 U.S.C.A. § 501(C)(3)).

(II) A VOLUNTEER FIRE COMPANY OR AMBULANCE, RELIGIOUS, CHARITABLE, FRATERNAL, VETERANS, CIVIC, SPORTSMEN, AGRICULTURAL FAIR OR AGRICULTURAL ASSOCIATION OR A SEPARATELY CHARTERED AUXILIARY OF AN ASSOCIATION ON A NONPROFIT 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 NONPROFIT 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.

(I) ACCEPTABLE MEANS OF PROVIDING WRITTEN NOTICE INCLUDE PROVIDING THAT NOTICE ON A MENU, A MENU BOARD, SEPARATE SIGNAGE POSTED IN A LOCATION THAT IS CONSPICUOUS FOR CONSUMERS TO VIEW, OR ON INDIVIDUAL FOOD PRODUCT LABELS.

(II) THE WRITTEN NOTICE SHALL CLEARLY COMMUNICATE THAT THE FOOD HAS BEEN PREPARED IN A PRIVATE HOME THAT IS NOT LICENSED OR INSPECTED. PHRASES SUCH AS "THESE BAKED GOODS ORIGINATE FROM PRIVATE HOMES THAT ARE NOT GOVERNMENT-LICENSED OR GOVERNMENT-INSPECTED," OR "THE FOOD OFFERED ON THIS TABLE COMES FROM PRIVATE HOMES THAT ARE NOT LICENSED OR INSPECTED," OR "FOOD OFFERED IN THIS BAKE SALE HAS BEEN PREPARED IN PRIVATE HOMES THAT ARE NOT LICENSED OR INSPECTED" MEET THIS REQUIREMENT. PERSONS MAY SUBMIT PROPOSED WRITTEN NOTICE LANGUAGE TO THE DEPARTMENT OR OTHER LICENSOR (AS APPLICABLE) FOR REVIEW.

(4) THE FOOD IS DONATED TO AN ORGANIZATION DESCRIBED UNDER

PARAGRAPH (2).

§ 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 - § 46.461. (Reserved).

Subchapter D. [EQUIPMENT, UTENSILS AND LINENS] (Reserved).

§ 46.501 – § 46.775. (Reserved).

Subchapter E. [WATER, PLUMBING AND WASTE WATER] (Reserved).

§ 46.801 - § 46.886. (Reserved).

Subchapter F. [PHYSICAL FACILITIES] (Reserved).

§ 46.901 - § 46.982. (Reserved).

Subchapter G. POISONOUS OR TOXIC MATERIALS (Reserved)

§ 46.1001 - § 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.

* * * * *

(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

* * * * *

(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:

* * * * *

(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:

* * * * *

(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:

* * * * *

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] SUBPART 3-603 OF the Model Food Code (RELATING TO CONSUMER ADVISORY) for animal foods that are raw, undercooked or not otherwise processed to eliminate pathogens[]].

* * * * *

(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 [a] an HACCP plan is required.*

(1) Before engaging in an activity that requires [a] 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 [a] 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)] SUBPART 8-201 OF the Model Food Code (RELATING TO FACILITY AND OPERATING PLANS).

* * * * *

(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)]

SUBPART 3-502 OF the Model Food Code (RELATING TO SPECIALIZED PROCESSING METHODS) for reduced oxygen packaging.

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

* * * * *

§ 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.*

(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. § 20.14).

(2) *Exemptions.* 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 the Retail Food Facility Safety Act:

(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]

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

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

(3) 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 section 5703(b)(1) of the Retail Food Facility Safety Act (relating to license required) if the licensor is the Department.

(4) 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 section 5703(b)(1) of the Retail Food Facility Safety Act if the licensor is an entity other than the Department.

(c) License interval. A license certificate issued by the Department under this chapter sets forth the license expiration date. The license interval varies, in accordance with the risk-based factors identified in SUBPART 8-401 OF the Model Food Code (RELATING TO FREQUENCY) AND ANNEX 5 OF THE MODEL FOOD CODE (RELATING TO CONDUCTING RISK-BASED INSPECTIONS, as follows:

(1) 24-month license interval.

(i) The license interval is 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 (time/temperature Control for Safety Foods (TCS foods)) for hot holding.

(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 in subparagraph (i) are convenience store operations, hot dog carts, and coffee shops.

(iii) The license interval for a retail food facility is 24 months if the retail food facility would otherwise be subject to the 18-month license interval 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 SUBPART 8-401 OF 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.

ACTIVE MANAGERIAL CONTROL IS ACHIEVED AND DOCUMENTED
WHEN THE CONDITIONS DESCRIBED IN SUBSECTION (D) ARE
ACHIEVED BY THE LICENSEE.

(2) 18-month license interval.

(i) The license interval is 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.

(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 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 ~~area~~ 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 is 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 THE foodborne illness risk factors PRESENTED 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 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 THE foodborne illness risk factors PRESENTED in paragraph (1). ACTIVE MANAGERIAL CONTROL IS ACHIEVED AND DOCUMENTED WHEN THE CONDITIONS DESCRIBED IN SUBSECTION (D) ARE ACHIEVED BY THE LICENSEE.

(3) 12-month license interval.

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

(A) Has an extensive menu and THAT entails handling of raw ingredients.

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

(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 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 area AREAS) that includes INCLUDE ready-to-eat foods from a café, salad bar or hot food bar.

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

(iv) The license interval for a retail food facility is 12 months if the retail food facility would otherwise be subject to the 18-month license interval 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 THE foodborne illness risk factors PRESENTED in paragraph (1). ACTIVE MANAGERIAL CONTROL IS ACHIEVED AND DOCUMENTED WHEN THE CONDITIONS DESCRIBED IN SUBSECTION (D) ARE ACHIEVED BY THE LICENSEE.

(4) 6-month license interval.

(i) The license interval is 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 in subparagraph (i) are preschools, hospitals, nursing homes and establishments conducting processing at retail.

(iii) The license interval for a retail food facility is 6 months if the retail food facility would otherwise be subject to the 12-month license interval 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 THE foodborne illness risk factors PRESENTED in paragraph (1). ACTIVE MANAGERIAL CONTROL IS ACHIEVED AND DOCUMENTED WHEN THE CONDITIONS DESCRIBED IN SUBSECTION (D) ARE ACHIEVED BY THE LICENSEE.

(D) ACHIEVING AND DOCUMENTING ACTIVE MANAGERIAL CONTROL.

ACTIVE MANAGERIAL CONTROL IS ACHIEVED AND DOCUMENTED WHEN ALL OF THE FOLLOWING CONDITIONS ARE MET:

(1) THE PREVIOUS THREE INSPECTIONS OF THE RETAIL FOOD FACILITY, CONDUCTED AT THE APPROPRIATE RISK-BASED LICENSING INSPECTION INTERVAL AS DESCRIBED IN SUBSECTION (C), DOCUMENT THROUGH THE LICENSEE'S INSPECTION REPORTS THAT:

(I) THE RETAIL FOOD FACILITY WAS IN OVERALL COMPLIANCE.

(II) AMONG THOSE THREE INSPECTION REPORTS THERE HAVE BEEN NO REPEATS OF PREVIOUSLY-IDENTIFIED RISK-FACTOR VIOLATIONS.

(III) IF A HACCP PLAN IS REQUIRED UNDER § 46.1122 (RELATING TO HACCP PLANS), THERE HAVE BEEN NO VIOLATIONS OF THAT HACCP PLAN.

(2) WITHIN THE PREVIOUS THREE INSPECTIONS OF THE RETAIL FOOD FACILITY, CONDUCTED AT THE APPROPRIATE RISK-BASED LICENSING INSPECTION INTERVAL AS DESCRIBED IN SUBSECTION (C), THERE HAVE BEEN NO FOUNDED CONSUMER COMPLAINTS RELATING TO FOOD SAFETY.

(3) WITHIN THE PREVIOUS THREE INSPECTIONS OF THE RETAIL FOOD FACILITY, CONDUCTED AT THE APPROPRIATE RISK-BASED LICENSING INSPECTION INTERVAL AS DESCRIBED IN SUBSECTION (C), THERE HAVE BEEN NO REPORTED AND CONFIRMED INCIDENTS OF FOODBORNE ILLNESS ASSOCIATED WITH THE FACILITY.

(4) THE RETAIL FOOD FACILITY IS IN COMPLIANCE WITH THE FOOD EMPLOYEE CERTIFICATION ACT.

(5) THE RETAIL FOOD FACILITY HAS WRITTEN PROCEDURES THAT – AT A MINIMUM – ADDRESS ALL RISK FACTORS, IF THE FACILITY DOES ONE OR MORE OF THE FOLLOWING:

(I) SERVES LARGE NUMBERS OF PEOPLE AND/OR PREPARES FOOD A DAY IN ADVANCE, SUCH AS A RETAIL FOOD FACILITY AT A SPORTS STADIUM, ENTERTAINMENT COMPLEX, CONFERENCE CENTER, BANQUET HALL OR OFF-SITE CATERING FACILITY.

(II) SERVES TRANSIENT GROUPS OF PEOPLE, SUCH AS A MOBILE RETAIL FOOD FACILITY OR TEMPORARY FOOD FACILITY AT A FAIR OR EVENT.

(III) SERVES CONSUMERS WHICH ARE A HIGHLY SUSCEPTIBLE POPULATION, SUCH AS A PRESCHOOL, NURSING HOME OR HOSPITAL.

§ 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 with 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:

* * * * *

(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.

* * * * *

(3) If a retail food facility is required in § 46.1122(a) (relating to HACCP plans) to operate under [a] 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).

* * * * *

(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.

(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)] (10) 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.

(11) Remit a fee owed the Department under section 5703(j) of the Retail Food Facility Safety Act (relating to license required) within the time prescribed by the Department.

(12) Remit a 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 either of the following:

(i) The effective date of the final adjudication assessing the civil penalty.

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

SUBCHAPTER I. FOOD EMPLOYEE CERTIFICATION ACT COMPLIANCE

§ 46.1201. FOOD EMPLOYEE CERTIFICATION ACT COMPLIANCE.

(A) *STATUTORY REQUIREMENT.* THE FOOD EMPLOYEE CERTIFICATION ACT REQUIRES THAT A RETAIL FOOD FACILITY HAVE AT LEAST ONE EMPLOYEE WHO HOLDS A VALID CERTIFICATE PRESENT AT THE RETAIL FOOD FACILITY OR IMMEDIATELY ACCESSIBLE AT ALL HOURS OF

OPERATION AND WHO IS THE PERSON IN CHARGE OF THE RETAIL FOOD FACILITY WHEN PHYSICALLY PRESENT AND ON DUTY.

(B) *GENERAL RECOGNITION OF CERTIFICATION PROGRAMS.* FOR PURPOSES OF COMPLIANCE WITH THE FOOD EMPLOYEE CERTIFICATION 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. A CERTIFICATE OF COMPLETION OF SUCH A PROGRAM IS "CERTIFICATE" FOR PURPOSES OF THE REQUIREMENT REFERENCED IN SUBSECTION (A) AND IS ADEQUATE PROOF OF COMPLIANCE.

(C) *POSTING OF CERTIFICATE.* A RETAIL FOOD FACILITY SHALL POST THE ORIGINAL CERTIFICATE OF ITS CERTIFIED EMPLOYEE IN PUBLIC VIEW AT ITS BUSINESS LOCATION.

(D) *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 WHEN THE LIST IS REVISED.

(2) POST THE CURRENT LIST ON ITS AGENCY WEBSITE:

WWW.AGRICULTURE.STATE.PA.US.

(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

Subpart C. MISCELLANEOUS PROVISIONS

CHAPTER 76. ~~FOOD EMPLOYEE CERTIFICATION (RESERVED).~~

§ 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—The Food Employee Certification Act (3 Pa.C.S. §§ 6501—6510).

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 3 Pa.C.S. § 5702 (relating to definitions).

§ 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 when the list is revised.

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

(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

Department of Agriculture
Notice of Final Rulemaking
7 Pa. Code Chapters 46 and 76
Food Code; Food Employee Certification
I.D. No. 2-174

List of Commentators who Requested Additional Information
and a Copy of the Final-Form Regulation

The following persons offered comments with respect to the proposed rulemaking in the above matter, and requested additional information and a copy of the final-form regulation:

1. *Commentator:* Pennsylvania Association for Sustainable Agriculture

Contact Name and Address:

Susan Beal, DVM
Agricultural Science Advisor
Pennsylvania Association for Sustainable Agriculture
PO Box 419, Millheim, PA 16854

2. *Commentator:* Pennsylvania Catholic Conference

Contact Name and Address:

Ball, Murren & O'Connell
Thomas A Capper, Esq.
2303 Market Street
Camp Hill, PA 17011

PROPOSED RULEMAKING

DEPARTMENT OF AGRICULTURE

[7 PA. CODE CHS. 46 AND 76]

Food Code; Food Employee Certification

The Department of Agriculture (Department) proposes to amend Chapters 46 and 76 (relating to food code; and food employee certification) to read as set forth in Annex A.

Statutory Authority

Sections 5701—5714 of 3 Pa.C.S. (relating to Retail Food Facility Safety Act), 3 Pa.C.S. §§ 5721—5737 (relating to Food Safety Act), the act of July 2, 1935 (P. L. 589, No. 210) (31 P. S. §§ 645—660g), known as the Milk Sanitation Law, section 1705(d) of The Administrative Code of 1929 (71 P. S. § 445(d)) and 3 Pa.C.S. §§ 6501—6510 (relating to Food Employee Certification Act) provide the legal authority for this proposed rulemaking.

The Retail Food Facility Safety Act charges the Department with responsibilities regarding the licensure, inspection, cleanliness and sanitation of “retail food facilities” (such as restaurants) in this Commonwealth. This includes the responsibility to promulgate regulations necessary to implement the Retail Food Facility Safety Act 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” (see 3 Pa.C.S. § 5707(a) (relating to powers of department)) (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 1 year, but requires that these license intervals be established by regulation and that the regulations 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 (see 3 Pa.C.S. § 5734(a) (relating to registration of food establishments)); (2) promulgate regulations and food safety standards necessary to the proper enforcement of the food safety requirements in the Food Safety Act (see 3 Pa.C.S. § 5733(a) (relating to rules and regulations)); and (3) construe the Food Safety Act and its attendant regulations in a manner that is as consistent with Federal statutory and regulatory authority as practicable (see 3 Pa.C.S. § 5736 (relating to construction of subchapter)).

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 the Milk Sanitation Law. (See section 19 of the Milk Sanitation Law (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 (see 3 Pa.C.S. § 6504(a) (relating to certification of employees)) and authorizes the Department to promulgate regulations necessary for the proper enforcement of the Food Employee Certification Act (see 3 Pa.C.S. § 6505 (relating to rules and regulations)).

Purpose

The act of November 23, 2010 (P. L. 1039, No. 106) (Act 106) accomplished a significant overhaul of the food-related statutes administered and enforced by the Department. It repealed the Public Eating and Drinking Places Law and the Food Act and supplanted these statutes 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 the statutes they replaced, there are also a number of changes that necessitate this proposed rulemaking.

The proposed rulemaking seeks to: (1) adopt the terminology and implement the changes necessitated or authorized by Act 106; (2) incorporate, to the extent practicable, the standards and requirements of the Model Food Code as the food safety standards and requirements for this Commonwealth; (3) establish retail food facility license intervals of greater than 1 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 in Chapter 76 to reflect changes produced by Act 106.

Background

The Model Food Code is the product of a collaborative effort among the Department, the United States Food and Drug Administration, the United States Department of Agriculture 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 regulations in 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 (see 3 Pa.C.S. § 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, which revised or replaced a number of the food-related statutes as previously described.

Need for the Proposed Rulemaking

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

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 in this proposed rulemaking 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 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 also made significant revisions to the Food Employee Certification Act. The proposed rulemaking is needed to implement these changes.

The Department is satisfied there are no reasonable alternatives to proceeding with the proposed rulemaking.

Overview of the Major Provisions of the Proposed Rulemaking

Proposed amendments to § 46.3 (relating to definitions) delete a number of terms that are defined in the Model Food Code to maintain a common vocabulary of food safety terminology. When 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 rulemaking 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 Chapter 46.

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

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

The list of the types of retail food facilities that are exempt from licensure under the Retail Food Facility Safety Act are proposed to be amended in § 46.1141 (relating to license requirement) to reflect that 3 Pa.C.S. § 5703(b) (relating to license required) 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 published an order at 41 Pa.B. 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 it might cause confusion in those jurisdictions where the licensor is an entity other than the Department.

Proposed amendments to § 46.1141(c) establish retail food facility license intervals based on risk-based factors identified in the Model Food Code as authorized under section 5703(g) of the Retail Food Facility Safety Act.

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 3 Pa.C.S. § 6503(c) (relating to certification programs) that the Department recognize certain certification programs as adequate for purposes of meeting the requirements of the Food Employee Certification Act. It would also require the Department to maintain, post on the Department's web site and readily provide copies of that list of acceptable certification programs.

Affected Individuals and Organizations

The proposed rulemaking would impact 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 proposed rulemaking. Fewer foodborne illness incidents will benefit owners, operators and 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 rulemaking would bring the Commonwealth'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, web sites, forms and the electronic licensing system, the proposed rulemaking would not impose costs or have 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 rulemaking would not appreciably expand or alter the Department's role in administering and enforcing these underlying statutes.

Political subdivisions. The proposed rulemaking would not impose costs or have 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 requirements 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. Chapter 46 embodies many of the provisions of the Model Food Code. 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 this Commonwealth. This should result in some indeterminate cost savings to the general public.

Paperwork Requirements

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

Effective Date

The proposed rulemaking will be effective 1 month following final-form publication in the *Pennsylvania Bulletin*.

Sunset Date

There is not a sunset date for the proposed rulemaking. The Department will review the efficacy of these regulations on an ongoing basis.

Public Comment Period / Contact Person

Interested persons are invited to submit written comments regarding the proposed rulemaking within 30 days following publication in the *Pennsylvania Bulletin*. Comments should 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

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on August 1, 2012, the Department submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House and Senate Standing Committees on Agriculture and Rural Affairs. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Department, the General Assembly and the Governor of comments, recommendations or objections raised.

GEORGE D. GREIG,
Secretary

Fiscal Note: 2-174. (1) General Fund; (2) Implementing Year 2011-12 is \$5,000; (3) 1st Succeeding Year 2012-13 is \$0; 2nd Succeeding Year 2013-14 is \$0; 3rd Succeeding Year 2014-15 is \$0; 4th Succeeding Year 2015-16 is \$0; 5th Succeeding Year 2016-17 is \$0; (4) 2010-11 Program—\$1,835,780; 2009-10 Program—\$1,341,812; 2008-09 Program—\$1,088,400; (7) General Government Operations—Bureau of Food Safety; (8) recommends adoption.

Annex A

TITLE 7. AGRICULTURE

PART III. BUREAU OF FOOD SAFETY AND LABORATORY SERVICES

Subpart A. SOLID FOODS

CHAPTER 46. FOOD CODE

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

§ 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, which the Secretary, by regulation, determines are used, or are intended to be used, solely for a purpose 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 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 con-

nection 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. §§ 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 holds a current license. The term is synonymous with the term "permit holder" in the Model Food Code.

Licensors—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] 660g).

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 that is operated and used for 5 consecutive days or more 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 in 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 fruits which are washed, colored or otherwise treated in their unpeeled, natural form prior to marketing, or as otherwise defined in section 5722 of the Food Safety Act (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 § 46.42 (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]

(i) 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.

(ii) 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. §§ 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.]

(Editor's Note: The following section is new and printed in regular type to enhance readability.)

§ 46.4. Adoption of Model Food Code.

The provisions, terms, procedures, appendices and standards 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) This chapter.

Subchapter B. [MANAGEMENT AND PERSONNEL]
 (Reserved)

(Editor's Note: As part of this proposed rulemaking, the Department is proposing to rescind Subchapter B which appears in 7 Pa. Code pages 46-17—46-28, serial pages (356767), (356768) and (301595)—(301604).)

- Sec.
 46.101. (Reserved).
 46.102. (Reserved).
 46.111—46.115. (Reserved).
 46.131—46.137. (Reserved).
 46.151—46.153. (Reserved).

Subchapter C. FOOD
 [CHARACTERISTICS]

§ 46.201. [Food shall be safe, unadulterated and honestly presented] (Reserved).

[Food shall be safe, unadulterated and—in accordance with § 46.421(b) (relating to accurate representation)—honestly presented.]

FOOD SOURCES

§ 46.211. [Food sources] (Reserved).

[Food shall be obtained from sources that comply with the Food Act, the Public Eating and Drinking Places Law and this chapter. Records of food sources shall be maintained and made available for review upon request by the Department.]

§ 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 the following apply:

- (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 (26 U.S.C.A. § 501(c)(3)).

(ii) A volunteer fire company or ambulance, religious, charitable, fraternal, veterans, civic, sportsmen, agricultural fair or agricultural association or a separately chartered auxiliary of an association on a nonprofit 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 nonprofit basis. (32)

(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.

(Editor's Note: As part of this proposed rulemaking, the Department is proposing to rescind §§ 46.213—46.216 which appear in 7 Pa. Code pages 46-31—46-32, serial pages (301607) and (301608).)

- Sec.
 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).

(Editor's Note: As part of this proposed rulemaking, the Department is proposing to rescind §§ 46.218—46.222, 46.241—46.251, 46.261, 46.262, 46.281—46.286, 46.301—46.307, 46.321—46.323, 46.341—46.344, 46.361—46.366, 46.381—46.385, 46.401, 46.402, 46.421—46.423, 46.441 and 46.461 which appear in 58 Pa. Code pages 46-32—46-63, serial pages (301608)—(301639).)

- Sec.
 46.218—46.222. (Reserved).
 46.241—46.251. (Reserved).
 46.261. (Reserved).
 46.262. (Reserved).
 46.281—46.286. (Reserved).
 46.301—46.307. (Reserved).
 46.321—46.323. (Reserved).
 46.341—46.344. (Reserved).
 46.361—46.366. (Reserved).
 46.381—46.385. (Reserved).
 46.401. (Reserved).
 46.402. (Reserved).
 46.421—46.423. (Reserved).
 46.441. (Reserved).
 46.461. (Reserved).

Subchapter D. [EQUIPMENT, UTENSILS AND LINENS] (Reserved)

(Editor's Note: As part of this proposed rulemaking, the Department is proposing to rescind Subchapter D which appears in 58 Pa. Code pages 46-63—46-97, serial pages (301639), (301640), (351231), (351232) and (301643)—(301673).)

- Sec.
 46.501. (Reserved).
 46.521—46.523. (Reserved).
 46.541—46.544. (Reserved).
 46.561—46.563. (Reserved).
 46.581—46.595. (Reserved).
 46.611—46.615. (Reserved).
 46.631—46.634. (Reserved).
 46.651. (Reserved).
 46.652. (Reserved).
 46.671—46.676. (Reserved).
 46.691—46.693. (Reserved).
 46.711—46.719. (Reserved).
 46.731. (Reserved).
 46.751—46.753. (Reserved).
 46.771—46.775. (Reserved).

Subchapter E. [WATER, PLUMBING AND WASTE WATER] (Reserved)

(Editor's Note: As part of this proposed rulemaking, the Department is proposing to rescind Subchapter E which appears in 58 Pa. Code pages 46-97—46-110, serial pages (301673)—(301686).)

- Sec.
 46.801—46.806. (Reserved).
 46.821—46.825. (Reserved).
 46.841—46.844. (Reserved).
 46.861—46.863. (Reserved).
 46.881—46.886. (Reserved).

Subchapter F. [PHYSICAL FACILITIES] (Reserved)

(Editor's Note: As part of this proposed rulemaking, the Department is proposing to rescind Subchapter F which appears in 58 Pa. Code pages 46-110-46-120, serial pages (301686)-(301696).)

- Sec. (Reserved).
- 46.901. (Reserved).
- 46.902. (Reserved).
- 46.921. (Reserved).
- 46.922. (Reserved).
- 46.941-46.946. (Reserved).
- 46.961-46.965. (Reserved).
- 46.981. (Reserved).
- 46.982. (Reserved).

Subchapter G. [POISONOUS OR TOXIC MATERIALS] (Reserved)

(Editor's Note: As part of this proposed rulemaking, the Department is proposing to rescind Subchapter G which appears in 58 Pa. Code pages 46-121-46-125, serial pages (301697)-(301701).)

- Sec. (Reserved).
- 46.1001. (Reserved).
- 46.1002. (Reserved).
- 46.1021-46.1029. (Reserved).
- 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.

* * * * *

(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

* * * * *

(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:

* * * * *

(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:

* * * * *

(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:

* * * * *

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[]].

* * * * *

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

§ 46.1122. HACCP plans.

(a) When [a] an HACCP plan is required.

(1) Before engaging in an activity that requires [a] an HACCP plan, a retail food facility applicant or retail food facility operator shall submit to the Department or licenser 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 [a] 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.

* * * * *

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

* * * * *

§ 46.1123. Confidentiality of trade secrets.

The Department or licenser 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 licenser 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 licenser 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 licenser, unless otherwise provided in subsection (b).

(b) [Exceptions.

(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. § 20.14).

(2) [Exemptions: 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 the Retail Food Facility Safety Act:

[(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.]

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

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

(3) 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 section 5703(b)(1) of the Retail Food Facility Safety Act (relating to license required) if the licenser is the Department.

(4) 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 section 5703(b)(1) of the Retail Food Facility Safety Act if the licenser is an entity other than the Department.

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

(1) 24-month license interval.

(i) The license interval is 24 months with 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 (time/temperature Control for Safety Food (TCS foods)) for hot holding.

PROPOSED RULEMAKING

(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 in subparagraph (i) are convenience store operations, hot dog carts and coffee shops.

(iii) The license interval for a retail food facility is 24 months if the retail food facility would otherwise be subject to the 18-month license interval 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 noncompliance with provisions regarding 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.*

(i) The license interval is 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.

(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 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 area), institutional facilities that do not serve a highly susceptible population and quick food service operations.

(iii) The license interval for a retail food facility is 18 months if the retail food facility would otherwise be subject to the 12-month license interval 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 in paragraph (1).

(iv) The license interval for a retail food facility is 18 months if the retail food facility would otherwise be subject to the 24-month license interval 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 in paragraph (1).

(3) *12-month license interval.*

(i) The license interval is 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).

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

(ii) Examples of the type of retail food facility that would typically be subject to the 12-month license interval 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 area) that includes ready-to-eat foods from a café, salad bar or hot food bar.

(iii) The license interval for a retail food facility is 12 months if the retail food facility would otherwise be subject to the 6-month license interval 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 in paragraph (1).

(iv) The license interval for a retail food facility is 12 months if the retail food facility would otherwise be subject to the 18-month license interval 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 in paragraph (1).

(4) *6-month license interval.*

(i) The license interval is 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 in subparagraph (i) are preschools, hospitals, nursing homes and establishments conducting processing at retail.

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

* * * * *

(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.

* * * * *

(3) If a retail food facility is required in § 46.1122(a) (relating to HACCP plans) to operate under [a] 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).

* * * * *

(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.

(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) (10) 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.

(11) Remit a fee owed to the Department under section 5703(j) of the Retail Food Facility Safety Act (relating to license required) within the time prescribed by the Department.

(12) Remit a 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 either of the following:

(i) The effective date of the final adjudication assessing the civil penalty.

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

Subpart C. MISCELLANEOUS PROVISIONS

CHAPTER 76. FOOD EMPLOYEE CERTIFICATION

(Editor's Note: As part of this proposed rulemaking, the Department is proposing to rescind §§ 76.1—76.17 and 76.19 which appear in 58 Pa. Code pages 76-1—76-18, serial pages (304941)—(304958).)

Sec.
76.1—76.17. (Reserved).
76.19. (Reserved).

(Editor's Note: Sections 76.20 and 79.21 are new and printed in regular type to enhance readability.)

§ 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—The Food Employee Certification Act (3 Pa.C.S. §§ 6501—6510).

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 3 Pa.C.S. § 5702 (relating to definitions).

§ 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 maintains a current list of Department-recognized certification programs. The Department will:

(1) Publish the current list in the *Pennsylvania Bulletin* annually and when the list is revised.

(2) Post the current list on the Department's web site at www.agriculture.state.pa.us.

(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

[Pa.B. Doc. No. 12-1514. Filed for public inspection August 10, 2012, 9:00 a.m.]

GAME COMMISSION

[58 PA. CODE CH. 141]

Hunting and Trapping; Permitted Devices

To effectively manage the wildlife resources of this Commonwealth, the Game Commission (Commission) proposed at its June 26, 2012, meeting to amend § 141.18 (relating to permitted devices) to permit the use of electronic crow decoys to hunt crows.

The proposed rulemaking will not have an adverse impact on the wildlife resources of this Commonwealth.

The authority for the proposed rulemaking is 34 Pa.C.S. (relating to Game and Wildlife Code) (code).

The proposed rulemaking was made public at the June 26, 2012, meeting of the Commission. Comments can be sent, until September 21, 2012, to the Director, Bureau of Information and Education, Game Commission, 2001 Elmerton Avenue, Harrisburg, PA 17110-9797.

1. Purpose and Authority

Each year the Commission is asked to review the potential use of certain devices for hunting or trapping purposes that are otherwise prohibited by statute or regulation. As part of the review process, the Commission generally reviews to what degree use of a given device

might negatively impact principles of resource conservation, equal opportunity or public safety. The Commission has recently been requested to review the use of electronic crow decoys for use in the hunting of crows. After thoughtful review, the Commission determined that use of these devices for crow hunting purposes would be acceptable due to negligible impacts to the previously mentioned principles.

Section 2102(b)(1) of the code (relating to regulations) authorizes the Commission to "promulgate regulations relating to seasons and bag limits for hunting or furtaking, the possession of certain species or parts thereof, the number and types of devices and equipment allowed, the identification of devices and the use and possession of devices." Section 2102(a) of the code provides that "The commission shall promulgate such regulations as it deems necessary and appropriate concerning game or wildlife and hunting or furtaking in this Commonwealth, including regulations relating to the protection, preservation and management of game or wildlife and game or wildlife habitat, permitting or prohibiting hunting or furtaking, the ways, manner, methods and means of hunting or furtaking, and the health and safety of persons who hunt or take wildlife or may be in the vicinity of persons who hunt or take game or wildlife in this Commonwealth." The amendments to § 141.18 are proposed under this authority.

2. Regulatory Requirements

The proposed rulemaking will amend § 141.18 to permit the use of electronic crow decoys to hunt crows.

3. Persons Affected

Persons wishing to hunt crows through the use of crow decoys within this Commonwealth may be affected by the proposed rulemaking.

4. Cost and Paperwork Requirements

The proposed rulemaking should not result in additional cost or paperwork.

5. Effective Date

The proposed rulemaking will be effective upon final publication in the *Pennsylvania Bulletin* and will remain in effect until changed by the Commission.

6. Contact Person

For further information regarding the proposed rulemaking, contact Richard R. Palmer, Director, Bureau of Wildlife Protection, 2001 Elmerton Avenue, Harrisburg, PA 17110-9797, (717) 783-6526.

CARL G. ROE,
Executive Director

Fiscal Note: 48-347. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 58. RECREATION

PART III. GAME COMMISSION

CHAPTER 141. HUNTING AND TRAPPING

Subchapter A. GENERAL

§ 141.18. Permitted devices.

The following devices may be used to hunt or take wildlife:

* * * * *



COMMONWEALTH OF PENNSYLVANIA
GOVERNOR'S OFFICE OF GENERAL COUNSEL

January 14, 2014

Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17120

RE: NOTICE OF FINAL RULEMAKING
Department of Agriculture
7 Pa. Code Chapters 46 and 76
Food Code; Food Employee Certification
I.D. No. 2-174
Proposed Rulemaking: 42 Pa. Bulletin 5218 (August 11, 2012)
Approved by Office of General Counsel: January 8, 2014

Dear Sir or Madam:

Please find enclosed a copy of the above-referenced final-form regulation (Preamble and Annex "A"). Copies of the Regulatory Analysis Form and Notice of Proposed Rulemaking are also enclosed. This material is submitted to you in accordance with the Regulatory Review Act (at 71 P.S. § 745.5a(a)). The Department's responses to the comments received with respect to the proposed version of this regulation are set forth in the Preamble, and if applicable, incorporated into the Annex "A" of the final-form regulation. Please be aware that the Department, pursuant to 71 P.S. § 745.5a(b), on this same date, sent a copy of the text of the final-form regulation to each commentator who requested such information pursuant to 71 P.S. § 745.5a(a). As required by 71 P.S. § 745.5a(a), also enclosed with this submission is the list of commentators who requested additional information.

I respectfully request the Commission's approval of this final-form regulation. The Department will provide any assistance you may require to facilitate a thorough review of this final-form regulation. Thank you for your consideration of this document.

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

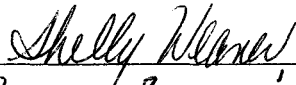
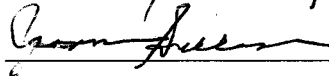

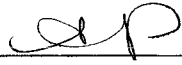

TYPE OF REGULATION

- Proposed Regulation
- X 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

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RECEIVED
IRRC

FILING OF REGULATION

<u>DATE</u>	<u>SIGNATURE</u>	<u>DESIGNATION</u>
		<i>HOUSE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS</i>
1-14-14		MAHER MAJORITY CHAIR <u>JOHN MAHER</u>
1-14-14		PETRARCA MINORITY CHAIR
		<i>SENATE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS</i>
1-14-14		VOGEL MAJORITY CHAIR <u>ELDER A. VOGEL, JR.</u>
1-14-14		SCHWANK MINORITY CHAIR
1-14-14		IRRG <i>INDEPENDENT REGULATORY REVIEW COMMISSION</i>
		<i>ATTORNEY GENERAL (for Final Omitted only)</i>
		<i>LEGISLATIVE REFERENCE BUREAU (for Proposed only)</i>

January 8, 2014