

RULES AND REGULATIONS

Title 7—AGRICULTURE

DEPARTMENT OF AGRICULTURE

[7 PA. CODE CH. 49]

Shellfish

The Department of Agriculture (Department) amends Chapter 49 (relating to shellfish) to read as set forth in Annex A.

Statutory Authority

The Food Act (act) (31 P. S. §§ 20.1—20.18) and section 1705(d) of The Administrative Code of 1929 (71 P. S. § 445(d)) provide the legal authority for this final-form rulemaking.

The act charges the Department with the responsibility to: (1) regulate, register and inspect food establishments in this Commonwealth under section 14(a) of the act (31 P. S. § 20.14(a)); (2) promulgate regulations and food safety standards necessary to the proper enforcement of the food safety requirements in section 13(a) of the act (31 P. S. § 20.13(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, and would not unduly burden interstate commerce under section 16 of the act (31 P. S. § 20.16). Section 1705(d) of The Administrative Code of 1929 requires the Department to establish regulatory standards necessary to enforce food safety laws.

Purpose of the Final-Form Rulemaking

The National Shellfish Sanitation Program Model Ordinance (NSSP Model Ordinance) is the product of a collaborative effort among the Department, the Food and Drug Administration, various shellfish regulatory authorities in other states and nations, shellfish industry representatives, academia and consumers. The NSSP Model Ordinance represents the state-of-the-science with respect to shellfish safety, handling and processing and, in the event of a foodborne illness outbreak relating to shellfish, facilitates the trace-back of shellfish to its source harvest area. Food safety science is an evolving body of knowledge. It is the Department's intention to adopt regulatory food safety standards that reflect current recommended National standards and to amend these standards in the future as necessary to track with relevant revisions to these National standards. The NSSP Model Ordinance is reviewed and updated regularly, at meetings of the Interstate Shellfish Sanitation Conference.

The final-form rulemaking: (1) updates the Department's shellfish food safety standards to reflect the current state of food science knowledge; (2) brings these standards into greater conformity with those of other states by establishing standards and procedures recommended in the widely-adopted NSSP Model Ordinance; (3) improves the Department's ability to trace-back foodborne illness outbreaks regarding shellfish; and (4) facilitates interstate and intrastate commerce in shellfish by promoting consistency in shellfish standards among various jurisdictions.

Comments and Responses

Notice of proposed rulemaking was published at 36 Pa.B. 936 (February 25, 2006) affording the public, the Legislature and the Independent Regulatory Review Com-

mission (IRRC) the opportunity to offer comments. Of these, only IRRC offered comments. IRRC's comments, and the Department's responses, follow:

Comment: IRRC recommended that proposed § 49.2 (relating to scope) be revised by inserting a reference to an Internet address at which the NSSP Model Ordinance can be viewed by the regulated community.

Response: The Department has implemented this recommendation in the final-form rulemaking.

Comment: IRRC suggested that proposed § 49.42 (relating to plumbing) be revised to reflect that plumbing should be sized, installed and maintained in accordance with the applicable requirements of the Pennsylvania Construction Code Act (35 P. S. §§ 7210.101—7210.1103).

Response: The Department has implemented this recommendation in the final-form rulemaking.

Comment: IRRC recommended that proposed § 49.53 (relating to utensils and equipment construction) be revised by adding information on the source and availability of the "Shellfish Industry Construction Guide" and a reference to an Internet address at which that document can be viewed by the regulated community.

Response: The Department has implemented this recommendation in the final-form rulemaking.

Fiscal Impact

Commonwealth. The final-form rulemaking imposes no costs and has no fiscal impact on the Commonwealth.

Political subdivisions. The final-form rulemaking imposes no costs and has no fiscal impact upon political subdivisions.

Public sector. The final-form rulemaking imposes no costs and has no fiscal impact on the private sector. Since the NSSP Model Ordinance is the widely-accepted industry standard for shellfish sanitation, the private sector (approximately 95 shellfish dealers) is either already in compliance with this standard or can readily come into compliance with this standard without appreciable costs.

General public. The final-form rulemaking imposes no costs and has no fiscal impact on the general public. The final-form rulemaking enhances public health and safety.

Paperwork Requirements

The final-form rulemaking is not likely to impact upon the paperwork generated by the Department or shellfish facilities.

Effective Date

This final-form rulemaking takes effect upon publication in the *Pennsylvania Bulletin*.

Additional Information

Individuals who need information about the final-form rulemaking should contact Garry Orner, Department of Agriculture, Bureau of Food Safety and Laboratory Services, 2301 North Cameron Street, Harrisburg, PA 17110-9408, (717) 787-4315.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on February 13, 2006, the Department submitted a copy of the notice of proposed rulemaking, published at 36 Pa.B. 936, to 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, IRRC and the Committees were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Department has considered all comments from IRRC, the House and Senate Committees and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on September 6, 2006, the final-form rulemaking was deemed approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on September 7, 2006, and approved the final-form rulemaking.

Findings

The Department finds that:

(1) Public notice of intention to adopt this final-form rulemaking 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 the comments received were considered.

(3) The amendments that were made to this final-form rulemaking in response to comments received do not enlarge the purpose of the proposal published at 36 Pa.B. 936.

(4) The adoption of the final-form rulemaking 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 statutes, orders the following:

(1) The regulations of the Department, 7 Pa. Code Chapter 49, are amending by amending §§ 49.1, 49.3—49.6, 49.31, 49.41, 49.43—49.45, 49.47, 49.51, 49.54—49.56, 49.61 and 49.62, by adding § 49.7 and by deleting §§ 49.11—49.20 and 49.32—49.34 to read as set forth at 36 Pa.B. 936; and by amending §§ 49.2, 49.42 and 49.53 to read as set forth in Annex A.

(2) The Secretary of Agriculture shall submit this order, 36 Pa.B. 936 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, 36 Pa.B. 936 and Annex A with the Legislative Reference Bureau as required by law.

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

DENNIS C WOLFF,
Secretary

(Editor's Note: For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 36 Pa.B. 5941 (September 23, 2006).)

Fiscal Note: Fiscal Note 2-151 remains valid for the final adoption of the subject regulations.

Annex A**TITLE 7. AGRICULTURE****PART III. BUREAU OF FOOD SAFETY AND LABORATORY SERVICES****Subpart A. SOLID FOODS****CHAPTER 49. SHELLFISH****Subchapter A. GENERAL PROVISIONS****§ 49.2. Scope.**

A person who processes, distributes, ships, transports, stores, offers for sale or sells shellfish in this Commonwealth shall comply with this chapter and the NSSP Model Ordinance. The NSSP Model Ordinance can be viewed at www.cfsan.fda.gov/~ear/nss2-toc.html.

Subchapter D. SHELLFISH PROCESSING: SANITARY FACILITIES AND CONTROLS**§ 49.42. Plumbing.**

(a) Plumbing must be designed, constructed and installed in accordance with Chapter 3 of the Pennsylvania Construction Code Act (35 P. S. §§ 7201.301—7201.304), in a manner that prevents contamination of the water supply or the creation of an unsanitary condition.

(b) There may be no cross-connections between the approved pressure water supply and water from a nonapproved source. There may be no fixtures or connections through which the approved pressure supply might be contaminated by backsiphonage. When required, adequate devices shall be installed to protect fixtures and equipment against backflow and backsiphonage.

(c) Blower drains may not be directly connected with the sewers, but shall have a minimum air gap of 4 inches. Corrosion resistant piping having square sanitary threads shall be used to a point of 2 inches above the overflow level of the tank and so constructed as to be easily cleanable.

(d) Drains or waste lines may not be located above shellfish storage or processing areas.

Subchapter E. SHUCKING AREA AND EQUIPMENT**§ 49.53. Utensils and equipment construction.**

(a) Food contact surfaces of utensils and equipment, including those used for the handling of ice, must be designed to be easily cleaned, kept in good repair and constructed of safe material.

(b) *"The Shellfish Industry Equipment Construction Guide,"* developed for use with the Public Health Service-States-Industry Cooperative Program for the Certification of Interstate Shellfish Shippers, as appended to the "Guide for the Control of Molluscan Shellfish" (developed under the purview of the Interstate Shellfish Sanitation Conference and published by the United States Department of Health and Human Services; Public Health Services; Food and Drug Administration) is incorporated by reference. The *"Shellfish Industry Equipment Construction Guide"* can be viewed at www.cfsan.fda.gov/~ear/nss2-43a.html.

(c) Equipment and utensils must be designed, installed and operated in accordance with the "Shellfish Industry Equipment Construction Guide," and the standards and criteria established by the National Sanitation Foundation, unless otherwise established by this chapter.

(d) Devices which use compressed air to circulate wash water around and through the product, must be properly designed and constructed as to be easily dismantled for cleaning, examination and repair. The design and construction will be approved by the Department. Blowers shall follow the guidelines of the "Shellfish Industry Equipment Construction Guide."

(e) Single service articles or containers must be made from clean, sanitary, safe materials and may not impart odors, color or taste, or contribute to the contamination of shellfish. Articles and packages intended for single service use may not be reused.

(f) Pots, pans and utensil washers must be designed, constructed, installed, maintained and operated to comply with the manufacturer's instructions and in accordance with the applicable standards for commercial spray-type washing machines established by the National Sanitation Foundation.

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