

# Regulatory Analysis Form

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INDEPENDENT REGULATORY  
REVIEW COMMISSION

IRRC Number: 2526

(1) Agency

Department of Agriculture

(2) I.D. Number (Governor's Office Use)

2-151

(3) Short Title

Shellfish

(4) PA Code Cite

7 Pa. Code Chapter 49

(5) Agency Contacts & Telephone Numbers

Primary Contact: Garry R Orner (717) 787-4315 x 214

Secondary Contact: Sheri Dove (717) 787-4315 x 205

(6) Type of Rulemaking (check one)

- Proposed Rulemaking  
 Final Order Adopting Regulation  
 Final Order, Proposed Rulemaking Omitted

(7) Is a 120-Day Emergency Certification Attached?

- No  
 Yes: By the Attorney General  
 Yes: By the Governor

(8) Briefly explain the regulation in clear and nontechnical language.

The primary purpose of the final-form regulation is to protect human health by improving the regulation relating to the sanitary control of raw or processed shellfish sold for human consumption. The final-form regulation will also bring this Commonwealth's shellfish standards into greater conformity with the National Shellfish Sanitation Program Model Ordinance (NSSP Model Ordinance) – the recognized state-of-the-science with respect to shellfish safety. Most States are moving toward shellfish regulations that adopt or implement the NSSP Model Ordinance. The NSSP Model Ordinance promotes and improves the sanitation of shellfish moving in interstate and intrastate commerce, facilitates cooperation with other Federal and state jurisdictions and promotes a uniform approach to shellfish sanitation.

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(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

No.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

This regulation will update the current regulation to adopt and implement the provisions of the NSSP Model Ordinance. This will help safeguard human health, further the cause of food safety and – by bringing this Commonwealth's shellfish standards into conformity with standards of other States – facilitate interstate commerce in shellfish.

(12) State the public health, safety, environmental or general welfare risks associated with nonregulation.

If the regulation is not implemented, this Commonwealth would be out-of-step with the growing number of States that have implemented the provisions of the NSSP Model Ordinance. A consequence of this might be some increase in risk to human health, and/or some difficulty in conducting trace-backs in investigations of outbreaks of foodborne illness involving shellfish. In addition, Pennsylvania's shellfish dealers might encounter difficulty moving their product in interstate commerce if regulatory standards remain out-of-step with those of surrounding jurisdictions.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

The public will benefit from this regulation, in that it will facilitate tracebacks in the event of a foodborne illness outbreak involving shellfish.

There are also approximately 95 shellfish dealers in this Commonwealth. These persons will benefit from the regulation in that it will facilitate interstate commerce in shellfish.

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(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

The Department of Agriculture does not anticipate the regulation will adversely affect any person or business.

(15) 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.)

Owners, operators and employees of "shellfish dealers" will be required to comply with the regulation.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

Much of the public input behind this regulation was offered through the process of developing the NSSP Model Ordinance. This document represents the state-of-the-science with respect to food safety issues involving shellfish, and is the product of input from the shellfish industry, state and federal regulatory agencies, academia and the public. The NSSP is reviewed and reconsidered at each biannual meeting of the Interstate Shellfish Sanitation Conference (ISSC).

(17) 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.

This regulation is not expected to result in appreciable or measurable costs or savings to the regulated community. To the extent the regulation helps prevent or limit foodborne illness outbreaks involving shellfish and facilitate commerce in shellfish, this may result in some savings to the shellfish industry. These savings are not readily measurable, though.

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(18) 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.

The regulation is not expected to result in costs or savings to local governments.

(19) 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.

The regulation is not expected to result in costs or savings to State government.

## Regulatory Analysis Form

(20) 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
<b>SAVINGS:</b>	\$	\$	\$	\$	\$	\$
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
<b>Total Savings</b>	0	0	0	0	0	0
<b>COSTS:</b>						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
<b>Total Costs</b>	0	0	0	0	0	0
<b>REVENUE LOSSES:</b>						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
<b>Total Revenue Losses</b>	0	0	0	0	0	0

(20a) Explain how the cost estimates listed above were derived.

This regulation is intended to create uniformity and update the current shellfish regulation to meet current standards and practices that are already in widespread use throughout the shellfish industry. No additional costs or savings to State or local governments are anticipated.

## Regulatory Analysis Form

(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3 2002-2003	FY -2 2003-2004	FY -1 2004-2005	Current FY 2005-2006
Shellfish component of Food Safety Enforcement budget (Estimated)	\$205,049	\$259,320	\$242,530	\$250,000 (estimate)

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

There are not expected to be any adverse effects or costs resulting from this regulation.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

Non-regulatory alternatives were not considered. The changes and improvements that need to be accomplished can only be accomplished by amending the *current* regulations relating to shellfish.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

No alternative regulatory schemes were considered. The NSSP Model Ordinance prescribes the nationally-recognized state-of-the-science standards for shellfish regulation, and for this reason no alternative regulatory schemes were considered.

## Regulatory Analysis Form

(24) 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 regulation.

The regulation is not more stringent than Federal standards. It will bring the Commonwealth's shellfish standards into greater conformity with the NSSP Model Ordinance – the recognized standard for shellfish regulation. The NSSP Model Ordinance is not a Federal statute or regulation, but is an evolving product of a collaborative effort among Federal and State government authorities, shellfish industry representatives, academia, and the public, and is used nationwide as a model for shellfish safety and trace-back standards.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

The regulation will not put Pennsylvania at a competitive disadvantage with other states. To the contrary, it will bring Pennsylvania's shellfish standards into greater uniformity with those of the increasing number of States that are implementing the NSSP Model Ordinance, and will facilitate interstate shellfish commerce.

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

No, the regulation will not affect the regulations of the Department or other State agencies.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

The Department does not plan any public hearings or informational meetings. The current shellfish regulation and the NSSP Model Ordinance standards are well known in the shellfish industry.

## Regulatory Analysis Form

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

The regulation will not increase or change paperwork requirements.

(29) 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.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The regulation will be effective upon the date of promulgation. Compliance will be required immediately. This will not present any appreciable problems for the affected shellfish industry, in that the standards of the NSSP Model Ordinance are already widely adhered to and recognized as the appropriate standards for shellfish.

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

The Department will review the efficacy of the regulation on an ongoing basis.



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

By: \_\_\_\_\_  
(Deputy Attorney General)

DATE OF APPROVAL \_\_\_\_\_

Check if applicable  
Copy not approved. Objections attached.

Copy below is hereby certified to be true and  
correct copy of a document issued, prescribed or  
promulgated by:

(AGENCY) \_\_\_\_\_

DOCUMENT/FISCAL NOTE NO. 2-151

DATE OF ADOPTION \_\_\_\_\_

BY Dennis C. Wolf  
DENNIS C WOLF

TITLE  
SECRETARY  
Pennsylvania Department of Agriculture

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

BY Andrew C. Clark  
Andrew C. Clark

DATE OF APPROVAL  
JUN 28 2006

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

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

Notice of Final-Form Regulation

Title 7 - AGRICULTURE  
7 Pa. Code Chapter 49

Shellfish

# FINAL RULEMAKING

## DEPARTMENT OF AGRICULTURE

### [7 PA. CODE CH. 49]

#### Shellfish

The Department of Agriculture (Department) hereby revises the regulation at 7 Pa. Code 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 regulation.

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 set forth 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 Regulation*

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 regulation: (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 National Shellfish Sanitation Program (NSSP) Model Ordinance; (3) improves the Department's ability to trace-back foodborne illness outbreaks related to shellfish; and (4) facilitates interstate and intraState commerce in shellfish by promoting consistency in shellfish standards among various jurisdictions.

### *Comments and Responses*

A notice of proposed rulemaking was published at 36 *Pennsylvania Bulletin* 936 (February 25, 2006), affording the public, the Legislature and the Independent Regulatory Review Commission (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 regulation.

*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 regulation.

*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 regulation.

### *Fiscal Impact*

*Commonwealth:* The final-form regulation imposes no costs and has no fiscal impact on the Commonwealth.

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

*Public Sector:* The final-form regulation 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 regulation imposes no costs and has no fiscal impact on the general public. The final-form regulation enhances public health and safety.

#### *Paperwork Requirements*

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

#### *Effective Date*

This final-form regulation will take effect upon publication in the *Pennsylvania Bulletin*.

#### *Additional Information*

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

#### *Regulatory Review*

Under § 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), the Department submitted a copy of the Notice of Proposed Rulemaking published at 36 *Pennsylvania Bulletin* 936 (February 25, 2006) on February 13, 2006 to the Independent Regulatory Review Commission and to the Chairpersons of the House and Senate Standing Committees on Agriculture and Rural Affairs for review and comment. In compliance with § 5(b.1), the Department also provided the Commission and the Committees with copies of all comments received, as well as other documentation.

In preparing this final-form regulation, the Department has considered all comments received from the Commission, the Committees and the public.

This final-form regulation was (deemed) approved by the House Agricultural and Rural Affairs Committee on \_\_\_\_\_, was (deemed) approved by the Senate Agriculture and Rural Affairs Committee on \_\_\_\_\_, and was (deemed) approved by the Commission on \_\_\_\_\_.

#### *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 their attendant regulations at 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments 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 36 *Pennsylvania Bulletin* 936 (February 25, 2006).

(4) The adoption of the 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 statutes, orders the following:

(1) The current regulations of the Department of Agriculture at 7 Pa. Code Chapter 49 (relating to shellfish) are revised to read as set forth in Annex "A."

(2) The Secretary of Agriculture shall submit this order, 36 *Pennsylvania Bulletin* 936 (February 25, 2006) 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 *Pennsylvania Bulletin* 936 (February 25, 2006) 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*

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

§ 49.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless [the context clearly indicates otherwise] otherwise defined in the NSSP

Model Ordinance:

*[Adulterated or misbranded shellfish]*--The term includes shellfish which meet one of the following conditions:

- (i) Harvested from closed waters.
- (ii) Shucked, packed or otherwise processed in a plant which has not been certified by the Department under this chapter or not currently listed on the United States Food and Drug Administration's Interstate Certified Shellfish Shippers List, available from: Chief, Shellfish Sanitation Branch, HFF-344, Food and Drug Administration, 200 "C" Street, S. W., Washington, D. C. 20204, (202) 485-0149, Telex: 898488 PHS PKLN ROVE
- (iii) Contaminated as determined by bacteriological or other analysis.
- (iv) Consisting in whole or in part of filthy, putrid or decomposed substance, or if it is otherwise unfit for food.

(v) Prepared, packed or held under or exposed to unsanitary conditions where it may become contaminated with filth, or whereby it may have been rendered injurious to health.

(vi) Not labeled in accordance with this chapter.

*Backsiphonage*--The flowing back of used, contaminated or polluted water from a plumbing fixture or vessel or other source into a potable water supply pipe due to negative pressure in the pipe.

*Cross connection*--A physical connection or arrangement between two otherwise separate piping systems, one of which contains potable water, and the other, water of unknown or questionable safety, or steam, gases or chemicals, whereby there may be a flow from one system to the other, the direction of flow depending on the pressure differential between the two systems.]

*Dealer*--A shellstock shipper, shucker-packer, repacker, reshipper or depuration processor.

*Department*--The Department of Agriculture of the Commonwealth [or local department of health approved by the Department].

\* \* \* \* \*

[*Employee*--A person employed by a shellfish processor, distributor, shipper or reshipper who does or may handle or come in contact with handling, storing, transporting or selling and distributing shell stock or shellfish.]

*Facility*--A structure.

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

Freight-forwarder--A person who transports shellfish for a third party owner by vehicle or vessel, or who stores shellfish at a location for a short period of time while the shellfish are in transit.

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.

[*Lot of shellfish*--A collection of bulk shellstock or containers of shellstock of no more than one day's harvest from a single defined growing area harvested by one or more harvesters; or a collection of containers of no more than 1 day's shucked shellfish product produced under conditions as nearly uniform as possible, and designated by a common container code or marking.]

*NSSP Model Ordinance or National Shellfish Sanitation Program Model Ordinance--*  
As set forth in the *Guide for the Control of Molluscan Shellfish* 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, or the most current successor document.

\* \* \* \* \*

[*Plant*--An establishment where shellfish are processed or stored.

*Processing*--The act of depurating, shucking, packing or repacking of shellfish.]

\* \* \* \* \*

[*Retail sale*--Sale to the ultimate consumer or to another person who will not resell the product.



*Sanitize*--To effectively treat equipment and utensils by a process that provides enough accumulative heat or concentration of chemicals for enough time to reduce the bacterial count, including pathogens, to a safe level on utensils and equipment.]

*Secretary*--The Secretary of the Department.

[*Shellfish*--Edible species of oysters, clams and mussels, either shucked or in the shell, fresh or fresh frozen, whole or in part. The term does not include scallop species of the family Pectinidae.

*Shellstock*--Shellfish which remain intact in the original shells.]

\* \* \* \* \*

[*Shucked shellfish*--Shellfish which have been removed from their shells.]

*Shucker-packer*--A person who shucks and packs shellfish or who acts as a [shell stock] shellstock shipper or reshipper, or who repacks shellfish originating from other [certified sources] shellfish facilities that are certified in accordance with § 49.3 (relating to certification and compliance).

[*Wholesale sale*--A sale to anyone other than the ultimate purchasing consumer.]

## § 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 THE FOLLOWING INTERNET ADDRESS: <http://www.cfsan.fda.gov/~ear/nss2-toc.html>.

## § 49.3. [Permits] Certification and compliance.

(a) A [person] dealer may not engage commercially in the wholesale sale, shipping, processing, purchasing or selling of shellfish without the following:

(1) Compliance with this chapter, [except as stated in § 49.4(d) (relating to records and labeling)] the NSSP Model Ordinance and the Food Act.

(2) Application for and receipt of a valid shellfish [plant permit] facility certificate from the Department.

(b) A shellfish [plant permit will] facility certificate shall show the dealer's name, address and [permit] certification number. The activities of the [permittee] dealer shall be limited to activities covered by the [permit] certification. The [permit] certification number will indicate the type of shellfish [plant] facility the dealer is authorized to operate [as follows:]. These types of shellfish facilities, and acceptable abbreviations, are as follows:

\* \* \* \* \*

(5) DP--Depuration processor.

(c) The shellfish [plant permit] facility certificate shall be posted [on the plant premises] in the facility in a conspicuous place.

(d) The [permit] certification requirements do not apply to [:

(1) The] the sale of shellfish for consumption on the premises or by a retail food establishment that sells shellfish to ultimate consumers.

[(2) A wholesale shellfish distributor or reshipper who does not break down for repacking any quantity of shellstock or break a unit container of shucked shellfish.

(3) Anyone who provides for only the transportation of shellfish.]

(e) The Department is empowered to revoke or suspend a shellfish [plant permit] facility certification held by a [proprietor] dealer who violates this chapter, or who violates any provision of the NSSP Model Ordinance.

(f) Whenever the shellfish [plant permit] facility certification is revoked or suspended, the [permit holder] ~~certificateholder~~ CERTIFICATE HOLDER will be notified in writing of the violations which caused the revocation or suspension. The Department will notify the United States Food and Drug Administration (FDA) of the action when interstate certified shellfish dealers are involved so that the dealer's business name and [permit] certification number may be removed from the FDA Interstate Certified Shellfish Shippers List.

(g) A person required to obtain [a permit] shellfish facility certification from the Department under this section shall apply annually for the [permit] certificate on forms provided by the Department. The [permit] certification expires automatically on October 31 following the date of issue.

#### **§ 49.4. Records and labeling.**

[(a)] A dealer shall maintain complete, accurate and legible transaction records which provide the information necessary to trace purchases and sales of shellfish back to their source. [The records shall include the growing area name; the name, address and permit number of the shipper; the amount and type of shellfish; the date of receipt; and the date of sale. Shellfish records shall be subject to inspection by the Department.] A dealer shall keep and retain records and maintain product labeling in compliance with the standards and requirements of this chapter and the NSSP Model Ordinance and the Food Act.

Current HACCP plans for molluscan shellfish shall be readily available and easily identified for the Department.

[(1) Records covering purchases and sales of fresh shellfish shall be retained for a minimum of 1 year.

(2) Records covering purchases and sales of frozen shellfish shall be retained for at least 2 years or for a period that exceeds the shelf-life of the product, if that is longer than 2 years.

(b) An individual package of shellstock, and each individual package of fresh or frozen shucked shellfish, shall have permanently affixed on the package, an easily visible, durable, waterproof tag or label approved by the Department.

(1) The tag or label on the shellstock container shall contain the following information: the dealer's name, address, shellfish permit number, growing area identification, the date of harvest, type and quantity of shellstock. When waxed cardboard boxes are used, the required information may be printed on the sides of the box.

(2) An individual package of fresh or frozen shucked shellfish shall have permanently recorded on the principal display panel the dealer's or processor's shellfish plant permit number and sell by date. The sidewall is considered the principal display panel. Packages of shucked shellfish containing 1/2 gallon--64 ounces--or more, shall have the dealer's shellfish plant permit number and the packer's name printed or embossed on the sidewall of the package, and the date shucked marked on both the lid and also the side wall or bottom. The date shall consist of either the number of the day of the year or the abbreviation for the

month and number of the day of the month. The year shall be added for frozen shellfish. Frozen shellfish shall be clearly labeled as frozen in a type size of equal prominence to the name of the shellfish and located immediately adjacent thereto.

(c) Required label and product identification shall be provided in a legible and indelible form.

(d) The fraudulent use of tags or the placing of fraudulent or misleading information on the tags is considered a violation of this chapter.

(e) Public eating and drinking places licensed under the act of May 23, 1945 (P. L. 926, No. 369), known as the Public Eating and Drinking Place Law (35 P. S. §§ 655.1--655.13) and establishments authorized to conduct retail sales shall receive shellstock and fresh or frozen shucked shellfish labeled and identified according to subsections (b)--(d), and shall maintain for 90 days the tags and accurate records of the sources and quantity of all lots of shellfish.]

**§ 49.5. Inspection and sampling.**

(a) The Department may inspect [plants] facilities falling under this chapter to ascertain compliance or noncompliance with this chapter. [Plants involved in the interstate shipment of shellfish are subject to inspection by the Department and its employees and authorized agents at least four times per year. Other plants are subject to inspection by the Department and its employees and authorized agents at least once per year.]

(b) [The Department and its employees and agents may conduct additional inspections, including the following:] After the Department's personnel present identification, the

shellfish facility operator and its personnel shall allow the Department to determine if the shellfish facility is in compliance with this chapter by allowing Department personnel access to the shellfish facility, allowing inspection and providing information and records to which the Department is entitled under the Food Act or this chapter, during the shellfish facility's hours of operation and other reasonable times if the facility is not open during normal business hours.

[(1) Follow-up inspections.

(2) Inspections to determine compliance with environmental protection acts or regulations or requirements of an order issued by the Department.]

(c) The Department and its [employees] employees and agents may also conduct inspections whenever a person presents information to the Department giving the Department reason to believe that there exists a violation of this chapter, of a [permit] shellfish facility certification issued under this chapter, or of orders issued by the Department.

(d) [Nothing in this section places duty or obligation upon the Department to conduct a minimum number of inspections per year, to conduct a minimum number of inspections during a certain period or to inspect for particular reasons.

(e)] The Department and its authorized agents may secure samples of shellfish and processed shellfish products for laboratory examination from any lot of shellfish and will be permitted to examine the records of the facility to obtain information pertaining to shellfish harvested, purchased, received, processed, sold, held, distributed or shipped, and to personnel employed.

[(f)](e) The Department or its authorized agent is authorized to [embargo] detain a shellfish product if there is cause to believe it is adulterated or misbranded. It is unlawful to remove or dispose of [an embargoed] a detained product without [permission of one of the following:

- (1) The Department or its authorized agent who placed the embargo.
- (2) A court.] a determination of the Secretary, in accordance with section 6 of the Food Act (31 P. S. § 20.6), authorizing the removal or disposition.

[(g)](f) Laboratory analyses to be performed shall be conducted in accordance with the most current edition of the following:

- (1) The American Public Health Association's *Recommended Laboratory Procedures for the Examination of Seawater and Shellfish*[, available from: American Public Health Association, 1015 15th Street, N. W., Washington, D.C. 20005, (202) 789-5600].
- (2) The United States Food and Drug Administration's *Bacteriological Analytical Manual*[, available from: Association of Official Analytical Chemists, Inc., 1111 N. 19th Street, Suite 210, Arlington, VA 22209, (703) 522-3032].
- (3) *Official Methods of Analysis of the Association of Official Analytical Chemists*[, available from: Association of Official Analytical Chemists, Inc., 1111 N. 19th Street, Suite 210, Arlington, VA 22209, (703) 522-3032].
- (4) *Compendium of Methods for the Microbiological Examination of Foods*, compiled by the American Public Health Association's Technical Committee on Microbiological Methods for Foods[, available from: American Public Health Association, 1015 15th Street, N. W., Washington, D.C. 20005, (202) 789-5600].

(5) *Standard Methods for the Examination of Water and Wastewater*, prepared and published jointly by the American Public Health Association[, American Waterworks Association and the Water Pollution Control Federation, available from: American Public Health Association, 1015 15th Street, N. W., Washington, D.C. 20005, (202) 789-5600].

**§ 49.6. Source.**

(a) A [person] dealer in this Commonwealth may not have in his possession for processing, offer for sale or sell shellfish unless the shellfish have been obtained from interstate dealers who are [approved by the Department and are] listed in the United States Food and Drug Administration's Interstate Certified Shellfish Shippers List, or [intrastate] intraState dealers [permitted] certified by the Department.

(b) A [person] dealer who knowingly or willfully alters or damages or loans or transfers to another [person] dealer a shellfish [permit] facility certification number or shellfish tags, or a [person] dealer who uses the shellfish [permit] facility certification number or shellfish tags other than the [person] dealer to whom it was issued, is in violation of this chapter.

**§ 49.7. Freight-forwarders.**

A freight-forwarder shall maintain shellfish (other than frozen shellfish) at an ambient temperature of 45° Fahrenheit while being transported. A freight-forwarder shall maintain shellfish (other than frozen shellfish) at an ambient temperature of 45° Fahrenheit when maintained in a staging or layover area for more than 1 hour.



**Subchapter B. PACKING, STORING AND SHIPPING**  
**OF SHELLFISH (Reserved)**

**§ 49.11. [General.] [RESERVED].**

[(a) Shellfish which do not comply with this chapter and are subsequently returned to the packer, shucker, dealer or repacker may not be used for human consumption.

(b) Frozen shellfish products may not be thawed to be processed or sold as fresh shellfish products.

(c) A container of shellstock or shellfish with the label or mandatory information missing, that cannot be identified and relabeled correctly, may not be sold.

(d) Shellfish offered for sale at the wholesale market level may not exceed the bacteriological criteria established by the National Shellfish Sanitation Program Manual, Part II.]

**§ 49.12. [Transportation.] [RESERVED].**

[A vehicle used for the transport or movement of shellstock in bulk, bagged, containerized or otherwise packaged, shall be constructed, operated, maintained and kept clean to prevent contamination, deterioration or decomposition of the shellstock.]

**§ 49.13. [Cleanliness.] [RESERVED].**

[Shellstock sold, distributed or processed shall be reasonably free of mud and debris.]

**§ 49.14. [Refrigeration.] [RESERVED].**

[(a) Shellstock shall be shipped and stored at temperatures not exceeding 45°F to minimize the potential for unacceptable microbial growth and product deterioration.

(b) Shucked shellfish meats shall be cooled to an internal temperature of 45°F or less within 4 hours after shellfish are shucked.

(c) Frozen shellfish shall be kept frozen and shall be stored at a temperature of 0°F or below. Packages of frozen shellfish shall show the date or code of packing, and be conspicuously labeled “Perishable—Keep Frozen.”

(d) A mechanically refrigerated facility shall be provided with a numerically-scaled indicating thermometer accurate to  $\pm 3^{\circ}\text{F}$ , located to measure the air temperature in the warmest part of the facility. Recording thermometers, accurate to  $\pm 3^{\circ}\text{F}$  may be used in lieu of indicating thermometers.]

**§ 49.15. [Storage.] [RESERVED].**

[(a) The floors and walls of the shellstock storage rooms shall be smooth, impervious and easily cleaned. Storage areas shall be protected against flooding. Animals or rodents may not have access to storage rooms. Shellstock storage areas may not serve as passageways or storage areas for other materials.

(b) Shellfish products in storage shall be protected from contamination and maintained at temperatures not exceeding 45°F to minimize microbial growth and contamination.

(c) Ice used in the storage of shellstock or packaged shucked stock shall be obtained from a source using a Department approved water supply, and it shall be protected from contamination during storage and handling.

(d) Shellstock from different sources and of different species shall be kept separate and while being held in dry storage shall be stored in facilities so constructed and operated that shellstock will be protected from contamination, and be kept at temperatures not exceeding 45°F that will minimize microbial growth.

(e) Shellstock and shucked shellfish shall be stored a minimum distance of 6 inches above the floor and shall be protected from contamination.]

**§ 49.16. [Packing of shellstock.] [RESERVED].**

[(a) Shellstock shall be packed and shipped in clean single-use containers, of clean, nontoxic material, under conditions which will prevent contamination and spoilage and shall be sealed so that tampering can be detected.

(b) Sacks, boxes and other shellstock packing containers shall be identified with a durable, waterproof tag or label under § 49.5 (relating to inspection and sampling).]

**§ 49.17. [Repacking of shellstock.] [RESERVED].**

[(a) Only clean and wholesome shellstock of the same lot shall be repackaged and in a manner that will protect against contamination and spoilage.

(b) Shellstock from different lots may not be comingled.

(c) A container of repackaged shellstock shall be labeled under § 49.5 (relating to inspection and sampling).]

**§ 49.18. [Packing of shucked shellfish.] [RESERVED].**

[(a) Shellfish meats shall be thoroughly drained and cleaned as necessary and packaged promptly without being exposed to contamination or spoilage.

(b) Shucked shellfish destined for the retail market shall be packed and shipped in single-use containers of clean, impervious, nontoxic material and shall be sealed so that tampering can be detected.

(c) Shucked shellfish products found stored, packed or shipped in unapproved containers shall be removed from sale.

(d) Packaging of shucked shellfish in containers other than those in which they were initially packed shall be done only by repackers who comply with this chapter.

(e) A container of shucked shellfish shall be labeled under § 49.4 (relating to records and labeling).]

**§ 49.19. [Repacking of shucked shellfish.] RESERVED.**

[(a) Shucked shellfish to be repacked shall be obtained from certified sources and received at the repacking plant in shipping containers at a temperature of not more than 45°F.

(b) Shellfish from different lots may not be commingled during repackaging.]

**§ 49.20. [Reshipping.] RESERVED.**

[(a) Shellstock and shucked shellfish may be reshipped in compliance with this chapter.

(b) A reshipper may not shuck shellstock, package or repackage shellfish. A reshipper may not remove or alter an original label or tag, except that additional information such

as name, address and the date of shipment by the reshipper shall be properly added to shipments of shellstock.]

\* \* \* \* \*

**Subchapter C. CONSTRUCTION AND MAINTENANCE  
OF PHYSICAL FACILITIES**

**§ 49.31. Submission of plans.**

(a) Whenever a shellfish processing, depuration or controlled purification [plant] facility is constructed, remodeled or altered and whenever an existing structure is converted to use as a shellfish processing, depuration or controlled purification [plant] facility, properly prepared plans and specifications for the construction, remodeling or conversion shall be submitted to the Department for review and approval before construction, remodeling or conversion is begun.

(b) The plans and specifications [shall] must indicate the proposed layout, arrangement, mechanical plans and construction materials of work areas and the type and model of proposed fixed equipment and facilities. A shellfish processing [plant] facility, depuration or controlled purification plant may not be constructed, remodeled, altered or converted unless the plans and specifications are first approved by the Department. The approval will be based on compliance with this [subchapter, § 49.15 (relating to storage) and Subchapters D and E (relating to shellfish processing: sanitary facilities and controls; and shucking area and equipment) and the Department's Guidelines for Preparation of Plans--Food Service Facilities. Copies of the guidelines may be obtained from the

Department of Agriculture, Bureau of Food Safety and Laboratory Services, 2301 N. Cameron St., Harrisburg, Pennsylvania 17110, (717) 772-8353] chapter and the NSSP Model Ordinance.

**§ 49.32. [Floors.] [RESERVED].**

[Floor surfaces shall be constructed of durable materials impervious to water. The floor surfaces shall be easily cleanable in all rooms and areas in which shellfish are stored or processed, in which utensils are washed, in walk-in refrigerators and dressing or locker rooms. Floors shall be kept clean, in good repair and graded to floor drains that shall be provided in rooms where floors are subjected to flooding-type cleaning or where normal operations release or discharge water or other liquid waste onto the floor.]

**§ 49.33. [Walls and ceilings.] [RESERVED].**

(a) The interior wall surfaces of rooms in which shellfish are shucked or packed shall be smooth, impervious, light-colored and easily cleanable.

(b) Ceilings in shellfish shucking and packing establishments shall be constructed of smooth, light-colored, cleanable, corrosion resistant and impervious material.]

**§ 49.34. [Lighting.] [RESERVED].**

(a) Safe and adequate lighting shall be provided in handwashing areas, dressing and locker rooms and toilet rooms, and in areas where shellfish are processed, or where equipment and utensils are cleaned, and containers and other packaging materials are stored. The lighting level requirements are as follows:

(1) Permanently fixed artificial light sources shall be installed to provide at least 35 foot candles of light on shellfish processing surfaces and at equipment or utensil-washing work levels.

(2) Permanently fixed artificial light sources shall be installed to provide the following, at a distance of 30 inches from the floor:

(i) At least 20 foot candles of light in utensil and equipment storage areas and in lavatory and toilet areas.

(ii) At least 10 foot candles of light in walk-in refrigerating units, dry storage areas and in other areas.

(b) Shielding to protect against broken glass falling onto exposed shellfish, containers or packaging materials shall be provided for lighting fixtures located over or within shellfish storage or processing areas.]

\* \* \* \* \*

**Subchapter D. SHELLFISH PROCESSING:  
SANITARY FACILITIES AND CONTROLS**

**§ 49.41. Water supply.**

(a) Potable water of sufficient quantity to meet the needs of the shellfish [plant] facility shall be provided from a source approved by the Department or be under permit from the Department of Environmental Protection. Water quality [shall] must meet the requirements of 25 Pa. Code Chapter 109 (relating to safe drinking water).

Noncommunity water supplies shall be designed, constructed and operated in accordance

with the Department of Environmental Protection's Bureau of Water Supply and Community Health Manual and 25 Pa. Code Chapter 109.

(b) Hot and cold water under pressure shall be provided to each plumbing fixture used for cleaning, washing or sanitizing purposes in:

\* \* \* \* \*

**§ 49.42. Plumbing.**

(a) Plumbing [shall] ~~must be sized, installed and maintained in compliance with the provisions of the local plumbing code or, in the absence thereof~~ BE DESIGNED, CONSTRUCTED AND INSTALLED IN ACCORDANCE WITH CHAPTER 3 OF THE PENNSYLVANIA CONSTRUCTION CODE ACT (35 P.S. SECTIONS 7201.301 – 7201.304), in a manner that prevents contamination of the water supply or the creation of an unsanitary condition.

\* \* \* \* \*

**§ 49.43. Toilet facilities.**

(a) [Conveniently located, separate toilets shall be provided for each sex. When the plant has fewer than ten employees, toilet facilities shall be provided, but need not be separate for each sex.] At least one conveniently-located toilet facility shall be provided for employees. There need not be a separate toilet facility for each gender.

\* \* \* \* \*

**§ 49.44. [Lavatories] Hand wash sinks.**



(a) [Lavatories] Hand wash sinks shall be provided, adequate in number and size for the number of [employees] employees, convenient to work areas and equipped with cold and hot running water. Hot water of at least [100°F] the minimum temperature required by the NSSP Model Ordinance shall be provided [either from a controlled temperature source with a maximum temperature of 115°F, or] from a hot and cold mixing or combination faucet. [Lavatories] Hand wash sinks shall be located within or immediately adjacent to toilets and within processing areas.

(b) [There shall be at least one lavatory for each 15 employees.

(c) Hand cleansing soap or detergent and approved sanitary towels or other approved hand-drying devices shall be provided at [lavatories] hand wash sinks.

[(d) Handwashing signs shall be posted at each lavatory location directing employees to wash their hands before starting work and after each interruption.

(e) (c) \* \* \*

**§ 49.45. Sewage.**

Sewage disposal systems shall be approved by the local authority and [shall] **must** comply with 25 Pa. Code Chapters 71, 73 and 243 (relating to the administration of sewage facilities planning program; standards for onlot sewage treatment facilities; and nuisances), and The Clean Streams Law (35 P. S. §§ 691.1--691.1001).

\* \* \* \* \*

**§ 49.47. [Arthropod] Insect and rodent control.**

(a) Safe and effective measures shall be used to prevent the entry of insects, rodents and other vermin, and to kill and capture insects and vermin which enter the [plant] facility despite other control measures.

\* \* \* \* \*

(d) The storage and use of pesticides in [shellfish plants] a shellfish facility shall be prohibited unless used in full compliance with the manufacturer's label or used under the control of a certified pesticide applicator.

### Subchapter E. SHUCKING AREA AND EQUIPMENT

#### § 49.51. Shucking.

\* \* \* \* \*

(d) [Shellfish shucking and packing operations shall be conducted in separate rooms and shall be protected from contamination by splash or by other means from adjacent areas. Packing rooms shall be of sufficient size to permit sanitary handling of the product and thorough cleaning of the equipment.

(e) When shucking and packing operations occur in separate rooms, a delivery window or area shall be provided so that shuckers do not have direct access to the packing area.

(f) A shellfish shucker may not go into or through the packing room for any purpose, except when he operates in a dual shucking packing capacity. If the shucker is operating in a dual capacity, [he] the shucker shall first change to clean clothing and thoroughly wash his hands and exposed portions of his arms.

[(g)] (e) \* \* \*

**§ 49.53. Utensils and equipment construction.**

\* \* \* \* \*

(b) *The Shellfish Industry Equipment Construction Guides GUIDE*, developed for use with the Public Health Service-States-Industry Cooperative Program for the Certification of Interstate Shellfish Shippers, [published by the United States Department of Health and Human Services, Appendix B of the 1988 NSSP Manual, and the uniform sanitation standards and criteria established by the National Sanitation Foundation, available from: National Sanitation Foundation, Post Office Box 1468, 3475 Plymouth Road, Ann Arbor, Michigan 48106, (313) 769-8010,] ~~are incorporated by reference~~ 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 THE FOLLOWING INTERNET ADDRESS:

<http://www.cfsan.fda.gov/~ear/nss2-43a.html>.

\* \* \* \* \*

**§ 49.54. Bactericidal treatment of utensils and equipment.**

(a) Adequate cleaning facilities, including three-compartment sinks, or utensil washing machines, brushes, detergents, sanitizers, hot water and pressure hoses shall be available

for use within the shellfish [plant] facility for proper cleaning and sanitizing of equipment and utensils.

\* \* \* \* \*

(c) If there is a need for a slop sink or device to discard liquid waste, the sink or device shall be provided in addition to the three-compartment sink. Cleaning wastes may not be emptied into sinks used for hand washing, or the processing of shellfish or the cleaning and sanitizing of utensils.

\* \* \* \* \*

(e) Equipment too large or impractical to treat by the methods in subsection (c) or (d) may be [treated using one of the following methods] cleaned, followed by spraying or swabbing the equipment with a chemical sanitizing solution of at least twice the minimum strength required for the particular sanitizing solution when used for immersion sanitization. This may be accomplished by either of the following systems:

(i) [With live steam from a hose, in the case of equipment in which steam can be confined] A clean-out-of-place system (C.O.P.) that allows the equipment to be moved (for cleaning purposes) from the position in which it is ordinarily used.

(ii) [By rinsing with boiling water] A central cleaning system that pipes a supply of hot or cold water, with or without chemicals, to a number of cleaning stations placed throughout the shellfish processing area.

[(iii) By spraying or swabbing with a chemical sanitizing solution of at least twice the minimum strength required for the particular sanitizing solution when used for immersion sanitization.]

\* \* \* \* \*

**§ 49.55. Equipment and utensil handling and storage.**

\* \* \* \* \*

(c) Unused equipment and materials not necessary to [plant] facility operation may not be stored in rooms used for [shell stock] shellstock storage, shucking, packing, repacking or in equipment and container store rooms.

**§ 49.56. General maintenance.**

\* \* \* \* \*

(b) Only authorized equipment and persons shall be permitted in the shellfish processing area. Dogs, cats, birds or other animals or unauthorized persons may not be allowed in areas of the shellfish [plant] facility that are used for processing, holding, storing or transporting of shellfish except that patrol dogs accompanying security or police officers are permitted.

**Subchapter F. [EMPLOYEE] EMPLOYEE HEALTH AND CLEANLINESS**

**§ 49.61. Health.**

(a) A person, while infected with a disease in a communicable form that can be transmitted by foods or who is a carrier of organisms that cause such a disease, or while afflicted with a boil, an infected wound or an acute respiratory infection, may not work in a shellfish [plant] facility in a capacity in which there is a likelihood of the person

contaminating food or food-contact surfaces with pathogenic organisms or transmitting disease to other persons.

(b) An owner or manager who has reason to suspect that an [employee] employee has contracted a communicable disease shall immediately notify the Department. Pending appropriate action by the health officials, the [employee] employee shall be excluded from the [plant] facility.

**§ 49.62. Cleanliness.**

(a) [Employes] Employees and other persons who handle shellfish shall wash their hands and exposed portions of their arms with soap and warm water before beginning work, and during work as often as necessary following other activities, such as smoking, eating, cleaning or visits to the toilet. Hands, or rubber gloves when used, shall be washed and sanitized before manually handling shellfish.

\* \* \* \* \*

(c) [Employes] Employees shucking or handling shellfish meat shall wear clean aprons or coats and effective hair restraints. When manual handling of shellfish meat becomes necessary, sanitized rubber gloves or the equivalent shall be worn, or the hands shall be washed and [disinfected] sanitized immediately before the manual handling. Finger cots, gloves or shields, if worn by shuckers, shall be sanitized as often as necessary and shall be made of nonabsorbent material.

\* \* \* \* \*

# PROPOSED RULEMAKING

## DEPARTMENT OF AGRICULTURE

[7 PA. CODE CH. 49]

### Shellfish

The Department of Agriculture (Department) proposes to amend 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 proposed 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 set forth 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*

The proposed 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 National Shellfish Sanitation Program (NSSP) Model Ordinance; (3) improves the Department's ability to trace-back foodborne illness outbreaks related to shellfish; and (4) facilitates interstate and intrastate commerce in shellfish by promoting consistency in shellfish standards among various jurisdictions.

#### *Background*

The 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.

As more states adopt the NSSP Model Ordinance as a basis for their respective shellfish regulations, the Com-

monwealth's current shellfish regulations become more out-of-step with shellfish industry practices and the state-of-the-science with respect to shellfish safety. This Commonwealth's shellfish industry is, in many respects, ahead of the Department in terms of sanitation and recordkeeping requirements to keep its products competitive in interstate commerce. The proposed rulemaking brings the Department current with widely-used and well-regarded industry standards for shellfish.

#### *Need for the Proposed Rulemaking*

The proposed rulemaking establishes uniform shellfish standards and tracks neighboring states, and thereby facilitates interstate commerce in shellfish. It also helps protect human health and facilitates the trace-back of shellfish to its harvest area in the event of a foodborne illness outbreak involving shellfish. 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 Subchapter A (relating to general provisions) defines terms in the same language as presented in the NSSP Model Ordinance and also expands defined terms.

Proposed Subchapters B and C (relating to packing, storing and shipping of shellfish; and construction and maintenance of physical facilities) supplant the Department's current regulatory standards for shellfish with the standards prescribed in the current version of the NSSP Model Ordinance.

#### *Affected Individuals and Organizations*

The proposed rulemaking helps protect public health in the event of a foodborne illness outbreak involving shellfish. It also helps this Commonwealth's shellfish dealers by establishing regulatory standards that are consistent with those of other states and nations, thereby facilitating commerce.

#### *Fiscal Impact*

##### *Commonwealth*

The proposed rulemaking imposes no costs and has no fiscal impact on the Commonwealth.

##### *Political subdivisions*

The proposed rulemaking imposes no costs and has no fiscal impact upon political subdivisions.

##### *Private sector*

The proposed 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 proposed rulemaking imposes no costs and has no fiscal impact on the general public. The proposed rulemaking enhances public health and safety.

##### *Paperwork Requirements*

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

*Effective Date*

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

*Sunset Date*

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

*Public Comment Period/Contact Person*

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

*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 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.

DENNIS C WOLFF,  
*Secretary*

**Fiscal Note:** 2-151. No fiscal impact; (8) recommends adoption.

**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**

**§ 49.1. Definitions.**

The following words and terms, when used in this chapter, have the following meanings, unless [ the context clearly indicates otherwise ] otherwise defined in the NSSP Model Ordinance:

[ *Adulterated or misbranded shellfish*—The term includes shellfish which meet one of the following conditions:

(i) Harvested from closed waters.

(ii) Shucked, packed or otherwise processed in a plant which has not been certified by the Department under this chapter or not currently listed on the United States Food and Drug Administration's Interstate Certified Shellfish Shippers List, available from: Chief, Shellfish Sanitation Branch, HFF-

344, Food and Drug Administration, 200 "C" Street, S. W., Washington, D. C. 20204, (202) 485-0149, Telex: 898488 PHS PKLN ROVE

(iii) Contaminated as determined by bacteriological or other analysis.

(iv) Consisting in whole or in part of filthy, putrid or decomposed substance, or if it is otherwise unfit for food.

(v) Prepared, packed or held under or exposed to unsanitary conditions where it may become contaminated with filth, or whereby it may have been rendered injurious to health.

(vi) Not labeled in accordance with this chapter.

*Backsiphonage*—The flowing back of used, contaminated or polluted water from a plumbing fixture or vessel or other source into a potable water supply pipe due to negative pressure in the pipe.

*Cross connection*—A physical connection or arrangement between two otherwise separate piping systems, one of which contains potable water, and the other, water of unknown or questionable safety, or steam, gases or chemicals, whereby there may be a flow from one system to the other, the direction of flow depending on the pressure differential between the two systems. ]

*Dealer*—A shellstock shipper, shucker-packer, repacker, reshipper or depuration processor.

*Department*—The Department of Agriculture of the Commonwealth [ or local department of health approved by the Department ] .

\* \* \* \* \*

[ *Employee*—A person employed by a shellfish processor, distributor, shipper or reshipper who does or may handle or come in contact with handling, storing, transporting or selling and distributing shell stock or shellfish. ]

*Facility*—A structure.

*Food Act*—The Food Act (31 P. S. §§ 20.1–20.18).

*Freight-forwarder*—A person who transports shellfish for a third party owner by vehicle or vessel, or who stores shellfish at a location for a short period of time while the shellfish are in transit.

*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.

[ *Lot of shellfish*—A collection of bulk shellstock or containers of shellstock of no more than one day's harvest from a single defined growing area harvested by one or more harvesters; or a collection of containers of no more than 1 day's shucked shellfish product produced under conditions as nearly uniform as possible, and designated by a common container code or marking. ]

*NSSP Model Ordinance or National Shellfish Sanitation Program Model Ordinance*—As set forth in the *Guide for the Control of Molluscan Shellfish* 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, or the most current successor document.

\* \* \* \* \*

[ *Plant*—An establishment where shellfish are processed or stored.

*Processing*—The act of depurating, shucking, packing or repacking of shellfish. ]

\* \* \* \* \*

[ *Retail sale*—Sale to the ultimate consumer or to another person who will not resell the product.

*Sanitize*—To effectively treat equipment and utensils by a process that provides enough accumulative heat or concentration of chemicals for enough time to reduce the bacterial count, including pathogens, to a safe level on utensils and equipment. ]

*Secretary*—The Secretary of the Department.

[ *Shellfish*—Edible species of oysters, clams and mussels, either shucked or in the shell, fresh or fresh frozen, whole or in part. The term does not include scallop species of the family Pectinidae.

*Shellstock*—Shellfish which remain intact in the original shells. ]

\* \* \* \* \*

[ *Shucked shellfish*—Shellfish which have been removed from their shells. ]

*Shucker-packer*—A person who shucks and packs shellfish or who acts as a [ shell stock ] shellstock shipper or reshipper; or who repacks shellfish originating from other [ certified sources ] shellfish facilities that are certified in accordance with § 49.3 (relating to certification and compliance).

[ *Wholesale sale*—A sale to anyone other than the ultimate purchasing consumer. ]

#### § 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.

#### § 49.3. [ Permits ] Certification and compliance.

(a) A [ person ] dealer may not engage commercially in the wholesale sale, shipping, processing, purchasing or selling of shellfish without the following:

(1) Compliance with this chapter, [ except as stated in § 49.4(d) (relating to records and labeling) ] the NSSP Model Ordinance and the Food Act.

(2) Application for and receipt of a valid shellfish [ plant permit ] facility certificate from the Department.

(b) A shellfish [ plant permit will ] facility certificate shall show the dealer's name, address and [ permit ] certification number. The activities of the [ permittee ] dealer shall be limited to activities covered by the [ permit ] certification. The [ permit ] certification number will indicate the type of shellfish [ plant ] facility the dealer is authorized to operate [ as

follows: ]. These types of shellfish facilities, and acceptable abbreviations, are as follows:

\* \* \* \* \*

(5) DP—Depuration processor.

(c) The shellfish [ plant permit ] facility certificate shall be posted [ on the plant premises ] in the facility in a conspicuous place.

(d) The [ permit ] certification requirements do not apply to [ :

(1) The ] the sale of shellfish for consumption on the premises or by a retail food establishment that sells shellfish to ultimate consumers.

[ (2) A wholesale shellfish distributor or reshipper who does not break down for repacking any quantity of shellstock or break a unit container of shucked shellfish.

(3) Anyone who provides for only the transportation of shellfish. ]

(e) The Department is empowered to revoke or suspend a shellfish [ plant permit ] facility certification held by a [ proprietor ] dealer who violates this chapter, or who violates any provision of the NSSP Model Ordinance.

(f) Whenever the shellfish [ plant permit ] facility certification is revoked or suspended, the [ permit holder ] certificateholder will be notified in writing of the violations which caused the revocation or suspension. The Department will notify the United States Food and Drug Administration (FDA) of the action when interstate certified shellfish dealers are involved so that the dealer's business name and [ permit ] certification number may be removed from the FDA Interstate Certified Shellfish Shippers List.

(g) A person required to obtain [ a permit ] shellfish facility certification from the Department under this section shall apply annually for the [ permit ] certificate on forms provided by the Department. The [ permit ] certification expires automatically on October 31 following the date of issue.

#### § 49.4. Records and labeling.

[ (a) ] A dealer shall maintain complete, accurate and legible transaction records which provide the information necessary to trace purchases and sales of shellfish back to their source. [ The records shall include the growing area name; the name, address and permit number of the shipper; the amount and type of shellfish; the date of receipt; and the date of sale. Shellfish records shall be subject to inspection by the Department. ] A dealer shall keep and retain records and maintain product labeling in compliance with the standards and requirements of this chapter and the NSSP Model Ordinance and the Food Act. Current HACCP plans for molluscan shellfish shall be readily available and easily identified for the Department.

[ (1) Records covering purchases and sales of fresh shellfish shall be retained for a minimum of 1 year.

(2) Records covering purchases and sales of frozen shellfish shall be retained for at least 2 years or for a period that exceeds the shelf-life of the product, if that is longer than 2 years.

(b) An individual package of shellstock, and each individual package of fresh or frozen shucked shellfish, shall have permanently affixed on the package, an easily visible, durable, waterproof tag or label approved by the Department.

(1) The tag or label on the shellstock container shall contain the following information: the dealer's name, address, shellfish permit number, growing area identification, the date of harvest, type and quantity of shellstock. When waxed cardboard boxes are used, the required information may be printed on the sides of the box.

(2) An individual package of fresh or frozen shucked shellfish shall have permanently recorded on the principal display panel the dealer's or processor's shellfish plant permit number and sell by date. The sidewall is considered the principal display panel. Packages of shucked shellfish containing 1/2 gallon—64 ounces—or more, shall have the dealer's shellfish plant permit number and the packer's name printed or embossed on the sidewall of the package, and the date shucked marked on both the lid and also the side wall or bottom. The date shall consist of either the number of the day of the year or the abbreviation for the month and number of the day of the month. The year shall be added for frozen shellfish. Frozen shellfish shall be clearly labeled as frozen in a type size of equal prominence to the name of the shellfish and located immediately adjacent thereto.

(c) Required label and product identification shall be provided in a legible and indelible form.

(d) The fraudulent use of tags or the placing of fraudulent or misleading information on the tags is considered a violation of this chapter.

(e) Public eating and drinking places licensed under the act of May 23, 1945 (P. L. 926, No. 369), known as the Public Eating and Drinking Place Law (35 P. S. §§ 655.1—655.13) and establishments authorized to conduct retail sales shall receive shellstock and fresh or frozen shucked shellfish labeled and identified according to subsections (b)—(d), and shall maintain for 90 days the tags and accurate records of the sources and quantity of all lots of shellfish. ]

§ 49.5. Inspection and sampling.

(a) The Department may inspect [ plants ] facilities falling under this chapter to ascertain compliance or noncompliance with this chapter. [ Plants involved in the interstate shipment of shellfish are subject to inspection by the Department and its employes and authorized agents at least four times per year. Other plants are subject to inspection by the Department and its employes and authorized agents at least once per year. ]

(b) [ The Department and its employes and agents may conduct additional inspections, including the following: ] After the Department's personnel present identification, the shellfish facility operator and its personnel shall allow the Department to determine if the shellfish facility is in compliance

with this chapter by allowing Department personnel access to the shellfish facility, allowing inspection and providing information and records to which the Department is entitled under the Food Act or this chapter, during the shellfish facility's hours of operation and other reasonable times if the facility is not open during normal business hours.

[ (1) Follow-up inspections.

(2) Inspections to determine compliance with environmental protection acts or regulations or requirements of an order issued by the Department. ]

(c) The Department and its [ employes ] employees and agents may also conduct inspections whenever a person presents information to the Department giving the Department reason to believe that there exists a violation of this chapter, of a [ permit ] shellfish facility certification issued under this chapter, or of orders issued by the Department.

(d) [ Nothing in this section places duty or obligation upon the Department to conduct a minimum number of inspections per year, to conduct a minimum number of inspections during a certain period or to inspect for particular reasons.

(e) ] The Department and its authorized agents may secure samples of shellfish and processed shellfish products for laboratory examination from any lot of shellfish and will be permitted to examine the records of the facility to obtain information pertaining to shellfish harvested, purchased, received, processed, sold, held, distributed or shipped, and to personnel employed.

[ (f) ](e) The Department or its authorized agent is authorized to [ embargo ] detain a shellfish product if there is cause to believe it is adulterated or misbranded. It is unlawful to remove or dispose of [ an embargoed ] a detained product without [ permission of one of the following:

(1) The Department or its authorized agent who placed the embargo.

(2) A court. ] a determination of the Secretary, in accordance with section 6 of the Food Act (31 P. S. § 20.6), authorizing the removal or disposition.

[ (g) ](f) Laboratory analyses to be performed shall be conducted in accordance with the most current edition of the following:

(1) The American Public Health Association's *Recommended Laboratory Procedures for the Examination of Seawater and Shellfish*[ , available from: American Public Health Association, 1015 15th Street, N. W., Washington, D.C. 20005, (202) 789-5600 ].

(2) The United States Food and Drug Administration's *Bacteriological Analytical Manual*[ , available from: Association of Official Analytical Chemists, Inc., 1111 N. 19th Street, Suite 210, Arlington, VA 22209, (703) 522-3032 ].

(3) *Official Methods of Analysis of the Association of Official Analytical Chemists*[ , available from: Association of Official Analytical Chemists, Inc., 1111 N. 19th Street, Suite 210, Arlington, VA 22209, (703) 522-3032 ].

(4) *Compendium of Methods for the Microbiological Examination of Foods*, compiled by the American Public Health Association's Technical Committee on Microbiological Methods for Foods, available from: American Public Health Association, 1015 15th Street, N. W., Washington, D.C. 20005, (202) 789-5600.

(5) *Standard Methods for the Examination of Water and Wastewater*, prepared and published jointly by the American Public Health Association, American Waterworks Association and the Water Pollution Control Federation, available from: American Public Health Association, 1015 15th Street, N. W., Washington, D.C. 20005, (202) 789-5600.

§ 49.6. Source.

(a) A [person] dealer in this Commonwealth may not have in his possession for processing, offer for sale or sell shellfish unless the shellfish have been obtained from interstate dealers who are [approved by the Department and are] listed in the United States Food and Drug Administration's Interstate Certified Shellfish Shippers List, or [intrastate] intrastate dealers [permitted] certified by the Department.

(b) A [person] dealer who knowingly or willfully alters or damages or loans or transfers to another [person] dealer a shellfish [permit] facility certification number or shellfish tags, or a [person] dealer who uses the shellfish [permit] facility certification number or shellfish tags other than the [person] dealer to whom it was issued, is in violation of this chapter.

§ 49.7. Freight-forwarders.

A freight-forwarder shall maintain shellfish (other than frozen shellfish) at an ambient temperature of 45° Fahrenheit while being transported. A freight-forwarder shall maintain shellfish (other than frozen shellfish) at an ambient temperature of 45° Fahrenheit when maintained in a staging or layover area for more than 1 hour.

Subchapter B. (Reserved)

(Editor's Note: As part of this proposed rulemaking, the Department is proposing to delete the existing text of §§ 49.11—49.20, which appears in 7 Pa. Code pages 49-8—49-12, serial pages (217570)—(217574).)

§§ 49.11—49.20. (Reserved).

Subchapter C. CONSTRUCTION AND MAINTENANCE OF PHYSICAL FACILITIES

§ 49.31. Submission of plans.

(a) Whenever a shellfish processing, depuration or controlled purification [plant] facility is constructed, remodeled or altered and whenever an existing structure is converted to use as a shellfish processing, depuration or controlled purification [plant] facility, properly prepared plans and specifications for the construction, remodeling or conversion shall be submitted to the Department for review and approval before construction, remodeling or conversion is begun.

(b) The plans and specifications [shall] must indicate the proposed layout, arrangement, mechanical plans and construction materials of work areas and the type and model of proposed fixed equipment and facilities. A shellfish processing [plant] facility, depuration or con-

trolled purification plant may not be constructed, remodeled, altered or converted unless the plans and specifications are first approved by the Department. The approval will be based on compliance with this [subchapter, § 49.15 (relating to storage) and Subchapters D and E (relating to shellfish processing: sanitary facilities and controls; and shucking area and equipment) and the Department's Guidelines for Preparation of Plans—Food Service Facilities. Copies of the guidelines may be obtained from the Department of Agriculture, Bureau of Food Safety and Laboratory Services, 2301 N. Cameron St., Harrisburg, Pennsylvania 17110, (717) 772-8353] chapter and the NSSP Model Ordinance.

(Editor's Note: As part of this proposed rulemaking, the Department is proposing to delete the existing text of §§ 49.32—49.34, which appears in 7 Pa. Code pages 49-14—49-15, serial pages (217576)—(217577).)

§§ 49.32—49.34. (Reserved).

Subchapter D. SHELLFISH PROCESSING: SANITARY FACILITIES AND CONTROLS

§ 49.41. Water supply.

(a) Potable water of sufficient quantity to meet the needs of the shellfish [plant] facility shall be provided from a source approved by the Department or be under permit from the Department of Environmental Protection. Water quality [shall] must meet the requirements of 25 Pa. Code Chapter 109 (relating to safe drinking water). Noncommunity water supplies shall be designed, constructed and operated in accordance with the Department of Environmental Protection's Bureau of Water Supply and Community Health Manual and 25 Pa. Code Chapter 109.

(b) Hot and cold water under pressure shall be provided to each plumbing fixture used for cleaning, washing or sanitizing purposes in:

\* \* \* \* \*

§ 49.42. Plumbing.

(a) Plumbing [shall] must be sized, installed and maintained in compliance with the provisions of the local plumbing code or, in the absence thereof, in a manner that prevents contamination of the water supply or the creation of an unsanitary condition.

\* \* \* \* \*

§ 49.43. Toilet facilities.

(a) [Conveniently located, separate toilets shall be provided for each sex. When the plant has fewer than ten employees, toilet facilities shall be provided, but need not be separate for each sex.] At least one conveniently-located toilet facility shall be provided for employees. There need not be a separate toilet facility for each gender.

\* \* \* \* \*

§ 49.44. [Lavatories] Hand wash sinks.

(a) [Lavatories] Hand wash sinks shall be provided, adequate in number and size for the number of [employees] employees, convenient to work areas and equipped with cold and hot running water. Hot water of at least [100°F] the minimum temperature required by the NSSP Model Ordinance shall be provided [either from a controlled temperature source with

a maximum temperature of 115°F, or ] from a hot and cold mixing or combination faucet. [ Lavatories ] Hand wash sinks shall be located within or immediately adjacent to toilets and within processing areas.

(b) [ There shall be at least one lavatory for each 15 employes.

(c) ] Hand cleansing soap or detergent and approved sanitary towels or other approved hand-drying devices shall be provided at [ lavatories ] hand wash sinks.

[ (d) Handwashing signs shall be posted at each lavatory location directing employes to wash their hands before starting work and after each interruption.

(e) ] (c) \* \* \*

§ 49.45. Sewage.

Sewage disposal systems shall be approved by the local authority and [ shall ] must comply with 25 Pa. Code Chapters 71, 73 and 243 (relating to the administration of sewage facilities planning program; standards for onlot sewage treatment facilities; and nuisances), and The Clean Streams Law (35 P. S. §§ 691.1—691.1001).

§ 49.47. [ Arthropod ] Insect and rodent control.

(a) Safe and effective measures shall be used to prevent the entry of insects, rodents and other vermin, and to kill and capture insects and vermin which enter the [ plant ] facility despite other control measures.

\* \* \* \* \*

(d) The storage and use of pesticides in [ shellfish plants ] a shellfish facility shall be prohibited unless used in full compliance with the manufacturer's label or used under the control of a certified pesticide applicator.

Subchapter E. SHUCKING AREA AND EQUIPMENT

§ 49.51. Shucking.

\* \* \* \* \*

(d) [ Shellfish shucking and packing operations shall be conducted in separate rooms and shall be protected from contamination by splash or by other means from adjacent areas. Packing rooms shall be of sufficient size to permit sanitary handling of the product and thorough cleaning of the equipment.

(e) When shucking and packing operations occur in separate rooms, a delivery window or area shall be provided so that shuckers do not have direct access to the packing area.

(f) ] A shellfish shucker may not go into or through the packing room for any purpose, except when he operates in a dual shucking packing capacity. If the shucker is operating in a dual capacity, [ he ] the shucker shall first change to clean clothing and thoroughly wash his hands and exposed portions of his arms.

[ (g) ] (e) \* \* \*

§ 49.53. Utensils and equipment construction.

\* \* \* \* \*

(b) The Shellfish Industry Equipment Construction Guides, developed for use with the Public Health Service-States-Industry Cooperative Program for the Certification of Interstate Shellfish Shippers, [ published by the United States Department of Health and Human

Services, Appendix B of the 1988 NSSP Manual, and the uniform sanitation standards and criteria established by the National Sanitation Foundation, available from: National Sanitation Foundation, Post Office Box 1468, 3475 Plymouth Road, Ann Arbor, Michigan 48106, (313) 769-8010, ] are incorporated by reference.

\* \* \* \* \*

§ 49.54. Bactericidal treatment of utensils and equipment.

(a) Adequate cleaning facilities, including three-compartment sinks, or utensil washing machines, brushes, detergents, sanitizers, hot water and pressure hoses shall be available for use within the shellfish [ plant ] facility for proper cleaning and sanitizing of equipment and utensils.

\* \* \* \* \*

(c) If there is a need for a slop sink or device to discard liquid waste, the sink or device shall be provided in addition to the three-compartment sink. Cleaning wastes may not be emptied into sinks used for hand washing, or the processing of shellfish or the cleaning and sanitizing of utensils.

\* \* \* \* \*

(e) Equipment too large or impractical to treat by the methods in subsection (c) or (d) may be [ treated using one of the following methods ] cleaned, followed by spraying or swabbing the equipment with a chemical sanitizing solution of at least twice the minimum strength required for the particular sanitizing solution when used for immersion sanitization. This may be accomplished by either of the following systems:

(i) [ With live steam from a hose, in the case of equipment in which steam can be confined ] A clean-out-of-place system (C.O.P.) that allows the equipment to be moved (for cleaning purposes) from the position in which it is ordinarily used.

(ii) [ By rinsing with boiling water ] A central cleaning system that pipes a supply of hot or cold water, with or without chemicals, to a number of cleaning stations placed throughout the shellfish processing area.

[ (iii) By spraying or swabbing with a chemical sanitizing solution of at least twice the minimum strength required for the particular sanitizing solution when used for immersion sanitization. ]

\* \* \* \* \*

§ 49.55. Equipment and utensil handling and storage.

\* \* \* \* \*

(c) Unused equipment and materials not necessary to [ plant ] facility operation may not be stored in rooms used for [ shell stock ] shellstock storage, shucking, packing, repacking or in equipment and container store rooms.

§ 49.56. General maintenance.

\* \* \* \* \*

(b) Only authorized equipment and persons shall be permitted in the shellfish processing area. Dogs, cats, birds or other animals or unauthorized persons may not

be allowed in areas of the shellfish [ plant ] facility that are used for processing, holding, storing or transporting of shellfish except that patrol dogs accompanying security or police officers are permitted.

Subchapter F. [ EMPLOYE ] EMPLOYEE HEALTH  
AND CLEANLINESS

§ 49.61. Health.

(a) A person, while infected with a disease in a communicable form that can be transmitted by foods or who is a carrier of organisms that cause such a disease, or while afflicted with a boil, an infected wound or an acute respiratory infection, may not work in a shellfish [ plant ] facility in a capacity in which there is a likelihood of the person contaminating food or food-contact surfaces with pathogenic organisms or transmitting disease to other persons.

(b) An owner or manager who has reason to suspect that an [ employe ] employee has contracted a communicable disease shall immediately notify the Department. Pending appropriate action by the health officials, the [ employe ] employee shall be excluded from the [ plant ] facility.

§ 49.62. Cleanliness.

(a) [ Employes ] Employees and other persons who handle shellfish shall wash their hands and exposed portions of their arms with soap and warm water before beginning work, and during work as often as necessary following other activities, such as smoking, eating, cleaning or visits to the toilet. Hands, or rubber gloves when used, shall be washed and sanitized before manually handling shellfish.

\* \* \* \* \*

(c) [ Employes ] Employees shucking or handling shellfish meat shall wear clean aprons or coats and effective hair restraints. When manual handling of shellfish meat becomes necessary, sanitized rubber gloves or the equivalent shall be worn, or the hands shall be washed and [ disinfected ] sanitized immediately before the manual handling. Finger cots, gloves or shields, if worn by shuckers, shall be sanitized as often as necessary and shall be made of nonabsorbent material.



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July 21, 2006

Independent Regulatory Review Commission  
ATTN: Kim Kaufman, Director  
333 Market Street, 14<sup>TH</sup> Floor  
Harrisburg, PA 17120

**RE: FINAL-FORM REGULATION**  
**Department of Agriculture**  
**7 Pa. Code Chapter 49**  
**Shellfish**  
**Proposed Rulemaking: 36 Pa. Bulletin 936 (February 25, 2006)**  
**Approved by Office of General Counsel: June 28, 2006**

Dear Mr. Kaufman:

Please find enclosed a copy of the above-referenced final-form regulation. This material includes copies of the Preamble and Annex "A". Copies of the Notice of Proposed Rulemaking and Regulatory Analysis Form are also enclosed. I respectfully request the Independent Regulatory Review Commission review and approve the above-referenced final-form regulation in accordance with the requirements and procedures of the Regulatory Review Act.

This Department's responses to the comments received from the Independent Regulatory Review Commission (IRRC) with respect to the proposed regulation are set forth in the Preamble to the final-form regulation. There were no commentators other than IRRC. Copies of this final-form regulation have been delivered to the appropriate Legislative Committees (the House and Senate Agricultural and Rural Affairs Committees). In response to the requirement (at 71 P.S. § 745.5a(b) and 1 Pa. Code § 307.2(c)(7)) that this Department provide the names and addresses of commentators who requested additional information on the final-form regulation, the Department hereby relates that there were no such commentators.

The Department will provide you with any assistance you may require to facilitate a thorough review of this final-form regulation. Thank you for your attention to this matter.

Sincerely,

  
Dwight Jared Smith  
Assistant Counsel

Enclosures

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

RECEIVED

I.D. NUMBER: 2-151  
 SUBJECT: SHELLFISH  
 AGENCY: DEPARTMENT OF AGRICULTURE



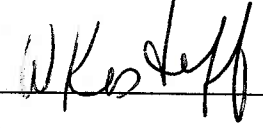

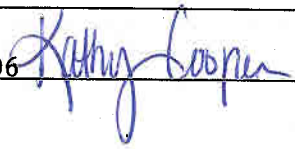
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INDEPENDENT REGULATORY  
REVIEW COMMISSION

**TYPE OF REGULATION**

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

**FILING OF REGULATION**

DATE	SIGNATURE	DESIGNATION
7-21-06		<b>HERSHEY</b> HOUSE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS
7-21-06		<b>DALEY</b>
7-21-06		<b>WAUGH</b> SENATE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS
7-21-06		<b>O'PAKE</b>
7-21-06		<b>IRRC</b> INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)