

**WEST VIRGINIA  
SECRETARY OF STATE  
NATALIE E. TENNANT  
ADMINISTRATIVE LAW DIVISION**

Form #2

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2009 JUN 29 PM 3:40

OFFICE WEST VIRGINIA  
SECRETARY OF STATE

**NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE**

AGENCY: West Virginia Department of Agriculture TITLE NUMBER: 61

RULE TYPE: Legislative CITE AUTHORITY: 19-29-1.3.4

AMENDMENT TO AN EXISTING RULE: YES  NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: \_\_\_\_\_

TITLE OF RULE BEING AMENDED: \_\_\_\_\_

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 23B

TITLE OF RULE BEING PROPOSED: West Virginia Shellfish Rule

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON July 27 AT 4:00 PM ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

West Virginia Department of Agriculture  
Regulatory and Environmental Affairs  
Herma Johnson, Director  
1900 Kanawha Blvd., East  
Charleston, WV 25305

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.



Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL



State of West Virginia  
**DEPARTMENT OF AGRICULTURE**  
Gus R. Douglass, Commissioner

Janet L. Fisher  
Deputy Commissioner

Steve Hannah  
Deputy Commissioner

**SUMMARY OF PROPOSED RULE**  
**West Virginia Shellfish Rule**  
**Title 61 – Series 23B**  
**NEW RULE**

This rule establishes the minimum requirements necessary to regulate the interstate and intrastate commerce of molluscan shellfish and to establish a program to protect the public health of consumers by assuring the sale or distribution of shellfish from safe sources and assuring shellfish have not been adulterated during cultivating, harvesting, processing, shipping, or handling.



State of West Virginia  
**DEPARTMENT OF AGRICULTURE**  
Gus R. Douglass, Commissioner

Janet L. Fisher  
Deputy Commissioner

Steve Hannah  
Deputy Commissioner

**STATEMENT OF CIRCUMSTANCES**  
**WEST VIRGINIA SHELLFISH RULE**  
**TITLE 61-SERIES 23B**  
**NEW RULE**

West Virginia must become a member state in the National Shellfish Sanitation Program/Interstate-Intrastate Shellfish Sanitation Conference in order for businesses to ship shellfish. This rule, along with standardization of our Aquaculture Officer will allow shipment of shellfish.

West Virginia businesses approached the Department requesting participation in this program. The fresh shellfish market is an important consumer segment of our economy for people who want fresh, healthy products, variety and source of protein. West Virginia is geographically positioned to be a regional gateway for fresh seafood/shellfish distribution and interstate business expansion to points West.

APPENDIX B

**FISCAL NOTE FOR PROPOSED RULES**

Rule Title: West Virginia Shellfish Rule

Type of Rule:  Legislative  Interpretive  Procedural

Agency: West Virginia Department of Agriculture

Address: 1900 Kanawha Blvd., East  
Charleston, WV 25305

Herma Johnson

Phone Number: 304-558-2227 Email: hjohnson@ag.state.wv.us

**Fiscal Note Summary**

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

This is a new rule for the Department of Agriculture. Estimates will be difficult to determine; however, initial start up of any program is costly. We know of two firms that currently are interested; however, after implementation, we feel more will apply to be part of the program. Currently, businesses in West Virginia are prohibited from shipping shellfish interstate per the United States Food and Drug Association until such time WVDA becomes a member state in the National Shellfish Sanitation Program. An Aquaculture Officer is employed with the Department; however, standardization for this officer must be completed prior to inspections, with continued training as necessary per FDA Standards. This training is only offered out of state and inspections are required twice a year at each facility; more, should there be violations. A fee of \$100.00 per facility per year is proposed to help offset these costs.

**Fiscal Note Detail**

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

<b>FISCAL YEAR</b>			
Effect of Proposal	Current Increase/Decrease (use "-")	Next Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
<b>1. Estimated Total Cost</b>	0.00	0.00	5,000.00
Personal Services			
Current Expenses			
Repairs & Alterations			
Assets			
Other			
<b>2. Estimated Total Revenues</b>	0.00	0.00	200.00

Rule Title: \_\_\_\_\_

Rule Title: West Virginia Shellfish Rule

**3. Explanation of above estimates (including long-range effect):**

Please include any increase or decrease in fees in your estimated total revenues.

The above estimates include firms we are currently aware of that want to participate in this program. The proposed fee per facility per year is \$100.00 with a penalty of \$100.00 if certificate is not applied for or renewed within the designated time frame in the proposed rule.

**MEMORANDUM**

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

Date: June 11, 2009

Signature of Agency Head or Authorized Representative

*Stoneburner*

**TITLE 61  
LEGISLATIVE RULE  
WEST VIRGINIA DEPARTMENT OF AGRICULTURE**

FILED

2009 JUN 29 PM 3:40

**SERIES 23B  
West Virginia Shellfish Rule**

OFFICE WEST VIRGINIA  
SECRETARY OF STATE

**§61-23A-1. General.**

1.1. Scope. -- Establishes the minimum requirements necessary to regulate the interstate and intrastate commerce of molluscan shellfish and to establish a program to protect the public health of consumers by assuring the sale or distribution of shellfish from safe sources and assuring shellfish have not been adulterated during cultivating, harvesting, processing, shipping, or handling.

1.2. Authority. -- W. Va. Code "19-29-1,3 and 4.

1.3. Filing Date. --

1.4. Effective Date. --

**§61-23A-2. Incorporated by Reference.**

2.1. The following documents are adopted in their entirety:

2.1.a. 21 CFR parts 123 and 1240.60;

2.1.b. The U. S. Food and Drug Administration "Fish and Fishery Products Hazards and Controls Guide";

2.1.c. 21 CFR part 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food.

2.1.d. The Seafood List, FDA's Guide to Acceptable Market Names for Seafood Sold In Interstate Commerce.

2.1.e. National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance" as published by the United States Food and Drug Administration. Copies can be obtained through the Interstate Shellfish Sanitation Conference web page at <http://www.issc.org>

**§61-23A-3. Definitions.**

3.1. In addition to definitions contained in the definition section of the Model Ordinance the following words and terms, when used in this chapter, shall have the

following meaning unless the context clearly indicates otherwise.

3.1.a. "Adulterated product that carries or contains any poisonous or deleterious substance or compound or pathogen in a quantity that may render it injurious to human health; was produced, processed, transported or held under unsanitary conditions; was treated with or exposed to chemicals, chemotherapeutics (drugs), heavy metals, pesticides, temperatures or any conditions in a manner that violates this rule; or was not produced according to an approved Hazard Analysis Critical Control Point (HACCP) plan.

3.1.b. "Commissioner" means the Commissioner of the West Virginia Department of Agriculture or his or her designee.

3.1.c. "Fish" means fresh or saltwater finfish, crustaceans, and other forms of aquatic life (including but not limited to, alligators, frogs, aquatic turtles, jellyfishes, and sea urchins and the roe of those animals) other than birds or mammals, and mollusks, where the animal life is intended for human consumption.

3.1.d. "Food Safety Hazard" means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

3.1.e. "ISSC" means the Interstate Shellfish Sanitation Conference.

3.1.f. "Official Sample" means any sample of water, soil, fish, shellfish, feed, drugs, pesticides, other ingredients, containers and/or products taken by the commissioner in accordance with this rule.

3.1.g. "Retail" means a retail sale which is defined as any sale to the ultimate consumer or his/her family, or to a person who will not sell the product.

3.1.h. "Wholesale" means any sale to any other person that the ultimate consumer or his or her family.

#### **§61-23A-4. Powers and Duties of the Commissioner.**

4.1. The commissioner may:

4.1.a. Enter and inspect, during reasonable hours, any location, where shellfish are processed, sold, stored or transported for human consumption. The inspection may include, but is not limited to photographing, videotaping, verifying, copying, and auditing computer files, records and papers relating to the processing of fish or shellfish for human food as is necessary to determine compliance with this rule and to investigate consumer complaints.

4.1.a.1. The inspection also may include, but is not limited to photographing, videotaping, verifying, and observing the premises, vehicles, personnel and activities;

4.1.b. Examine, sample and test water, fish, shellfish, pesticides, raw materials, other ingredients, containers, packaging, and products used or intended for use in the processing, storage, sale or transportation of shellfish for human consumption;

4.1.c. Cooperate with and enter into agreements with governmental agencies of this state and any other states, agencies of the federal government and foreign governments, and private associations in order to carry out the purpose and provisions of this rule;

4.1.d. Detain, embargo, or quarantine shellfish, processing areas, holding area, or transporting vehicles by affixing onto the detained, embargoed or quarantined item a tag or other appropriate marking, and giving notice of the detention, embargo or quarantine in writing to the processor, holder or transporter. The Commissioner may take this action when shellfish have been found to be or are believed to be:

4.1.d.1. In violation of the provisions of this rule; or

4.1.d.2. Infected with a human pathogen that could present a public health safety hazard.

4.1.d.2.a. Upon confirmation of a violation of this rule or the presence of a human pathogen, the Commissioner may seize and/or condemn the shellfish and order the shellfish disposed of as necessary to ensure the safety of consumers.

4.1.e. Embargo, detain, or quarantine a perishable product, even if the practical result is to bring about the involuntary disposal of the product.

4.1.e.1. The Commissioner shall exercise this power using all reasonable means to determine if the product is adulterated or otherwise not in compliance with this rule in as short a time frame as possible and shall promptly lift the embargo order if the product is found to be in compliance with this rule;

4.1.f. Issue, suspend, revoke or deny certifications in accordance with this rule;

4.1.g. Inspect and/or copy all records required by this rule. All requested records must be made available to the commissioner within 24 hours of his or her request. Records kept on computer files shall have a backup file on a separate disk, or hardcopy;

4.1.h. Develop appropriate inspection, embargo, quarantine, detainment and other regulatory forms as necessary for the enforcement of this rule; and

4.1.i. Assess civil penalties and refer violations to a court of competent jurisdiction for the violation of this rule as allowed under West Virginia laws. Nothing in this rule shall be construed as requiring the commissioner to assess a civil penalty, report for prosecution or institute an embargo, detainment, or quarantine for the violation of this rule when he or she believes that the public interest may best be served by a written notice.

4.2. The Commissioner shall be guided by the analytical test results when determining if shellfish conform to this rule and other rules and laws of the State of West Virginia.

**§61-23A-5. Certification.**

5.1. All commercial processors in the state of West Virginia shall:

5.1.a. Apply for a shellfish processors license and fall into at least one of the following categories;

5.1.a.1 Shellstock Shipper (SS)

5.1.a.2 Shucker – Packer (SP)

5.1.a.3. Repacker (RP)

5.1.a.4. Reshipper (RS); and

5.1.a.5. Depuration Processor (DP)

5.2. The Commissioner may deny, revoke or suspend license said certifications when he or she concludes that the seriousness of the violations, including irreparable harm to the environment, hazards to the health and safety of the public and economic damages to the public warrant that action.

5.3. The Commissioner shall not issue a shellfish dealer certification until the applicant has complied with all of the conditions set forth under in this rule. Once issued, the certificate remains valid unless voluntarily surrendered, suspended or revoked by the Commissioner. Once the certification is voluntarily surrendered, or revoked, the processor must reapply and submit all materials required under this section to receive a new certificate.

5.4 All shellfish certificates shall expire on June 30 of each year. The application shall be completed on forms supplied by the commissioner and returned no later than June 30 of the application year. The application shall be accompanied by a fee of one hundred dollars (\$100.00) per facility. The Commissioner shall add a penalty of \$100.00 to all certificates that are not applied for or renewed within this time limit. In no case shall a shellfish firm operate without a valid certificate issued by the Department. The certificate shall not be transferable with respect to the persons or locations.

**§61-23A-6. Laboratory Testing.**

6.1. The Commissioner of Agriculture shall establish and maintain or make provisions for approved laboratory testing facilities for the purpose of enforcing the analytical aspects

of this rule.

6.2. The methods used for analyzing samples will be those found in the Official Methods of Analysis by the Association of Analytical Chemists, or the United States, Food and Drug Administration Bacteriological Analytical Manual, or The Pesticide Analytical Manual, Volume I, and II, Foods and Feeds; other methods as approved by the commissioner, or as approved by the National Shellfish Sanitation Program under the 2007 version of the Guide for the Control of Molluscan Shellfish.

**§61-23A-7. Prohibited Acts.**

7.1. It is unlawful to:

7.1.a. Produce, hold, transport, sell or offer for sale shellfish in violation of this rule;

7.1.b. Sell or offer for sale shellfish for human consumption which is adulterated or not wholesome;

7.1.c. Remove any tag or order affixed by the Commissioner unless the removal is authorized by him or her;

7.1.d. Impede, hinder or otherwise prevent, or attempt to prevent the Commissioner in the performance of his or her duties in connection with the provisions of this rule;

7.1.e. Falsify or falsely log any values on any record or records required by this rule;

7.1.f. Remove or dispose of detained, embargoed, or quarantined shellfish by sale or otherwise without the permission of the Commissioner or the courts;

7.1.g. Continue shellfish operations until released from the embargo or cease and desist order by the Commissioner or the courts;

7.1.h. Process, sell or offer for sale to the public any molluscan shellfish unless it is obtained from a shellfish dealer listed in the most recent monthly publication of the Interstate Certified Shellfish Shippers as List published by the U.S. Food and Drug Administration;

7.1.i. Sell or offer for sale shellfish unless the label displays the acceptable market name or common name specified for the species in the most recent publication of "The Seafood List, FDA's Guide to Acceptable Market Names for Seafood Sold In Interstate Commerce";

7.1.j. Process shellfish for sale unless the processor has a valid certificate and inspected by the Commissioner or his or her designee;

## **§61-23A-8. Penalties.**

### **8.1. Civil Penalties**

8.1.a. Any person violating any of the provisions of this rule may be assessed a civil penalty of up to five hundred dollars for a first offense and up to five thousand dollars for subsequent offenses. In determining the amount of the civil penalty, the commissioner shall give due consideration to the history of previous violations of any person; the seriousness of the violation, including any irreparable harm to the environment, any hazards to the health and safety of the public and any economic damages to the public; and the demonstrated good faith of any person charged in attempting to achieve compliance with this rule before and after written notification of the violation.

8.1.b. The civil penalty is payable to the West Virginia Department of Agriculture and is collectable in any manner now or hereafter provided for the collection of debt. If any person liable to pay the civil penalty neglects or refuses to pay the same, the amount of the civil penalty, together with interest at ten percent, is a lien in favor of the state of West Virginia upon the property, both real and personal, of that person after the lien has been entered and docketed to record in the county where such property is situated. The clerk of the county, upon receipt of the certified copy of the lien, shall enter the lien to record without requiring payment of costs as a condition precedent to recording.

8.1.c. Nothing in this rule shall be construed as requiring the Commissioner to assess a civil penalty or to institute an embargo, detainment, quarantine or cease and desist order for violation of this rule when he or she believes that the public interest may best be served by a written notice of violation.

### **8.2. Criminal Penalties**

8.2.a. Any person who violates any provision of this rule is guilty of a misdemeanor, and upon conviction thereof:

8.2.a.1. Shall for the first offense be fined not less than fifty nor more than five hundred dollars;

8.2.a.2. Shall upon each subsequent offense be fined not less than one hundred nor more than one thousand dollars;

8.2.a.3. May be imprisoned in the county or regional jail not more than six months or both fined and imprisoned; and

8.2.a.4. Shall have his or her Shellfish Certificate suspended until the facility is in compliance with the provisions of this rule.

8.3. Magistrates have concurrent jurisdiction with circuit courts to enforce the provisions of this rule.

**§61-23A-9. Confidentiality of Trade Secrets.**

9.1. The commissioner may not make public information which relates to trade secrets and procedures, commercial or financial information obtained from a person or privileged or confidential information: Provided that when the information is necessary to carry out the provisions of this rule, this information may be revealed, subject to protective order, to any federal, state or local agency consultant or may be revealed, subject to protective order, at a closed hearing or in findings of fact issued by the commissioner.