



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF PUBLIC COMMENT PERIOD

AGENCY: Agriculture TITLE-SERIES: 61-23B
RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No
RULE NAME: West Virginia Shellfish

CITE STATUTORY AUTHORITY: §19-29-1, 3 and 4

COMMENTS LIMITED TO:

Written

DATE OF PUBLIC HEARING:

LOCATION OF PUBLIC HEARING:

DATE WRITTEN COMMENT PERIOD ENDS: 07/28/2023 10:00 AM

COMMENTS MAY BE MAILED OR EMAILED TO:

NAME: Jodee Martin

ADDRESS: WV Department of Agriculture

1900 Kanawha Boulevard, East, Charleston WV 25305

EMAIL: rulescomments@wvda.us

PLEASE INDICATE IF THIS FILING INCLUDES:

RELEVANT FEDERAL STATUTES OR REGULATIONS: Yes

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

INCORPORATED BY REFERENCE: Yes

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

PROVIDE A BRIEF SUMMARY OF THE CONTENT OF THE 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.

SUMMARIZE IN A CLEAR AND CONCISE MANNER CONTENTS OF CHANGES IN THE RULE AND A STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE:

Extension of the sunset date, incorporation by reference web address, updating laboratory testing requirements

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

N/A

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

N/A

C. ECONOMIC IMPACT OF THE RULE ON THE STATE OR ITS RESIDENTS:

N/A

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2023 Increase/Decrease (use "-")	2024 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services	0	0	0
Current Expenses	0	0	0
Repairs and Alterations	0	0	0
Assets	0	0	0
Other	0	0	0
2. Estimated Total Revenues	0	0	0

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

N/A

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Norman Bailey -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

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TITLE 61
LEGISLATIVE RULE
WEST VIRGINIA DEPARTMENT OF AGRICULTURE

SERIES 23B
WEST VIRGINIA SHELLFISH

§61-23B-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. --~~April 8, 2010.~~

1.4. Effective Date. --~~July 1, 2010.~~

1.5. Sunset Date. -- This rule shall terminate and have no further force or effect on August 1, 2033.

§61-23B-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's "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, U. S. Food and Drug Administration's Guide to Acceptable Market Names for Seafood Sold In Interstate Commerce; and

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

§61-23B-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 rule, have the following meaning unless the context clearly indicates otherwise.

3.1.a. "Adulterated" means a fish or fishery product 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 or products taken by the commissioner in accordance with this rule.

3.1.g. "Shellfish" means all species of:

3.1.g.1. Oysters, clams or mussels, whether;

3.1.g.1.A. Shucked or in the shell;

3.1.g.1.B. Raw, including post harvest processed;

3.1.g.1.C. Frozen or unfrozen;

3.1.g.1.D. Whole or in part; and

3.1.g.2. Scallops in any form, except when the final product form is the adductor muscle only.

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

§61-23B-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 areas, 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 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 copy all records required by this rule. All requested records shall 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 of the violation.

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.

§61-23B-5. Certification.

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

5.1.a. Apply for a shellfish processors certificate 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); or

5.1.a.5. Depuration Processor (DP).

5.2. The Commissioner may deny, revoke or suspend the certificate 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 certificate 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 or suspended or revoked by the Commissioner. Once the certificate is voluntarily surrendered, suspended or revoked, the processor must reapply for and submit all materials required under this section to receive a new certificate.

5.4. All shellfish certificates expire on June 30 of each year. The applicant shall complete the application on forms supplied by the Commissioner and return the application 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 persons or locations.

§61-23B-6. Laboratory Testing.

6.1. The Commissioner of Agriculture shall establish and maintain or contract with an approved laboratory testing facilities for the purpose of enforcing the analytical aspects of this rule.

6.2. The methods used for analyzing samples shall 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. The laboratory may use other methods approved by the Commissioner or approved by the National Shellfish Sanitation Program under the ~~2007~~ 2023 version of the Guide for the Control of Molluscan Shellfish. Only laboratories certified by a Laboratory Evaluation Officer in accordance with the NSSP Guide are able to perform NSSP methods.

§61-23B-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 issued 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"; or
- 7.1.j. Process shellfish for sale unless the processor has a valid certificate and has been inspected by the Commissioner or his or her designee.

§61-23B-8. Penalties.

8.1. Civil Penalties.

8.1.a. The Commissioner may assess any person violating any of the provisions of this rule 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 that 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 the 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 it, 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 the record in the county where the property is situated. The clerk of the county, upon receipt of the certified copy of the lien, shall enter the lien to the record without requiring payment of costs as a condition precedent to recording.

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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.

§61-23B-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.