



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: 61-23A
RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No
RULE NAME: West Virginia Fish Processing Rule
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: 07/28/2024 12:00 PM

COMMENTS MAY BE MAILED OR EMAILED TO:

NAME: Jodee Martin
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Charleston, WV 25305
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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:

Rule provides a vehicle for inspection of fish processing facilities in the state with the purpose of assuring the highest quality and safety of the finished product as possible.

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

updating CFR, extending the sunset date, striking 14.12 -14.20, striking 16.1.b.1 - 16.1.b.3., grading will require reinspection at appropriate intervals according the FDA Risk Guidance

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		
	2024 Increase/Decrease (use "-")	2025 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.

TITLE 61
LEGISLATIVE RULE
WEST VIRGINIA DEPARTMENT OF AGRICULTURE
SERIES 23A
WEST VIRGINIA FISH PROCESSING RULES

§§61-23A-1. General.

1.1. Scope. -- This rule is intended to provide a vehicle for uniform inspection of fish processing facilities in the state with the purpose of assuring the highest quality and safety of the finished product as possible.

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

1.3. Filing Date. -- ~~May 15, 1998.~~

1.4. Effective Date. -- ~~June 15, 1998.~~

1.5. Sunset Date. -- This rule shall terminate and have no further force or effect on August 1, 2034.

§§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 Guidance";

2.1.c. The U. S. Food and Drug Administration "National Shellfish Sanitation Program Manual of Operations Part I Sanitation of Shellfish Growing Areas" & "Part II Sanitation of the Harvesting, Processing and Distribution of Shellfish";

2.1.d. ~~21 CFR part 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food.~~ 21 CFR part 117 Current Good Manufacturing Practice, Hazardous Analysis, and Risk Based preventative Controls for Human Food.

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

§§61-23A-3. Definitions.

3.1. "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.

3.2. "Aquaculture" means the commercial production of fish or other aquatic life.

3.3. "Commissioner" means the Commissioner of Agriculture or his or her designee.

3.4. "Establishment number" means an official number assigned by the commissioner to each fish processing plant and included on the label or container of all fishery products produced by that plant.

3.5. "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.

3.6. "Fishery Product" means any human food product in which fish is a characterizing ingredient.

3.7. "Food safety hazard" means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

3.8. "Lot number" means a legible and permanently marked number on each container of cooked ready-to-eat and smoked fishery products which identifies the date the product was packaged.

3.9. "Modified atmosphere-packaging" means the food-packaging technique in which the air in the package or container is replaced by one or more gases, in various concentrations, before sealing. The purpose of this type of packaging is to extend the refrigerated shelf life of the product by limiting microbial growth or detrimental changes in the food.

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

3.11. "Processing" means handling, storing, heading, gutting, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, or holding. This definition does not apply to the operation of a retail establishment.

3.12. "Sanitary Zone" means a separation of operations by location, partition, air flow, or enclosed systems.

3.13. "Risk Assessment Basis" means considering grades from past inspections, violations, trends, conditions, observations and other information to estimate the likelihood of a danger or safety hazard occurring and to determine the frequency and priority of future inspections.

3.14. "Smoked or smoke-flavored fishery products" means the finished food prepared by: (1) Treating fish with salt (sodium chloride), and (2) Subjecting it to the direct action of smoke from burning wood, sawdust, or a similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

3.15. "Vacuum-packaged" means the food-packaging technique in which air in a package is removed before sealing.

3.16. "Water-phase salt content" means the percent salt(sodium chloride)in the finished product as determined by the method of analysis for water-phase salt content on the "Official Methods of Analysis of the Association of Official Analytical Chemists,"

3.17. "Wholesome" means in sound condition, clean, free from adulteration, and otherwise suitable for

use as human food.

§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, except fish hatcheries operated by the State of West Virginia or the United States of America, where fish or fishery products are processed, sold, stored or transported for human consumption. The inspection may include, but is not limited to photographing, video taping, verifying, copying, and auditing computer files, records and papers relating to the processing of fish 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, video taping, verifying, and observing the premises, vehicles, personnel and activities;

4.1.b. Examine, sample and test water, fish, pesticides, raw materials, other ingredients, containers, packaging, and products used or intended for use in the processing, storage, sale or transportation of fish or fishery products 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 fish or fishery products, 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 fish or fishery products 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 fish or fishery product and order the fish or fishery product 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 licenses 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. 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 whether fish or fishery products conform to this rule and other rules and laws of the State of West Virginia.

4.3. The Commissioner shall provide assistance, education, information, and training on The Hazard Analysis Critical Control Point system to improve the safety and quality of the aquaculture industry in West Virginia.

§§61-23A-5. Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) Plan.

5.1. Hazard analysis. Every processor shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. These food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

5.2. Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in subsection 5.1. of this section. A HACCP plan shall be specific to:

5.2.a. Each location where fish and fishery products are processed by that processor; and

5.2.b. Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in subsection 5.3. of this section are identical for all fish and fishery products grouped together or for all production methods grouped together.

5.3. The contents of the HACCP plan. The HACCP plan shall, at a minimum:

5.3.a. List the food safety hazards that are reasonably likely to occur, as identified in accordance with subsection 5.1 of this section, and that thus must be controlled for each fish and fishery product. The processor shall list food safety hazards that are reasonably likely to occur as a result of the following:

5.3.a.1. Natural toxins;

5.3.a.2. Microbiological contamination;

5.3.a.3. Chemical contamination;

5.3.a.4. Pesticides;

5.3.a.5. Drug residues;

5.3.a.6. Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;

5.3.a.7. Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be consumed without a process sufficient to kill the parasites;

5.3.a.8. Unapproved use of direct or indirect food or color additives; and

5.3.a.9. Physical hazards;

5.3.b. List the critical control points for each of the identified food safety hazards, including as appropriate:

5.3.b.1. Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and

5.3.b.2. Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest;

5.3.c. List the critical limits that must be met at each of the critical control points;

5.3.d. List the procedures, and their frequency, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

5.3.e. Include any corrective action plans that have been developed in accordance with subsection 6.2. of this rule, to be followed in response to deviations from critical limits at critical control points;

5.3.f. List the verification procedures, and their frequency, that the processor will use in accordance with subsection 7.1. of this rule;

5.3.g. Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

5.3.h. The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor. This signature signifies that the HACCP plan has been accepted for implementation by the firm. The HACCP plan shall be dated and signed:

5.3.h.1. Upon initial acceptance;

5.3.h.2. Upon any modification; and

5.3.h.3. Upon verification of the plan in accordance with subdivision 7.1.a of this rule.

5.4. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with subsection 10.2 of this rule they need not be included in the HACCP plan, and vice versa.

5.5. A processor which fails to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary or otherwise fail to operate in accordance with the requirements of this rule, renders the fish or fishery products of that processor adulterated. The Commissioner or his/her designee shall determine whether a processor's actions are consistent with ensuring the safety of food through an evaluation of the processors overall implementation of its HACCP plan, if one is required.

§§61-23A-6. Corrective Actions.

6.1. Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:

6.1.a. Following a corrective action plan that is appropriate for the particular deviation, or

6.1.b. Following the procedures set forth in subsection 6.3 of this section.

6.2. A processor may develop written corrective action plans, which become part of the processor's HACCP plan in accordance with section 5.7 of this rule, by which the processor predetermines the corrective actions that the processor will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

6.2.a. No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

6.2.b. The cause of the deviation is corrected.

6.3. When a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

6.3.a. Segregate and hold the affected product, at least until the requirements of subdivisions 6.3.b. and 6.3.c. of this section are met;

6.3.b. Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform the review;

6.3.c. Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

6.3.d. Take corrective action, when necessary, to correct the cause of the deviation; and

6.3.e. Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with section 9 of this rule., to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

6.4. The processor shall fully document all corrective actions taken in accordance with this section in

records that are subject to verification in accordance with paragraph 7.1.c.2. of this rule and the recordkeeping requirements of section 8 of this rule.

§61-23A-7. Verification.

7.1. Overall verification. Every processor shall verify that its HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:

7.1.a. Reassessment of the HACCP plan. A reassessment of the adequacy of the HACCP plan is required whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. These changes may include changes in the following: Raw materials or the source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with section 9 of this rule. Processors are required to immediately modify their HACCP plan whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of section 5 of this rule.

7.1.b. Ongoing verification activities. Ongoing verification activities include:

7.1.b.1. A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;

7.1.b.2. The calibration of process-monitoring instruments; and,

7.1.b.3. At the option of the processor, the performing of periodic end-product or in-process testing; and,

7.1.c. Records review. A review, including the signing and dating, by an individual who has been trained in accordance with section 9 of this rule, of the records that document:

7.1.c.1 The monitoring of critical control points. The purpose of this review is, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;

7.1.c.2. The taking of corrective actions. The purpose of this review is, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with section 6 of this rule. This review shall occur within 1 week of the day that the records are made; and

7.1.c.3 The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews is, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

7.2. Corrective actions. A processor shall immediately follow the procedures in section 6 of this rule. whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

7.3. Reassessment of the hazard analysis. Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. These changes may include, but are not limited to changes in: Raw materials or the source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with section 9 of this rule.

7.4. Recordkeeping. The processor shall document, in records that are subject to the recordkeeping requirements of section 8 of this rule, the calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraphs 7.1.b.2. through 7.1.b.3. of this section

§§61-23A-8. Records.

8.1. General record requirements. All records required by this section shall include:

- 8.1.a. The name and location of the processor or importer;
- 8.1.b. The date and time of the activity that the record reflects;
- 8.1.c. The signature or initials of the person performing the operation; and

8.1.d. Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

8.2. Record Retention

8.2.a. All records required by this section shall be retained at the processing facility or importer's place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.

8.2.b. Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility or the importer's place of business in the United States for at least 2 years after their applicability to the product being produced at the facility.

8.2.c. A processor may transfer records to a reasonably accessible location other than the packing site only if the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited at a remote processing site; however, a processor is required to immediately return the records to the packing site for official review by the Commissioner or his/her designee upon demand.

8.3. Official review. All records required by this section and all plans and procedures required by this section shall be available for review and copying by the Commissioner or his/her designee at reasonable times.

8.4. Records maintained on computers. A processor or importer may maintain its records on computers, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

8.5. Every operator of a fish processing plant shall keep a record of every transaction involving the sale and distribution of processed fish and fishery products. The records, in addition to the names and addresses of the persons or firms involved shall contain the code numbers of each lot involved.

8.6. Fish processing records shall be legibly written, printed or filed on electronic media in English and shall identify the product processed, identifying lot code, the number of containers per coding interval, and the year, and day and period when each lot was packaged.

§§61-23A-9. Training.

9.1. In order to qualify to perform the following functions, an individual shall submit documentation to the Commissioner that he or she has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or is otherwise qualified through job experience to perform these functions. The Commissioner may approve job experience to qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum as documented by the individual. A qualified individual may:

9.1.a. Develop a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of subsection 5.2 of this rule;

9.1.b. Reassess and modify the HACCP plan in accordance with the corrective action procedures specified in subdivision 6.3.c. of this rule, the HACCP plan in accordance with the verification activities specified in subdivision 7.1.a. of this rule, and the hazard analysis in accordance with the verification activities specified in section 7.3 of this rule; and

9.1.c. Perform the record review required by subdivision 7.1.c. of this rule; The qualified individual need not be an employee of the processor.

§§61-23A-10. Sanitation Control Procedures.

10.1. Sanitation SOP. The Commissioner recommends each processor have and implement a written sanitation standard operating procedure (SSOP) or similar document that is specific to each location where fish and fishery products are produced. The Commissioner recommends the SSOP specify how the processor will meet those sanitation conditions and practices that are to be monitored in accordance with subsection 10.2 of this section.

10.2. Sanitation monitoring. Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in 21 CFR Part 110 adopted by reference in subdivision 2.1.d. of this rule, that are both appropriate to the plant and the food being processed and relate to the following:

10.2.a. The safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;

10.2.b. The condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

10.2.c. The prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;

10.2.d. The maintenance of hand washing, hand sanitizing, and toilet facilities;

10.2.e. The protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

10.2.f. The proper labeling, storage, and use of toxic compounds;

10.2.g. The control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and

10.2.h. The exclusion of pests from the food plant.

10.2.i. The processor shall correct in a timely manner, those sanitation conditions and practices that are not met.

10.3. Sanitation control records. Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by subsection 10.2 of this section. These records are subject to the requirements of section 8 of this rule.

10.4. Relationship to HACCP plan. Sanitation controls may be included in the HACCP plan, required by subsection 5.3 of this rule; however, to the extent that they are monitored in accordance with subsection 10.2 of this section they need not be included in the HACCP plan.

§§61-23A-11. Processor Licensing.

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

11.1.a. Apply for a fish processing license from the Commissioner;

11.1.b. Submit a HACCP plan to the Commissioner with the request for licensing;

11.1.b.1. After the review of the HACCP Plan is considered adequate, the Commissioner may provisionally approve the HACCP Plan. Once the processor has successfully completed all the other requirements for licensing and has been issued a license, he/she may operate under the provisionally approved HACCP plan. The Commissioner shall review the actual operation of the HACCP plan, and may require revisions as necessary to protect the health and safety of consumers.

11.1.c. Submit for review and approval three(3) complete sets of blueprints or drawings with specifications that fully and clearly illustrate plans to which the applicant proposes to have the facility constructed or modified;

11.1.d. Submit to the West Virginia Department of Agriculture, with the request for licensing, a letter from the State or County Health Authorities stating that the plant's sewage system is acceptable;

11.1.e. Submit to the West Virginia Department of Agriculture, with the request for licensing, a letter from the State or County Health Authorities stating that the plant's potable water supply has been tested and is acceptable;

11.1.f. Submit the fee required in this subdivision along with application for license:

Class	Average Finished Product Pounding Processed Per Year	Annual Fee
Small	1-25,000	\$25.00
Medium	25,001 - 50,000	\$50.00
Large	over 50,000	\$75.00; and

11.1.g. Submit required materials for each location of processing operations on forms prescribed by the Commissioner.

11.2. Before issuing any license required by the provisions of this rule, the Commissioner shall inspect the applicant's establishment and review the HACCP plan and other license application materials. If the Commissioner is satisfied that the establishment is clean and sanitary, properly equipped, has met the requirements set forth by this rule and all employees are properly trained and have met requirements set forth in this rule, he or she shall issue the license which shall designate the establishment number of the plant.

11.3. Processors are responsible for having potable water supplies retested and certified by local or state health authorities:

11.3.a. Annually for approved public water supplies; and

11.3.b. Every six months for private wells or springs.

11.4. The Commissioner may deny, revoke or suspend any fish processing license 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.

11.5. The Commissioner shall not issue a "Fish Processing License" until the applicant has complied with all of the conditions set forth under this section. Once issued, the "Fish Processing License" remains valid unless voluntarily surrendered, suspended or revoked by the Commissioner. Once the Fish Processor License is voluntarily surrendered, or revoked, the processor must reapply and submit all materials required under this section to receive a new license.

§§61-23A-12. Buildings and Facilities.

12.1. The fish or fishery product must be processed in a manner to prevent contamination by exposure to areas, utensils, or equipment involved in earlier processing steps, refuse, or other safety hazards.

12.2. All utensils and surfaces of equipment that contact food during processing shall be cleaned and sanitized with effective cleaning and sanitizing preparations at the following intervals:

12.2.a. Cleaned at the end of the days operations;

12.2.b. Sanitized before the beginning of the days operations; and

12.2.c. Cleaned and sanitized after interruptions of the food processing process during which food

contact surfaces may have become contaminated.

12.3. Until properly cleaned and sanitized, employees' hands, gloves and outer garments and utensils and surfaces of equipment that contact raw product shall not contact 1) The fish or fishery product after it has entered the smoking chamber, 2) cooked product, or 3) ice.

12.4. Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, or food-contact surfaces to wash and sanitize their hands before they start work, after each absence from their post of duty, and when their hands have become soiled or contaminated, shall be conspicuously posted in the processing rooms, finished product packing rooms, and in all other areas where sanitary conditions are required.

12.5. Handwash facilities shall be conveniently located to permit use by all employees in fish preparation and processing areas. Handwashing facilities shall be accessible to these employees at all times.

12.6. Handwashing facilities shall be located in or immediately adjacent to toilet rooms or their vestibules, and readily understandable signs directing employees to wash and sanitize their hands after using toilet facilities and before returning to the processing or packing areas shall be conspicuously posted.

§§61-23A-13. Equipment.

13.1. All plant equipment and utensils must be properly maintained and designed and of such material and workmanship as to be adequately cleaned, sanitized and corrosion resistant. The design, construction, and use of equipment must prevent the contamination of food with lubricants, fuel, metal, fragments, wood fragments, contaminated water, or any other contaminants. All equipment must be installed and maintained as to facilitate the cleaning and sanitizing of the equipment and all adjacent spaces. Surfaces that contact food must be corrosion resistant when in contact with food. Food contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended purpose and the action of the food, and cleaning and sanitizing agents. Food contact surfaces must be maintained to protect the food from being contaminated from any source, including unlawful indirect food additives.

13.2. The containers used to transport, brine or store fish shall not be nested while they contain fish or otherwise handled during processing or storage in a manner conducive to contamination of their contents.

13.3. The cleaning and sanitizing of utensils and portable equipment shall be conducted in an area set aside for these purposes or in a segregated fashion so as to prevent contamination of the food.

13.4. Each freezer and cold storage compartment used to store and hold food shall be fitted with a thermometer or temperature recording device installed to show the temperature accurately within the compartment.

13.5. Instruments and controls used for measuring, regulating, or recording temperatures shall be accurate and maintained on a regular schedule, and adequate in number for their designated uses.

13.6. Thermometers or other temperature-measuring devices shall have an accuracy of + or - 2° Fahrenheit and graduations shall not exceed 2° Fahrenheit within a range of 10° Fahrenheit of the processing temperature. The accuracy of these devices shall be maintained.

13.7. Compressed air or other gases used to clean food-contact surfaces or equipment shall be treated or filtered in such a way that food is not contaminated with unlawful indirect food additives.

13.8. Each smoking chamber shall be equipped with a temperature monitoring device.

13.9. Equipment and utensils shall be positively marked or segregated in some way to ensure that equipment and utensils used to handle raw fish or fishery products are not used to handle fish or fishery products which have entered the smoking chamber or cooked ready-to-eat fish or fishery products until they are properly cleaned and sanitized.

§§61-23A-14. Product Management.

14.1. The evisceration of fish shall be conducted in an area segregated or separate from other processing operations. The evisceration shall be performed with minimal disturbance of the fish's intestinal tract contents. The fish, including the body cavity, shall be washed thoroughly with a vigorous spray or a continuous water flow system immediately following evisceration.

14.2. Sanitary zones shall be established around areas where unpackaged cooked or smoked product is handled and stored. Objects and employees that have come into contact with waste, raw product, or other insanitary objects shall be excluded from these areas.

14.3. Packaging material, equipment, employees, and in-process materials that enter a sanitary zone shall be treated in a manner that will minimize the risk of the introduction of microorganisms.

14.4. All operations including receiving, processing, and packaging shall be conducted utilizing clean and sanitary methods and shall be conducted as rapidly as practical and at temperatures that will not cause any material increase in bacterial or other microorganic content or any deterioration or contamination of the processed fish.

14.5. Unpackaged cooked ready-to-eat and smoked fish or fishery products shall be handled only with clean and sanitized hands, gloves or utensils. These products shall be handled with a minimum of manual contact.

14.6. Unprocessed fish, raw fish and fishery products, cooked ready-to-eat fishery products, smoked fishery products, and raw molluscan shellfish shall be physically separated from each other during refrigerated storage to minimize the possibility of cross contamination.

14.7. Refrigeration units used to store fish, fishery products, or raw materials during any stage before and during processing shall operate at a temperature at or below 40°F (4.4°C). All processed fish shall be distributed and sold at internal temperatures that do not exceed 40°F (4.4°C) except that processed fish that have a water-phase salt level of at least 17 percent do not require refrigeration.

14.8. Fish and fishery products shall be protected against contamination including contaminants which may drip, drain, or be drawn into the product before, during and after processing.

14.10. Shipping containers, retail packages, and shipping records relating to processed fish shall indicate by appropriate labeling, the perishable nature of the product. Frozen product shall indicate that the product shall remain frozen until thawed at refrigerated temperatures and shall not be refrozen. Refrigerated product shall clearly and conspicuously state "Keep Refrigerated at 40°F or below".

14.11. Each container of fishery product processed in accordance with the provisions of this rule shall have an establishment number which is legible and permanently marked. This establishment number shall

identify the plant where the product was produced. Each container of fishery products shall have a lot number which is legible and permanently marked. This lot number shall identify the date the product was produced.

~~14.12. Brining shall be carried out so the temperature of the brine does not exceed 60° F at the start of brining. If the brining time exceeds four hours, the brining must take place in a refrigerated area at 40° F or lower.~~

~~14.13. Different species of fish shall not be mixed in the same brining tank.~~

~~14.14. For dry salting, the fish shall be returned to a refrigerated area of 40° F or lower immediately after the application of salt.~~

~~14.15. Fish shall be rinsed with potable water after brining.~~

~~14.16. For hot process smoked fish to be air packaged, a controlled process shall be used to heat fish to a continuous temperature of at least 145° F through out each fish for a minimum of 30 minutes for fish brined to contain not less than 2.5 percent water phase salt in the loin muscle of the finished product.~~

~~14.17. For hot process smoked fish to be vacuum or modified atmosphere packaged, a controlled process shall be used to heat fish to a continuous temperature of at least 145° F through out each fish for a minimum of 30 minutes for fish brined to contain not less than 3.5 percent water phase salt in the loin muscle of the finished product.~~

~~14.18. Cold process smoked fish shall be produced by a control process that utilizes a temperature monitoring system positioned within the smoking chamber to assure that all products do not exceed process temperatures in accordance with one of the following methods:~~

~~14.18.a. The temperature in the smoking chamber does not exceed 90° F during a drying and smoking period that does not exceed 20 hours; or~~

~~14.18.b. The temperature in the smoking chamber does not exceed 50° F during a drying and smoking period that does not exceed 24 hours; or~~

~~14.18.c. The temperature in the smoking chamber does not exceed 120° F during a drying and smoking period that does not exceed 6 hours for cold process sablefish. —~~

~~14.19. For cold process fish to be air packaged, only fish that have been brined to contain not less than 2.5 percent water phase salt in the loin muscle of the finished product may be used.~~

~~14.20. For cold process fish to be vacuum or modified atmosphere packaged, only fish that have been brined to contain not less than 3.5 percent water phase salt in the loin muscle of the finished product may be used.~~

§§61-23A-15. Employees.

15.1. All employees shall thoroughly wash and sanitize their hands and forearms before starting work. All employees shall wash and sanitize hands during work hours as often as necessary to remove soil and contamination, after working with raw fish products, before handling ready-to-eat products, after visiting the toilet room, after using tobacco, or after eating or drinking.

15.2. Effective hair and beard restraints shall be used by employees who process, prepare or handle food to keep exposed hair and beards from food or food contact surfaces.

15.3. No person shall use tobacco, eat, or drink in food receiving, processing, packaging, storage or handling areas.

15.4. Employees shall maintain a high degree of personal cleanliness and shall conform to good hygienic practices during all working periods. Personal cleanliness includes clean clothing.

15.5. Employees shall remove all insecure jewelry, and shall remove from the hands and forearms any jewelry that cannot be properly sanitized.

15.6. Employees who have an illness, skin infections or communicable forms of infection, including but not limited to cuts, burns, boils, abrasions, wounds, open lesions or bandages on the hands, face or forearms shall not perform work activities in which there is a likelihood of contaminating food, food packaging or food contact surfaces until the medical condition is corrected. It is the duty of the supervisor to ask employees about such medical conditions and the duty of the employee to report them prior to the start of each workshift.

§§61-23A-16. Transport.

16.1. All fish transported for sale or processing for human food in the state of West Virginia shall be:

16.1.a. Alive when harvested from the water; and

16.1.b. Maintained alive; or maintained in a constant iced or mechanically refrigerated state ensuring an internal body temperature of 40°F (4.4°C) or below; except that:

~~16.1.b.1. Shellstock shall be maintained in a constantly iced or mechanically refrigerated state ensuring an internal body temperature of 50°F (10°C) or below after harvest;~~

~~16.1.b.2. Shucked shellfish shall be maintained in a constant iced or mechanically refrigerated state ensuring an internal temperature of 40°F (4.4°C) or below; and~~

~~16.1.b.3. Processed fish that have a water phase salt level of at least 17 percent do not require refrigeration.~~

16.2. All fish intended for human consumption shall be transported or held in clean non-toxic containers.

16.3. Unprotected raw fish and fishery products, cooked ready-to-eat fishery products, smoked fishery products and molluscan shellfish shall be physically separated to minimize the possibility of cross contamination during transport.

16.4. No other cargo shall be placed on or above fish or fishery products unless all cargo is packed in sealed, crush resistant waterproof containers.

16.6. Every reasonable effort shall be made to keep fish and fishery products intended for human consumption wholesome, unspoiled, and unadulterated.

16.7. Ice used for cooling fish and fishery products shall be made from drinking water certified potable by State or County Health authorities.

16.7.a. After use for cooling fish or fishery products, ice shall not be used as human food.

§§61-23A-17. Laboratory Testing.

17.1. 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.

17.2. The methods used for analyzing samples will be those found in the most recent editions of the Official Methods of Analysis by the Association of Analytical Chemists, or the United States, Food and Drug Administrations Bacteriological Analytical Manual, or The Pesticide Analytical Manual, Volume I, and II, Foods and Feeds; or other methods as approved by the commissioner.

§§61-23A-18. Prohibited Acts.

18.1. It is unlawful to:

18.1.a. Produce, hold, transport, sell or offer for sale fish, or fishery products in violation of this rule;

18.1.b. Sell or offer for sale any fish or fishery product for human consumption which is adulterated or not wholesome;

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

18.1.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;

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

18.1.f. Remove or dispose of detained, embargoed, or quarantined fish or fishery products by sale or otherwise without the permission of the Commissioner or the courts;

18.1.g. Continue fish processing operations until released from the embargo or cease and desist order by the Commissioner or the courts;

18.1.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 List published by the U.S. Food and Drug Administration;

18.1.i. Sell or offer for sale fish or fishery products 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";

18.1.j. Process fish or fishery products for sale unless the processor is licensed and inspected by the Commissioner;

18.1.k. Sell or offer for sale, fish or fishery products for human consumption which contain levels of chemicals or drugs in excess of the action levels listed in the tables in this subdivision:

18.1.k.a. Table 1 - Action levels for chemicals in Fish and Fishery products.

Chemical	Action Level
Aldrin plus Dieldrin	0.3 ppm
Chlordane	0.3 ppm
Endrin	0.3 ppm
Heptachlor plus Heptachlor epoxide	0.3 ppm
Chlordecone	0.3 ppm
DDT plus TDE plus DDE	5.0 ppm
Mirex	0.1 ppm
Toxaphene	5.0 ppm
PCB	2.0 ppm
Methyl Mercury	1.0 ppm
Sulfite (Shrimp only)	100.0 ppm

18.1.k.b. Table 2 - Action levels for drugs in Fish and Fishery products.

Drug	Action Level
Oxytetracycline	0.1 ppm
Sulfamerazine	0.0 ppm
Sulfadimethoxine plus ormetoprim	0.1 ppm; or

18.1.1. Slaughter or process products other than fishery products in a licensed fish processing facility.

§§61-23A-19. Penalties.

19.1. Civil Penalties

19.1.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.

19.1.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.

19.1.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.

19.2. Criminal Penalties

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

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

19.2.1.b. Shall upon each subsequent offense be fined not less than one hundred nor more than one thousand dollars;

19.2.1.c. May be imprisoned in the county or regional jail not more than six months or both fined and imprisoned; and

19.2.1.d. Shall have his or her Fish Processing License suspended until the facility is in compliance with the provisions of this rule.

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

§§61-23A-20. Confidentiality of Trade Secrets.

20.1. 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.

§§61-23A-21. Enforcement Policy.

21.1. The Commissioner shall inspect fish processors on a risk assessment basis with the purpose of assuring wholesome, unspoiled and unadulterated fish and fishery products. All processors inspected will receive a grade of "A", "B", "C", or "Unsatisfactory". After an initial inspection processors earning:

21.1.a. A grade of "A" during an inspection will require reinspection ~~at least once every three months~~ at appropriate intervals according to the FDA Risk Guidance;

21.1.b. A grade of "B" during an inspection will require reinspection at least once every two months;

21.1.c. A grade of "C" during an inspection will require reinspection at least once every month;

21.1.d. A grade of "Unsatisfactory" during an inspection shall result in the suspension of the Fish Processing License. When reinspection of the plant results in a grade of C or higher the Commissioner may reinstate the Aquaculture Processing License; and

21.1.e. A grade of "Failure" during an inspection shall result in the revocation of the "Fish Processing License" until the processor successfully reapplies for and is issued a new license.

21.2. In no way is this enforcement policy intended to prohibit the Commissioner from inspecting a producer's facility more frequently in the event that he or she believes it is necessary.

21.3. All fish and fishery products for sale as human food shall be processed and transported according to all provisions of this rule. Fish and fishery products transported or processed by private citizens exclusively

for the consumption by themselves, their immediate family, nonpaying guests, and employees, or fish transported in the operation of fish hatcheries by the state of West Virginia or the United States of America are exempt from this rule.

§61-23A-22. Humane Slaughter.

22.1. Fish, before being cut, must be rendered insensible to pain by a single blow, or by electrical, chemical, temperature or other means that is safe, rapid and effective; or

22.2. By slaughtering in accordance with any method of humane slaughter approved by the United States department of agriculture; or

22.3. By slaughtering in accordance with any method of humane slaughter approved by the commissioner.