

WEST VIRGINIA

SECRETARY OF STATE

KEN HECHLER

ADMINISTRATIVE LAW DIVISION

Form #3

FILED

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OFFICE OF WEST VIRGINIA SECRETARY OF STATE

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: West Virginia Department of Agriculture TITLE NUMBER: Chapter 19 Article 29-1 et seq.

CITE AUTHORITY

AMENDMENT TO AN EXISTING RULE: YES NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED:

TITLE OF RULE BEING AMENDED:

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: 23A

TITLE OF RULE BEING PROPOSED: West Virginia Fish Processing Rules

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

Robert G. Manning
Asst. Commissioner

9.00

Summary

West Virginia Fish Processing Rules

§61-23A-1 et seq.

Legislative Rule

This rule is intended to provide a vehicle for the 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.

This rule requires every processor of fish and fishery products for human to be licensed by the West Virginia Department of Agriculture. To facilitate licensing each processor must submit design plans for the facility where fish will be processed. The Commissioner will assure the facilities are then adequate for the sanitary processing of aquaculture products.

Each processor is responsible for developing their own Hazard Analysis Critical Control Point (HACCP) plan. These plans will reveal critical control points where the processor must pay careful attention to the assure product safety and quality.

The rules provide guidance for employee sanitation. The transportation requirements for fish and fishery products is outlined. The powers and duties of the Commissioner are outlined and prohibited acts are listed. The Commissioner is give authority to issue civil penalties up to five hundred dollars for the first offense and up to five thousand dollars for subsequent offenses.

DATE: August 15, 1994

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

Gus R. Douglass, Commissioner of Agriculture

FROM:

LEGISLATIVE RULE TITLE: West Virginia Fish Processing Rules
Chapter 19 Article 29-1 et seq.

1. Authorizing statute(s) citation _____

2. a. Date filed in State Register with Notice of Hearing
Filed July 15, 1994 with Secretary of State's office for 30 day comment period

- b. What other notice, including advertising, did you give
of the hearing?
Notified three persons with interest in aquaculture processing of the
_____ proposed rules by sending them a copy for their comment

- c. Date of Hearing(s) N/A

- d. Attach list of persons who appeared at hearing,
comments received, amendments, reasons for amendments.
Attached X No comments received _____
- e. Date you filed in State Register the agency approved
proposed Legislative Rule following public hearing:
(be exact)
August 15, 1994

- f. Name and phone number(s) of agency person(s) to
contact for additional information:
John Liggett (304) 558-2227

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

July 15, 1994 filed with Secretary of State's office for 30 day

comment period

b. Date of hearing: N/A

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

August 15, 1994

d. Attach findings and determinations and reasons:

Attached

Title 61
Legislative Rule
West Virginia Department of Agriculture

Series 23A
West Virginia Fish Processing Rules

§61-23A-1 General

1.1 Scope - these rules are 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 - WV Code 19-29-1 et seq.

1.3 Filing Date -

1.4 Effective Date -

1.5 This is a new legislative rule

§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. U. S. Food and Drug Administration "Fish and Fishery Products Hazards and Controls Guide".

2.1.c. U. S. Food and Drug Administration "National Shellfish Sanitation Program Manual of Operations 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

§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 HACCP plan.

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

3.3 "Commissioner" means the commissioner of agriculture or his/her designee.

3.4 "Fish" means fresh or saltwater fin fish, molluscan shellfish, crustaceans, and other forms of aquatic life other than birds or mammals.

3.5 "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.

3.6 "Official Sample" means any sample of water, soil, fish, feed, drugs, pesticides, other ingredients, containers and/or products taken by the commissioner or approved laboratory in accordance with these rules.

3.7 "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.

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

3.9 "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.

3.10 "Safety Hazard" means any biological, chemical, or physical property that may cause, allow, or contribute to an unacceptable human health risk in the final product or food.

3.11 "Smoked fish" means fish that is prepared by treating it with salt(sodium chloride) and then subjecting it to the direct action of smoke from burning wood, sawdust or similar material.

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

3.13 "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," 15th ed.(1990)

3.14 "Wholesome" means in sound condition, clean, free from adulteration, and otherwise suitable for use as human food.

3.15 "Fishery Product" means any edible human food product derived in whole or in part from fish, including fish that has been processed in any manner.

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

4.1 The commissioner has the power and authority to:

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. Such inspection includes, 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 Such inspection also includes, 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/or products used or intended for use in the processing, storage, sale and/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 by affixing thereto or in the vicinity of the fish or fishery product, processing area, holding area, or transporting vehicle a tag or other appropriate marking, and giving notice thereof 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.

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 such violation or pathogen he/she may seize and/or condemn 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 these rules. All requested records must be made available to the commissioner within 24 hours of his/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.

4.1.i. Assess civil penalties and refer violations to a court of competent jurisdiction for the violation of this rule. Nothing in these rules 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 these rules when he/she believes that the public interest may best be served by a written notice.

4.1.i. The Commissioner shall be guided by the analytical results when determining whether fish or fishery products conform to this rule and other rules and laws of the State of West Virginia.

4.1.j. The Commissioner shall provide assistance, education, information, and training on HACCP to improve the safety and quality of the aquaculture industry in West Virginia.

§61-23A-5. Hazard Analysis Critical Control Point Plan

5.1 All commercial processors of fish and fishery products for human consumption shall have and implement a written Hazard Analysis Critical Control Point Plan approved by the Commissioner, for each product and processing location using the U. S. Food and Drug Administration Fish and Fishery Products Hazards and Controls Guide.

5.2 The HACCP plan shall include all seven recognized principles of a HACCP plan:

5.2.a. Identify the potential safety hazards associated with food production at all stages, from growing, harvesting, processing, manufacturing, and distribution, until the point of consumption. Assess the likelihood of the hazards occurring and identify the preventative measures for their control;

5.2.b. Determine the critical control points, or points, procedures and operational steps, that can be controlled to eliminate or minimize the likelihood of the safety hazards occurring;

5.2.c. Establish the critical limits, or target levels and tolerances which must be met to ensure the critical control point is under control.

5.2.d. Establish a monitoring system to ensure control of each critical control point by scheduled testing or observations.

5.2.e. Establish corrective action to be taken when there is a deviation or loss of control at a critical control point identified by monitoring.

5.2.f. Establish a system for verification which includes supplementary tests and procedures to affirm that HACCP is working effectively.

5.2.g. Establish a record keeping system to document all procedures, monitoring, these principles and the HACCP plan.

5.3. Failure of a processor to have and implement a HACCP plan that complies with this rule or to meet other requirements set forth by these rules will render their fish and/or fishery products adulterated.

5.4. Processors producing their own fish for processing may have one combined HACCP plan addressing both production and processing.

§61-23A-6. Processor Licensing

6.1 All processors in the state of West Virginia shall:

6.1.a. Apply for a license from the commissioner.

6.1.b. Submit a HACCP plan to the commissioner with the request for licensing.

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

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

6.1.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 waste system is acceptable.

6.1.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 potable water supply has been tested and is acceptable.

6.1.f. Submit fee required along with application for license:

| Class | Average Finished Product Poundage Processed per Year | Annual Fee |
|--------|---|---------------|
| Small | 1-25,000 | \$25.00 |
| Medium | 25,001 - 50,000 | \$50.00 |
| Large | over 50,000 | \$75.00 |

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

6.2. 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 these rules and all employees are properly trained and have met requirements set forth in these

rules, he/she may issue the license.

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

6.3.a. Annually for approved public water supplies.

6.3.b. Every six months for private wells.

6.4. The commissioner may deny, revoke or suspend any aquaculture processing license when he/she concludes the seriousness of violations, including irreparable harm to the environment, hazards to the health and safety of the public and economic damages to the public warrant such action.

6.5. The commissioner shall deny the issuance of an "Aquaculture Processing License" until all conditions set forth under 61-CSR-23A-6 et seq. have been complied with. Once issued the "Aquaculture Processing License" shall remain 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 61-CSR-23A-6 et seq. to receive a new license.

§61-23A-7. Current Good Manufacturing Practices

7.1. Regulations applicable to Current Good Manufacturing Practices shall apply in determining whether the facilities used in the manufacture, processing, packing or holding of fish and fishery products for human consumption are safe, and whether these products have been processed under sanitary conditions.

§61-23A-8 Buildings and Facilities

8.1. The 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.

8.2 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:

8.2.a. Cleaned at the end of the days operations.

8.2.b. Cleaned and sanitized at least every four

hours during the processing of cooked, ready-to-eat fishery products.

8.2.c. Sanitized before the beginning of the days operations.

8.2.d. Cleaned and sanitized after any interruption during which food contact surfaces may have become contaminated.

8.3 Employees' hands, gloves, outer garments, utensils, and surfaces of equipment that contact raw product shall not contact product after it has entered the smoking chamber or cooked product or ice until properly cleaned and sanitized.

8.4. 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 post of duty, and when their hands have become soiled or contaminated, shall be conspicuously posted in the processing room(s), finished product packing room(s), and in all other areas where conditions require.

8.5. 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.

8.6. 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-9. Equipment

9.1 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 and 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.

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

9.3. Cleaning and sanitizing of utensils and portable equipment must be conducted in an area set aside for these purposes or in a segregated fashion so as to prevent contamination of food.

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

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

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

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

9.8. Each smoking chamber must be equipped with a temperature monitoring device so installed as to accurately indicate at all times the temperature of the air and of the fish within the smoking chamber.

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

§61-23A-10. Product Management

10.1. 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 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.

10.2. Sanitary zones shall be established around areas where cooked or smoked product is handled and stored. In such areas, objects and employees that have come into contact with waste, raw product, or other insanitary objects shall be excluded.

10.3. 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.

10.4. 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.

10.5. 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.

10.6. 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.

10.7. 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 refrigerated 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.

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

10.9. Vacuum-packaging or modified atmosphere-packaging of processed fish or fishery products shall only be conducted within the facilities of the manufacturer.

10.10. 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".

10.11. Each container of cooked ready-to-eat and smoked fishery products shall have an identifying code which shall be legible and permanently marked. This code shall identify the plant the product was produced and the date packaged.

§61-23A-11. Records

11.1. 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. Such records, in addition to the names and addresses of the persons or firms involved shall contain the code numbers of each lot involved.

11.2. 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-12. Employees

12.1. 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.

12.2. 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.

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

12.4. 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.

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

12.6. Employees who have an illness, skin infections

and/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 be excluded from work activities in which there is a likelihood of contaminating food, food packaging or food contact surfaces until the condition is corrected. It shall be the duty of the supervisor to ask employees about such medical conditions and the duty of the employee to report the same prior to the start of each workshift.

§61-23A-13. Transport

13.1 All fish transported for sale and/or processing for human food in the state of West Virginia shall be:

13.1.a. Alive and in good health when harvested from the water

13.1.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:

13.1.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.

13.1.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.

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

13.2 All fish intended for human consumption shall be transported or held in clean non-toxic, pathogen-free containers.

13.3 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.

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

13.5 All shipments of human food fish to other producers, wholesalers, retailers and/or processors shall be a written notification of any and all drugs, feed and color additives, pesticides and/or medicated feeds administered, including the name, address, and telephone number of the grower; name and dose of the drug, color additive, feed additive, pesticide or medicated feed and dose; date administered and length of required

withdraw period; date of sale; lot number of fish; this notification shall be signed by the grower.

13.5.a. If no drugs, feed and color additives, pesticides or medicated feeds have been administered, a written statement including the lot number of fish signed by the grower indicating such shall accompany the shipment.

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

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

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

§61-23A-14 Laboratory Testing

14.1 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.

14.2 The methods used for analyzing samples will be those found in the Official Methods of Analysis by the Association of Analytical Chemists, 15th edition 1990; or the United States, Food and Drug Administrations Bacteriological Analytical Manual, 7th edition, 1992; or The Pesticide Analytical Manual, Volume I, and II, Foods and Feeds; or other methods as approved by the commissioner.

§61-23A-15. Prohibited Acts

15.1 It shall be unlawful to:

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

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

15.1.c. Remove any tag or order affixed by the commissioner unless such removal is authorized by him/her.

15.1.d. Impede, hinder or otherwise prevent, or attempt to prevent the commissioner in the performance of his/her

duties in connection with the provisions of this rule.

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

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

15.1.g. Continue aquaculture operations until released from the cease and desist order by the Commissioner or the courts.

15.1.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.

15.1.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 annual publication of The Seafood List, FDA's Guide to Acceptable Market Names for Seafood Sold In Interstate Commerce.

15.1.j. Process fish or fishery products for sale unless the processor is licensed and inspected by the commissioner.

15.1.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 following tables:

15.1.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 | 100 ppm |

15.1.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 |

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

§61-23A-16. Penalties

16.1 Civil Penalties

16.1.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.

16.1.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 such a person after the same 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 such , shall enter same to record without requiring payment of costs as a condition precedent to recording.

16.1.c. Nothing in these rules 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 these rules when he/she believes that the public interest may best be served by a written notice.

16.2 Criminal Penalties

16.2.1 Any person who shall violate any provision of this rule shall be guilty of a misdemeanor, and upon conviction thereof,

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

16.2.1.b. Upon each subsequent offense shall be fined not less than one hundred nor more than one thousand dollars

16.2.1.c. Imprisoned in the county or regional jail not more than six months or both fined and imprisoned.

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

§61-23A-17. Confidentiality of Trade Secrets

17.1 The commissioner may not make public information which relates to trade secrets, 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.

§61-23-18. Enforcement Policy

18.1 The Commissioner will inspect aquaculture processing and retailers 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". Processors will initially be inspected at least once a week for a minimum of a one month period. After this initial inspection period processors earning:

18.1.a. A grade of "A" during an inspection will require reinspection at least once three months.

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

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

18.1.d. A grade of "Unsatisfactory" during an inspection shall result in the suspension of the Aquaculture Processing License. When reinspection of the plant results in

earning a grade of C or higher the commissioner may reinstate the Aquaculture Processing License.

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

18.2 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/she believes it is necessary.

18.3 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 and/or processed by a private citizen exclusively for the consumption of the citizen, their immediate family, nonpaying guests, and employees, and fish transported in the operation of fish hatcheries by the state of West Virginia or the United States of America shall be exempt from this rule.

18.4 Processors shall have three years from the effective date of this rule to comply with §61-23A-5 et seq., §61-23A-6.1.b., §61-23A-6.1.b.1. and §61-23A-6.2 concerning the implementation of HACCP. Processors shall have two years from the effective date of this rule to fully comply with all other sections of this rule.

Summary of Comments Received and Agency Response to
Title 61, Series 23A
West Virginia Fish Processing Rules

Note: In some cases the comments did not specify which section of the rule was applicable. For clarity, the comments are listed as if the commenter noted the actual section.

Comment 1: Two comments were received on the overall regulation. One commenter wrote "The rules are comprehensive, thorough, and contain teeth to effectively control the industry and its public safety threat." (Federal Hill Far, Inc.) The other wrote to recommend the revocation of the processing rules, citing questionable authority and dual inspection by the Department of Health and Human Services (Smith).

Agency response to comment 1: the WVDA believes that these regulations were authorized by the Production of the Nontraditional Agriculture Products Law (Chapter 19 Article 29-1 et seq.) "for the promotion, marketing, and regulation of nontraditional agriculture". WVDA currently inspects slaughterhouses for red meat and poultry, and a close reading of Chapter 19 Article 29-4 states that the commissioner shall promulgate rules "to include inspection of the meat from nontraditional agriculture intended for sale in commercial outlets. All nontraditional agriculture needing to be slaughtered shall be slaughtered in an inspected slaughterhouse." The Production of Nontraditional Agriculture Products Law (Chapter 19 Article 29-1 et seq) also states that "Only after consultation with the division of natural resources and the department of health and human resources" the commissioner shall promulgate these rules. These other agencies have been consulted and neither agency has expressed concern over promulgation of these rules.

Comment 2: One comment was received on the scope of the regulation, asserting that the scope is too broad and should only pertain to fish raised by aquaculture in this state (Smith).

Agency response to comment 2: The WVDA states on the summary that "This rule is intended to provide a vehicle for the uniform inspection of fish processing facilities in this state with the purpose of assuring the highest quality and safety of the finished product as possible." A close reading of the Production of Nontraditional Agriculture Products Law (Chapter 19 Article 29-1 et seq.) finds aquaculture to be defined as "the commercial production of fish/or other aquatic life". Production of many different species and types of aquatic organism is possible through the use of recirculating aquaculture systems. Because these organisms are not raised in West Virginia currently, does not preclude their production in the future. The commenter states 61-CSR-23A-3.8 will include every transportation company, food warehouse and restaurant that sells fish, however the definition of processing clearly states "This definition does not apply to the operation of a retail establishment." The WVDA believes it in the best interest of the public to inspect all fish

processed in West Virginia, and ensure it is handled safely until the product reaches market.

Comment 3: One comment was received concerning 61-CSR-23A-2.1.a the referencing of 21 CFR 123 and 21 CFR 1240. The commenter stated they did not know what 21 CFR 123 referred to. The commenter stated 21 CFR 1240 was not appropriate.(Smith)

Agency response to comment 3: 21 CFR 123 refers to the Proposal to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products, released in the Federal Register on January 28, 1994. This is the U.S. Food and Drug Administrations proposed rule concerning the processing of fish. The WVDA firmly believes that inspection standards and for fish processing should meet or exceed federal standards to ensure West Virginia's Aquaculture Industry. Currently 2 out of the 3 processors sell their products out of state but have had problems due to lack of inspection.

Agency Change to the Rule: WVDA has clarified 61-CSR-23A-2.1.a to reference 21 CFR 1240.60. This section covering shellfish is germane to the rule. Shellfish can and are produced through fresh and saltwater aquaculture practices.

Comment 4: One commenter stated 61-CSR-24A-3.1, the definition of "Adulteration" needs to be more specific.(Smith)

Agency response to comment 4: The WVDA believes the definition of "adulterated" is adequate to protect the safety of consumers. Limits for contaminants of greatest concern have been listed in 61-CSR-23A-15.1.k.a. and 61-CSR-23A-15.1.k.b. To attempt to specifically define limits for all potential adulterants and contaminants would be a time consuming exercise in futility. Contaminants other than those listed would require the commissioner to use her/his best professional judgement and the best scientific information available to protect the public.

Comment 5: One commenter wrote concerning 61-CSR-23A-3.2, stating procedures for the approval of laboratories should be included in this rule. (Smith)

Agency Change to the Rule: The WVDA shall establish and maintain or make provisions for approved laboratory testing. The definition of "Approved Laboratory", 61-CSR-23A-3.2 was deleted in response to a comment.

Comment 6: One commenter had questions concerning 61-CSR-23A-6. If the fish processing license is annual, what is the date for renewal, what are procedures for the denial, revocation or suspension of the license?(Smith) Another commenter suggests an initial fee system for the license.(Federal Hill Farm, Inc.)

Agency Change to the Rule: The WVDA has clarified 61-CSR-23A-6 et seq. in response to comments received. 61-CSR-23A-6.5 was added to specify procedures for license denial, suspension, and revocation. The rule states the license will

be denied unless all conditions met in 61-CSR-23A-6 are met. Once issued the license remains valid unless surrendered or revoked. To have a license reissued, the processor must reapply. 61-CSR-23A-18.1.e wa added to address license revocation.

Comment 7: One commenter state "Current Good Manufacturing Practices" should be adopted by reference(Smith).

Agency Change to the Rule: The WVDA modified the rule to adopt 21 CFR part 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food.

Comment 8: One commenter stated concerns with 61-CSR-23A-14.2 the methodology for analyzing samples.(Smith) The commenter was troubled with the section stating "or other methods as approved by the commissioner:

Agency response to comment 8: The WVDA strongly believes that in this rapidly changing area of agriculture, the commissioner must have the authority to approve methods as they are developed and approved by the U.S. Food and Drug Administration. this authority will ensure that this rapidly developing cooperative program will be successful in West Virginia.

Comment 9: One commenter states that criteria for the inspection grading system must be specified, and the firms being inspected have a right under the law to understand the standards they are being judged by.

Agency response to comment 9: The commenter is right the firms have the right to and will understand the standards they are being judged by. The WVDA is working with the U.S. FDA, the HACCP Seafood Alliance, and other experts to determine and define uniform inspection standards for fish processors. These standards will be promulgated well in advance of any inspection activities conducted by the WVDA.

Comment 10: One commenter suggests fish hatcheries operated by the State of West Virginia and the United States Government which are exempted by 61-CSR-23A-4-1.a be subject to inspection by the WVDA.(Federal Hill Farm, Inc.)

Agency response to comment 10: The WVDA does not believe the Production of Nontraditional Agriculture Products Law (Chapter 19 Article 29-1 et seq.) provides for one state agency (WVDA) to regulate another state agency (WVDNR)

Comment 11: One commenter suggest adding to 61-CSR-23A-4, Powers and Duties of the Commissioner, a section requiring the commissioner to provide new information and/or guidance to assist fish processors improve the quality of operation. (Federal Hill Trout Farm, Inc.)

Agency Change to the Rule: The WVDA has every intention of assisting processors comply with the HACCP system by providing

them with information and assistance and arranging training for the industry. The WVDA has revised 61-CSR-23A-6.3 formally adding to the commissioner's duties to assist processors by providing assistance and information as necessary to comply with HACCP regulations.

Comment 12: One commenter suggests that in 61-CSR-23A-6.3 "the testing be done by the health dept" and that the frequency of testing in 61-CSR-23A-6.3.a is excessive compared with the dairy industry.(Federal Hill Farm, Inc.)

Agency response to comment 12: The WVDA put the responsibility on processors in 61-CSR-23A-6.3 to arrange with the state or local health department to have their potable water retested at the appropriate intervals. The WVDA believes this responsibility lies with the processor. The WVDA believes the 6 month interval for retesting and certifying potable water supplies is reasonable, this is the same interval required for meat plants in West Virginia. The Dairy products receive much more screening than meat or fisheries products, and therefore do not require as frequent testing and certification.

Comment 13: One commenter states that the rules do not adequately address other foods processed in a fish house and possible contaminations of food from pathogens in pork, beef, dairy, fish, etc.

Agency Change to the Rule: The WVDA modified the rule to prohibit the slaughter and/or processing of anything other than fishery products in a fish processing plant.

Comment 14: One commenter suggests that the one year phase in period 61-CSR-23A-18.4 for HACCP is unrealistic.(WV Aquaculture Association)

Agency Change to the Rule: Due to the need for education and training, the WVDA has reconsidered the phase in period for HACCP. The U.S. Food and Drug Administration's the Proposal to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products has been delayed. WVDA has rewritten 61-CSR-23A-18.4, giving a 3 year deadline for 61-CSR-23A-5 et seq., 61-CSR-23A-6.1.b., 61-CSR-23A-6.1.b.1. and 61-CSR-23A-6.2 where the HACCP plan is referenced. The remainder of the 61-CSR-23A-1 et seq. rule will have a 2 year phase in period.

Comments 15: One commenter suggested adding a suspension of license under the penalties section 61-CSR-23A-16.1 civil penalties.

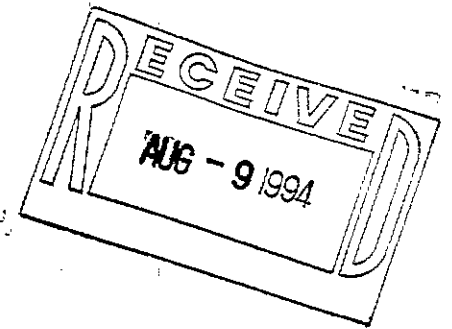
Agency response to comment: The WVDA has already included the suspension of aquaculture processing license, under 61-CSR-23A-18.1.d.

Comment 15: One commenter feels that the frequency of inspection in the Enforcement Policy, 61-CSR-23A-18 is unrealistic with respect to manpower and cost.(WV Aquaculture Association)

Agency response to comment: The WVDA is aware of the infant status of the aquaculture industry in West Virginia, and believes careful regulation will enhance rather than harm the industry. The U.S. Food and Drug Administration is moving ahead with its HACCP based inspection program for fish processing. The direct monetary cost to the processor of WVDA fish processor inspections will be \$0. The processor or his/her representative would in all probability have to be present for the physical inspection and review of HACCP Plan and records by the WVDA aquaculture inspector. Unless any great difficulties arise the entire inspection process would take approximately 6 hours or less to complete. After the initial implementation of a HACCP plan, it would require only a few extra minutes at each processing step for record keeping. Due to the serious nature of food safety concerns today, the aquaculture industry, even the small processor, would in all actuality benefit more from inspection, barring any violations than the time of inspection would hinder them. These comments underscore the need for education and training of the industry.

Federal Hill Farm
Rt 4, Box 270
Charles Town, WV 25414
August 3, 1994

John Liggett, Asst. Director
West Virginia Department of Agriculture
Regulatory Protection Division
1900 Kanawha Boulevard East
Charleston, WV 25305-0170



Dear Sir:

Thankyou for the oppurtunity to comment on the proposed Aquaculture regulations regarding Farm Rules sec31-23-1 et seq. and Fish Processing Rules Series 23A.

In General:

The rules are comprehensive, thorough, and contain teeth to effectively control the industry and its public safety threat. This is good.

However, in my opinion the failure of the legislation to address other government organizations who are already opporating with the intent to level the playing field is a mistake. When I entered aquaculture the scare to not start was the already numerous agencies who were regulating or threatening regulation. I fear that the stated goal of leveling the field will be to eliminate the players in the field. Therefore, I recommend:

1.DNR activity in aquaculture should be removed entirely except for its current role in all other agriculture enterprises of discharge permits. The rules should assume responsibility for and/or eliminate Sections 20-2-11, 20-2-12, 20-2-13, 20-2-48, Fish Importation permits, and probably numerous other sections of Chapter 20 of the Code of West Virginia.

2.Currently operating committees who regulate the use of private streams should not be involved in the industry. One such committee that threatened my business start for 3 months operates only quarterly with undeveloped criteria for decision making in aquaculture.

3.The legislation should recognize aquaculture farms as "not wildlife", but as producers of agricultural commodities. Aquaculture farms should be required to recognize their inventory as real property for tax assessment, and they should be protected from wildlife "common or state property" views currently enforced by the Department of Natural Resources. This issue has been the center of enormous trouble with government endorsed thievery of my property (fish) this spring.

4.Fish hatcheries operated by the State of West Virginia or the United States of America for fish produced for human consumption should be

HACCP reviewed. A level field and public interest are that if the fish are for human consumption they should be reviewed under HACCP rules. Politically acceptable variations to this public safety issue are: The hatchery system could provide fish for recreation only (catch and let go). If the fish are being removed for human food, then DNR should label that stream publicly as containing adulterated fish. Another suggestion, DNR could politically state that its public mission is to feed bears only. These variations are within the actual and desirable mission of the hatchery system: to increase wildlife with use of public money.

5. The rules should require the commissioner some level of obligation to feedback new ideas, techniques, or procedures which are not trade secrets but contribute to the public safety. Things such as sanitation in processing, procedures that reduce stress in fish handling, or record management are helpful to the industry. My criticism of HACCP is that it contains no feedback or education elements to improve the industry.

6. The Fish Processing Rules do not adequately address other foods processed in a fish house and possible contamination of food from pathogens in pork, beef, dairy, fish, etc. I wonder if this is a threat to the public? An example is turkeys or cheese smoked in a fish smoker.

Specific Areas of Concern regarding sec61-23-1

Sec4.2: "on at least an annual basis" is excessive. These tests for some chemicals are very expensive. It will stop the industry without some guidelines.

Sec4.7: 500 feet seems excessive.

Sec6.2: 500 feet seems excessive.

Sec6.6: 500 feet seems excessive. I would suggest a lower number or "threatening distance" statement in these sections. Effective management of fish operations requires that they be located near or beside other farm operations. My tanks are within 100 yds of my grain bins (fumigants), Dairy (chemicals and drugs), and barn yard (manure). Management would like them closer still.

Sec12.1.a: eliminate "except fish hatcheries..." for above general comment reasons.

Sec12: Add feedback obligation of new ideas to be made available to better solve problems.

Sec13.3: Eliminate "fish raised in fish hatcheries..."

Specific Suggestions Regarding Series 23A rules:

Sec4.1.a: Eliminate "fish hatcheries operated by the state"

Sec4 Add to this area the duty of Commissioner to provide new information and/or guidance to assist fish processors to improve quality of operation. This duty would address my concerns that HACCP contains no feedback to producers or system to implement new ideas.

Sec6.1.f: eliminate annual fee and implement an initial fee. This as proposed is a paperwork headache at the producer level. The fee goes who to?, What address?, What time? I can never remember all those things annually. I favor the dairy industry system of an initially issued license that is revoked if in violation of the rules.


Sec6.3: This is trouble and probably beyond competence of the producer. I would suggest that the testing be done by the health dept as the dairy industry does.

Sec6.3.b: Excessive compared to dairy experience of the past 40 years.

Sec16.1: One of penalties should be suspension of license. Is this done in Sec6.4?

This is the conclusion of my remarks.

Sincerely,



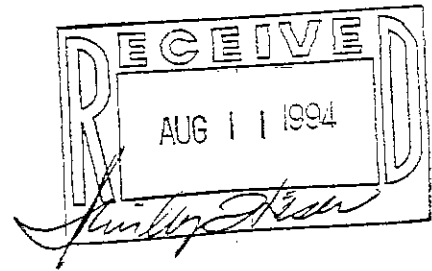
Ron Widmyer, President
Federal Hill Farm Inc

cc Aggy Spice, Est Service



Barbara J. Smith

1207 Larchwood Rd.
Charleston, WV 25314
304-342-1755



August 10, 1994

Mr. John Liggett
Regulatory Protection Division
West Virginia Department of Agriculture
1900 Kanawha Blvd., East
Charleston, West Virginia 25305

RE: Proposed WV Fish Processing Rules (61CSR23A)

Dear John,

I have reviewed the proposed "WV Fish Processing Rules" and appreciate the opportunity to comment on them. I urge you to revoke these rules 1.) because there is questionable authority for the regulation of fish processing in §19-29-1 et seq. and 2.) because if this rule passes, you will have set up another instance where both Health and Human Resources and Agriculture will be inspecting the same process in those fish processing plants that process West Virginia farm-raised fish (Agriculture) and other fish and fish products that are not agricultural products (oysters, tuna, lobsters, etc.). Health and Human Resources has clear authority to regulate the processing of all food. It does not serve the public interest, nor the interest of the firms being regulated to have more than one agency inspecting them if this situation can be avoided.

Although I urge revoking these rules, I will continue with comments to clarify this position and to comment on changes in the rule if it is allowed to go through the legislative process.

Authority It is questionable that the law gives authority for the regulation of fish processing. The purpose of the law (§19-29-1 et seq.) is to regulate the production, promotion and marketing of non-traditional agriculture (including aquaculture). It makes reference to health standards for non-traditional agriculture. I believe that the health standards are for the production of the fish and not for the processing of the fish. For instance, the requirements for the use of pesticides and drugs near the fish being raised is a legitimate "health" standard. I believe that this is the type of "health" standards that were referenced in this law.

Another indication that the purpose of the law did not include the processing of fish is in section §19-29-4 where the law specifies the authority to develop regulations for the inspection of meat from animals but does not in this section or elsewhere in the law give authority for regulations for the slaughter and processing of fish.

Scope of the regulation The summary to the rule states that the rule is intended to regulate all fish processing facilities in this state. The authority for this rule (§19-29-1 et seq.) covers fish raised by aquaculture in this state, not fish raised by aquaculture outside this state and not fish raised in the seas and lakes of the world by "fishing". The text of the rule needs to be amended to clearly state the rule regulates the processing of fish raised by aquaculture in this state only.

The text covers all fish and saltwater fish, mollusks, crustaceans, etc. I am not aware that lobsters, oysters, scallops, tuna, shark, etc. are capable of being raised by aquaculture in this state. If not raised by aquaculture, then the fish is not covered under the authority of the law.

The fiscal note states that only 3 firms would be regulated by this rule. The definition of a food processor would include many more operations than three in this state.

Some examples where the text is too broad:

The definition of "processing" includes handling and storing fish. This would make every transportation company, food warehouse and restaurant that sells fish a processor covered under this rule. (61CSR23A-3.8)

The commissioner [may] enter and inspect any location [except some fish hatcheries] where fish or fishery products are processed, sold, stored, or transported... (61CSR23A-4.1.a). This would allow access to all places, including retail operations, where there are fish.

61CSR23A-2.1.a. I do not find 21CFR123 in a published CFR nor in listings of Federal Register changes up to June 1 of this year. I do not know what this refers to. Also 21CFR1240 covers a multitude of subjects (persons with cholera, turtles, lather brushes, etc.) 21CFR1240.60 covers shellfish and I believe that this was the section that you intended to reference. However, see my comment that the regulation of shellfish would not be appropriate to this rule.

61CSR23A-3.1 The definition of "adulteration" needs to be more specific. Surely there are standards and criteria that will

Page Three
Proposed WV Fish Processing Rules (61CSR23A)
August 10, 1994

be used in your Division to determine if a particular poisonous or deleterious substance, quantity of pathogen, etc. would cause the fish to be adulterated. These need to be specified in this rule, as you have in 61CSR23A-15.1.k.a. and b. for chemicals and drugs. What standards would be used if chemicals or drugs not on this list are found?

61CSR23A-3.2 There should be procedures for the approval of laboratories in this rule. Section 14.1 only restates this definition.

61CSR23A-6 Is this an annual license? What is the date for renewal? Procedures for the denial, revocation or suspension of a license need to be specified.

61CSR23A-7 The "Current Good Manufacturing Practices" needs to be adopted by reference, or specified in this rule.

61CSR23A-14.2 Allowing the commissioner to approve methods without setting criteria for the validity of the test, nor for public notice of the method should not be allowed. The official methods stated in this section have been tested for validity and "ruggedness" and have been examined and approved by a panel of scientists. There should be no need for other methods to be used that have not been through this process.

61CSR23A-18.1 The criteria for the inspection grading system must be specified. This open-ended system - where no one knows what the standards for a "passing grade" are is not correct. The firms being inspected have a right under the law to understand what the standards are that they are being judged by.

Again I urge you to revoke this regulation and allow the Health and Human Services to have full inspection authority in this area in the interest of the public and the fish processing industry. Thank you for the opportunity to comment on this rule.

Sincerely,


Barbara J. Smith

FAX COVER PAGE

TO: Mr. Bill Warnick / Mr. John Liggett

LOCATION/COMPANY: WVDA

TELEPHONE NUMBER: 304-558-2201

FAX NUMBER: 304-558-2203

FROM: Aggy Spitz

LOCATION/COMPANY: RANDOLPH COUNTY, WVU EXTENSION SERVICE

TELEPHONE NUMBER: 304-636-2455

FAX NUMBER: 304-636-5887

NUMBER OF PAGES INCLUDING COVER PAGE: 3

ADDITIONAL MESSAGE: WVAA comments on
fish processing rules.

DATE AND TIME SENT: Aug. 15th 8:00 am

West Virginia Aquaculture Association, Inc.

201 Henry Avenue
P.O. Box 130
Elkins, WV 26241
Phone (304) 636-2455

August 14, 1994

Mr. John Liggett
West Virginia Department of Agriculture
Regulatory Protection Division
1900 Kanawha Blvd. E.
Charleston, WV 25305

Dear Mr. Liggett,

On behalf of the West Virginia Aquaculture Association, I would like to offer the following comments on the proposed West Virginia Fish Processing Rules, which were reviewed by the WVAA membership during our quarterly meeting on Saturday, August 13.

Currently there are only three fish processors in West Virginia. All three businesses fall under the category of small, 1 - 25,000 pounds processed per year listed in Section 6.1.f. The bulk of comments from these processors indicates that they perceive the proposed regulations as being excessive for small processors who catch, process, and deliver their products within the space of an afternoon. The processors feel that the proposed rules are envisioning much larger operations than currently exist within the state and that these proposed rules do not reflect the industry's current level of operation. Rather than allowing a one year phase in period as noted in Section 18.4, the processors suggested the development of individualized HACCP plans with a longer phase in period coupled with increasingly rigorous review. The proposed regulations as they now stand are seen as a threat to the future growth and development of the fish processing industry in West Virginia because they require implementations which are beyond the financial capabilities of most of the processors in the state. Under these excessive regulations and time periods for compliance, current West Virginia fish processors would be forced out of business.

The WVAA member processors feel that specifically, Section 18, Enforcement Policy, creates an unrealistic inspection schedule with respect to manpower and cost. They suggest that smaller producers of 1 - 25,000 pounds processed per year who receive a grade of "A", be inspected on a 6 months to one year basis unless consumer complaints are received.

With respect to Section 16.1, Penalties, processors suggested that a threat of license suspension for a certain time period be added to the monetary fines to protect product integrity.

With respect to Section 6.1.f., Processor licensing, the processors object to an annual fee for licensing if they are to

undergo frequent inspections. Rather, they suggest that licenses be granted to those who qualify, and that licenses to operate be revoked upon serious violations. With respect to Section 6.3., the processors strongly object to bearing the burden of cost for repeated water testing. The cost of water testing for the dairy industry is borne by the State Departments of Health. Why should the aquaculture industry be treated differently in this respect from other segments of agriculture? The responsibility for testing and certification of water supplies for fish processors should lie with the State Health Departments, not the individual processors.

As with the proposed Aquaculture Farm Rules, the WVAA member processors object strongly to the exclusion of state and federal hatcheries from inspection and regulation as specified in Section 4.1.a. in keeping with the fact that fish produced in state and federal hatcheries are released for recreational fishing into public waters. The majority of these fish are used for human consumption except in areas of catch and release only. If state and federally produced fish are not subject to the same inspection and regulation processes as farm-raised fish, then they are not to be considered safe for human consumption and should be publicized as such.

One criticism of the HACCP program is that there is no provisions for feedback or education for the producers and processors with respect to new products and techniques that can be used to improve operations.

Finally, WVAA appreciates the opportunity to comment on the proposed processing regulations. We are pleased to have the WVDA on our side and working to ensure the safety and integrity of our aquaculture products. WVAA would like to offer its future assistance to WVDA in helping to provide educational workshops, printed materials, consulting and HACCP plan development to new and potential aquaculture producers and processors if adequate funding could be secured. We would like to help in any way we can.

Sincerely,

Aggy Vanderpool Spicer
Aggy Vanderpool Spicer
Secretary, WVAA