

WEST VIRGINIA

SECRETARY OF STATE

KEN HECHLER

ADMINISTRATIVE LAW DIVISION

FILED

AUG 15 3 55 PM '94

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: 61

CITE AUTHORITY Chapter 19 Article 29.1 et seq.

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: 23

TITLE OF RULE BEING PROPOSED: West Virginia Aquaculture Farm 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.

Handwritten signature and title: Asst Commissioner

8.40

Summary

West Virginia Aquaculture Farm Rules

§61-23-1 et seq.

Legislative Rule

This rule is intended to provide a level playing field for all aquaculture producers in the state and assure the domesticated production of aquatic species is done in a manner that will assure the quality and the safety of the finished product.

This rule requires every producer of fish for human consumption to develop and implement a Hazard Analysis Critical Control Point, or HACCP, plan. The content of the HACCP plan will be individualized for each producing operation and the minimum contents of that plan are outlined in the rule.

The rule requires the Commissioner to maintain or provide for a laboratory testing facility for the purpose of enforcing the analytical aspects of this rule. The rule also provides actions levels for specific contaminants in fish and fishery products.

The rule outlines specific prohibited acts. The rule also gives authority to the Commissioner to assess civil penalties of up to five hundred dollars for a first offense and up to two thousand dollars for subsequent offenses.

The rule has a provision for maintaining the confidentiality of trade secrets.

The rule gives the Commissioner the authority to inspect, embargo, quarantine, issue cease and desist orders, cooperate or enter into agreements with other agencies or associations, and to develop appropriate regulatory forms as necessary.

The rule provides an enforcement policy which determines inspection frequency based on "risk assessment".

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: West Virginia Aquaculture Farm Rules

Type of Rule: Legislative Interpretive Procedural

Agency: WV Department of Agriculture

Address: Regulatory Protection Division
1900 Kanawha Blvd., East
Charleston, WV 25305

1. Effect of Proposed Rule

	ANNUAL FISCAL YEAR				
	INCREASE	DECREASE	CURRENT	NEXT	THIRDPARTY
<u>ESTIMATED TOTAL COST</u>	\$9000.00	\$	\$9000.00	\$8000.00	\$8000.00
PERSONAL SERVICES	0				
CURRENT EXPENSE	8000.00		8000.00	8000.00	8000.00
REPAIRS & ALTERNATIONS	0				
EQUIPMENT	1000.00		1000.00	0	0
OTHER	0				

2. Explanation of above estimates:

The equipment expense reflects the purchase of equipment necessary to perform inspection duties. The current expenses increase reflects added travel and miscellaneous expenses associated with the enforcement of these rules.

3. Objectives of these rules:

These rules are intended to provide a level playing field for all aquaculture producers in the state and assure the domesticated production of aquatic species is done in a manner that will assure the quality and safety of the finished product.

Rule Title: West Virginia Aquaculture Farm Rules

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

An estimated increase of \$8,000 annually for the enforcement of this rule.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific groups of Citizens.

We estimate the total cost per firm to be less than \$500. There are currently 60 growers who will be covered by these regulations. Many of those are already in compliance and there would be no additional expense to them.

C. Economic Impact on Citizens/Public at Large.

No impact.

Date: 07-15-94

Signature of Agency Head or Authorized Representative

Robert G. Neum

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.

N/A

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 X

TITLE 61
LEGISLATIVE RULE
WEST VIRGINIA DEPARTMENT OF AGRICULTURE

SERIES 23
Proposed West Virginia Aquaculture Farm Rules

§61-23-1. General

1.1 Scope - The Commissioner will inspect aquaculture production on a risk assessment basis with the sole purpose of assuring wholesome, unspoiled and unadulterated fish and fishery products.

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

61-23-2. Definitions

2.1 "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.

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

2.3 "Aquaculture production area" means the site and the immediate vicinity where fish are produced and kept for aquaculture purposes, i.e. tanks, raceways, ponds, etc.

2.4 "Aquaculture water source" means springs, wells, ponds, streams, lakes, rivers, impoundments and/or any other manmade or natural source of water where fish are grown or from which water is taken to conduct aquaculture.

2.5 "Chemotherapeutic" or "Drug" means any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals, other than man; and substances other than nutritive components, intended to affect the structure or any function of the animal body.

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

2.7 "Control" means managing the points, steps and procedures of an operation to maintain compliance with established criteria.

2.8 "Corrective Action" means procedures to be followed when a deviation occurs, including disposition of products, avoidance of further deviations, and records of actions taken as a result of the deviation.

2.9 "Critical Control Point" means any point, step or procedure in a production or food process where there is a high probability that improper control may cause, allow, or contribute to a safety hazard in the final product or food.

2.10 "Critical Limit" means the maximum or minimum value to which a physical, biological or chemical parameter must be controlled at a critical control point to minimize the risk of occurrence of the identified hazard.

2.11 "Deviation" means failure to meet a critical limit at a critical control point or follow the HACCP plan.

2.12 "Fish" means fresh or saltwater finfish, molluscan shellfish, crustaceans, and other forms of aquatic animal life other than birds or mammals.

2.13 "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.

2.14 "Hazard Analysis Critical Control Point Plan" or "HACCP Plan" is an inspectional or quality control plan in written form, approved by the commissioner that assesses hazards associated with growing, harvesting, processing, manufacturing, marketing, preparation and or use of fish as a food product, identifies critical control points on a flow chart of the operation, sets critical limits for critical control points, establishes monitoring system, standards for evaluating compliance with the plan and corrective actions for the identified critical control points, verification procedures, and a record keeping system.

2.15 "Log for Notice of Unusual Occurrence and Corrective Action" means a record for situations or safety hazards taking place that are not anticipated by the HACCP plan, and corrective actions taken as a result of such situations or safety hazards.

2.16 "Molluscan shellfish" means any edible species of fresh or frozen oysters, clams, mussels, or scallops or edible portions thereof, except when the scallop product consists entirely of the shucked adductor muscle.

2.17 "Monitoring" means a planned sequence of observations or measurements of critical limits designed to produce an accurate record

intended to insure that the critical limit maintains product safety.

2.18 "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.

2.19 "Pesticide" means any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest; any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant.

2.20 "Record" means a book, ledger or other written or printed means used to log required information.

2.21 "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.

2.22 "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.

2.23 "Shellstock" means live molluscan shellfish in the shell.

2.24 "Shucked shellfish" means molluscan shellfish that have one or both shells removed.

2.25 "Terrestrial Livestock" means cattle, sheep, horses, swine, goats, poultry and/or other domestic animals inhabiting the land.

2.26 "Verification" means methods, procedures, and tests used to determine if the HACCP system is in compliance with the HACCP Plan.

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

§61-23-3. Hazard Analysis Critical Control Point Plan

3.1 All producers of fish for human consumption shall have and implement a written Hazard Analysis Critical Control Point Plan approved by the commissioner, for each location where fish are grown.

3.2 The HACCP plan shall include all seven recognized principles of HACCP. The HACCP plan shall:

3.2.a. Identify the safety hazards associated with aquaculture production. Assess the likelihood of the hazards occurring and identify the preventative measures for their control;

3.2.b. Determine critical control points, or the points, procedures and operational steps that must be controlled to eliminate or minimize the likelihood of the safety hazards occurring; and will include as applicable:

- i) Site Selection
- ii) Aquaculture Water Source
- iii) Feed
- iv) Drugs
- v) Pesticides
- vi) Feed and Color Additives
- vii) Holding and Transportation

The commissioner may identify and require other critical control points based on inspection and/or observation of aquaculture operations to prevent an unacceptable risk to consumers.

3.2.c. Establish the critical limits, or target levels and tolerances that must be met to ensure the identified critical control points are under control.

3.2.d. Establish a monitoring system to ensure control of each critical control point by scheduled testing or observations, including procedures and frequency thereof, that will be used to control and monitor each critical control point to ensure compliance with the critical limits. Such procedures shall include calibration of instruments and the use of consumer complaints relating to a critical control point received by the producer.

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

3.2.f. Provide for a verification system to ensure the HACCP plan is working correctly. This system shall consist of procedures, tests and documentation as necessary to assess compliance with the HACCP plan and to ensure the HACCP plan is working effectively. The HACCP plan and all records shall be reviewed, evaluated and signed by the producer on at least an annual basis to confirm the adequacy of the HACCP plan and system.

3.2.g. provide for a record keeping system that will document all procedures, the monitoring of the critical control points, these principles and the HACCP plan.

3.2.g.1. Records shall be kept for critical control points, indicating that the critical control points have been monitored according to the approved HACCP plan.

3.2.g.2. Records shall indicate the actual values obtained during monitoring, documentation of the verification process and what corrective action was taken if critical limits were exceeded.

3.2.g.3. Records shall also include a Log for Notice of Unusual Occurrence and Corrective Action.

3.2.g.4. Records shall include the date, appropriate lot numbers, and signature of the individual logging the information.

3.3 Records required by this rule must kept for a minimum of 2 years unless otherwise specified. Records kept on computer files shall have a backup file on a separate disk, or hardcopy.

3.4 Failure of a producer of fish for human consumption to have and implement a HACCP plan that complies with this rule will render fish and/or fishery products adulterated and subject to actions under this rule.

§61-23-4. Site Selection and Water Source Critical Control Points

4.1 Aquaculture water sources shall be tested for pesticide and chemical residues by an approved laboratory prior to commencing aquaculture production, except aquaculture water sources utilizing a public water system certified by State or Local Health Authorities.

4.2 Aquaculture water sources utilizing surface waters shall be tested for pesticide and chemical residues by an approved laboratory on at least an annual basis, except aquaculture water sources utilizing a public water system certified by State or Local Health Authorities.

4.3 Aquaculture water sources and aquaculture production areas shall be tested by an approved laboratory whenever the commissioner suspects contamination which could present a safety hazard has occurred.

4.4 The commissioner may require testing for other possible contaminants that he/she concludes is necessary to protect the safety of consumers.

4.5 Terrestrial livestock shall be excluded by fencing or a permanent structure from the immediate vicinity of aquaculture water sources and aquaculture production areas where fish are raised for human consumption.

4.6 Septic systems shall not be located within 200 feet of an aquaculture water source or aquaculture production area in order to prevent fecal and other contamination of water where fish are raised for human consumption, except that tanks or other aquaculture production systems with an impervious barrier preventing possible contamination may be located closer.

4.7 Manure and/or sewage sludge shall not be applied within 50 feet of an aquaculture water source or aquaculture production area.

4.8 Every reasonable effort shall be made to keep water used for aquaculture production pure and free from contamination.

4.9 Permanent records of all analysis of aquaculture water sources and aquaculture production areas for contaminants shall be kept.

§61-23-5. Feed Critical Control Point

5.1 Aquaculture feeds shall conform to the West Virginia Commercial Feed Law (Chapter 19 -14-1 et seq.) and West Virginia Department of Agriculture Feed rules (Chapter 61-5-1 et seq.).

5.2 Medicated feeds shall not contain chemotherapeutics or drugs not approved by the U.S. Food and Drug Administration Center for Veterinary Medicine and the West Virginia Department of Agriculture.

§61-23-6. Drugs, Feed and Color Additives and Pesticides Critical Control Points

6.1 Only drugs approved for food fish aquaculture or listed as low regulatory priority by the U.S. Food and Drug Administration's Center for Veterinary Medicine, used under an Investigational New Animal Drug application or prescribed by a licensed veterinarian following FDA Compliance Policy Guide 7126.06, Extra-label Use of New Animal Drugs in Food-Producing Animals may be used for the production of human food fish. Except that veterinary biological products(vaccines) licensed by the United States Department of Agriculture Animal and Plant Health Inspection Service may be used.

6.2 Pesticides not registered with the U.S. Environmental Protection Agency for the use with fish intended as human food shall not be used in or land applied within 100 feet of aquaculture water sources or aquaculture production areas containing fish in aquaculture production for human food. Aerial application of pesticides not registered with the U.S. Environmental Protection Agency for use with fish intended as human food shall not be made within 500 feet of aquaculture water sources or aquaculture production areas containing fish in aquaculture production for human food.

6.3 A locked cabinet or area shall be maintained and used to store only drugs, medicated feeds and/or pesticides used for the production of fish for human consumption.

6.4 Drugs shall be used in accordance with FDA regulations and labelling. Feed and color additives shall be used according to FDA regulations and labelling. Biological veterinary products(vaccines) shall be used in accordance with USDA regulations and labelling. Pesticides shall be used in accordance with EPA regulations and labelling.

6.5 A permanent record shall be kept when drugs, pesticides, feed and color additives or medicated feeds are used to produce fish intended as human food. The record shall include the name and dose of any or all drugs, pesticides, feed and color additives, or medicated feeds; date

and/or dates administered and length of required withdraw period; date of sale; lot number of fish; and name and address of the purchaser of the treated fish.

6.6 Pesticides not approved for use with fish intended for human consumption shall not be used, stored or otherwise present within 500 feet of an aquaculture water source or aquaculture production area when fish are produced for human food.

6.7 Aquaculture pesticide use shall otherwise conform to the West Virginia Pesticide Control Act (Chapter 19-16A-1 et seq.).

6.8 Fish and fishery products containing levels of the following chemicals in excess of action levels set by the Food and Drug Administration in Table 1 will be considered adulterated and subject to actions under this rule.

6.8.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

6.9 Fish and fishery products containing levels of the following drugs in excess of action levels set by the Food and Drug Administration in Table 2 will be considered adulterated and subject to actions under this rule.

6.9.a 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

§61-23-7. Transport

7.1 All fish transported for sale and/or processing for human food in

the state of West Virginia shall be:

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

7.1.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:

7.1.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.

7.1.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.

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

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

7.3 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.

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

7.5 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.

7.5.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.

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

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

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

§61-23-8 Laboratory Testing

8.1 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.

8.2 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.

8.3 The commissioner shall collect, provide for the transportation, and analytical testing of all samples specifically required in the text of the West Virginia Aquaculture Farm Rules 61-CSR-23-1 et seq. The cost for additional analytical testing required by individual HACCP plans will be the individual farmer's responsibility.

§61-23-9. Prohibited Acts

9.1 It shall be unlawful to:

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

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

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

9.1.d. To 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.

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

9.1.f. To 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.

9.1.g. To continue aquaculture operations until released from the cease and desist order by the Commissioner or the courts.

§61-23-10. Penalties

10.1 Civil Penalties

10.1.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 two 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.

10.1.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.

10.1.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.

§61-23-11. Confidentiality of Trade Secrets

11.1 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.

§61-23-12. Powers and Duties of the Commissioner

12.1 The commissioner has the power and authority to:

12.1.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 are produced, 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 production of fish for human food as is necessary to determine compliance with this rule and to investigate consumer complaints. Such inspection also includes, but is not limited to photographing, video taping, observing, and verifying the premises, vehicles, personnel and activities;

12.1.b. Examine, sample and test water, soil, fish, feed, drugs, pesticides, other ingredients, containers and/or products used or intended for use in the production, storage and/or transportation of fish or fishery products for human consumption;

12.1.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;

12.1.d. Detain, embargo, quarantine or issue a cease and desist order by affixing thereto or in the vicinity of the aquaculture production area, holding area or transporting vehicle a tag or other appropriate marking, and giving notice thereof in writing to the producer, holder or transporter. The Commissioner may take this action when:

12.1.d.1. Fish or fishery products have been found by the commissioner to be or are believed to be in violation of the provisions of this rule. Upon confirmation of such violation he/she may condemn and order the fish or fishery product disposed of as necessary to ensure the safety of consumers.

12.1.d.2. Fish or fishery products have been found by the Commissioner to be or are believed to be infected with a fish or human pathogen that the Commissioner concludes could affect other aquaculture areas and wild fish stocks or present a public health hazard. Upon confirmation of such pathogen he/she may condemn and order the fish or fishery products disposed of as necessary to prevent the spread of the pathogen;

12.1.e. Embargo a perishable product, even if the practical result is to bring about the involuntary disposal of the product.

12.1.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.

12.1.f. Inspect or copy all records required by these rules. All records required by this rule must be presented to the commissioner during an on premise inspection.

12.1.g. Inspect all aquaculture water sources and aquaculture production areas producing fish for human food;

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

12.1.i. Assess civil penalties of up to two thousand dollars for the violation of this rule.

12.1.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.

12.1.k. The Commissioner shall appoint members to the Commissioner's Aquaculture Committee. The Commissioner's Aquaculture Committee shall meet at least annually with the purpose of evaluating the status of aquaculture and making recommendations to the commissioner concerning aquaculture. The Committee shall consist of four aquaculture producers, one aquaculture processor, two aquaculture educators, and shall be chaired by the commissioner or his/her designee.

12.2. The Commissioner shall be guided by the analytical results of an official sample when determining whether fish or fishery products conform to this rule and other rules or laws of the state of West Virginia;

§61-23-13 Enforcement Policy

13.1 Aquaculture farms will receive a grade of "A", "B", "C", or "Unsatisfactory". Farms will be initially inspected at least once every three months for a minimum of two inspections. After this initial inspection period:

13.1.a. A grade of "A" will require reinspection on at least an annual basis.

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

13.1.c. A grade of "C" during an inspection will require reinspection at least once every three months.

13.1.d. An aquaculture farm receiving a grade of "Unsatisfactory" will not be permitted to sell fish for use as human food until a subsequent inspection results in a grade of "A", "B" or "C".

13.2 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.

13.3 All fish raised for sale as human food shall be produced

according to all provisions in this rule. Fish raised exclusively for consumption of the producer, their immediate family, nonpaying guests, and employees, and fish raised in fish hatcheries operated by the State of West Virginia or the United States of America shall be exempt from these rules.

13.4 Aquaculture producers have three years to comply with Hazard Analysis Critical Control Point Plan, 61-CSR-3 et seq. and two years to comply with the remainder of the West Virginia Aquaculture Farm Rules.

Summary

West Virginia Aquaculture Farm Rules

§61-23-1 et seq.

Legislative Rule

This rule is intended to provide a level playing field for all aquaculture producers in the state and assure the domesticated production of aquatic species is done in a manner that will assure the quality and the safety of the finished product.

This rule requires every producer of fish for human consumption to develop and implement a Hazard Analysis Critical Control Point, or HACCP, plan. The content of the HACCP plan will be individualized for each producing operation and the minimum contents of that plan are outlined in the rule.

The rule requires the Commissioner to maintain or provide for a laboratory testing facility for the purpose of enforcing the analytical aspects of this rule. The rule also provides actions levels for specific contaminants in fish and fishery products.

The rule outlines specific prohibited acts. The rule also gives authority to the Commissioner to assess civil penalties of up to five hundred dollars for a first offense and up to two thousand dollars for subsequent offenses.

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The rule provides an enforcement policy which determines inspection frequency based on "risk assessment".

Summary of Comments Received and Agency Response to
Title 61, Series 23
West Virginia Aquaculture Farm Rules

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

Comment 1: One commenter wrote general comments concerning legislation, Production of Nontraditional Agriculture Products Law (Chapter 19 Article 29-1 et seq.), and removal of other agencies (WVDNR and unnamed committee) involvement in aquaculture. (Federal Hill Farm, Inc.)

Agency response to Comment 1: The WVDA cannot address changes to legislation in the rule making process. The roles of other agencies is not for the WVDA to decide.

Comment 2: One commenter suggests that 61-CSR-4.2 testing surface waters on at least an annual basis is excessive and very expensive. (Federal Hill Farm, Inc.) Another commenter references 61-CSR-4 excessive in the terms of time and cost. (WV Aquaculture Association)

Agency response to Comment 2: The WVDA believes that since fish farmers cannot control all upstream activities in a watershed an annual test for surface water is sensible. Well and spring fed systems would only require retesting if contamination is indicated or suspected. Additionally 61-CSR-8 provides for laboratory testing facilities for the purpose of enforcing the analytical aspects of this rule. The WVDA shall perform the analytical testing specifically required by the test of this rule in conjunction with an inspection of farm at no cost to the farmer. The WVDA aquaculture inspector shall collect and provide for the transport of samples to the lab. The WVDA believes that under these conditions the analytical testing requirements are reasonable.

Agency Change to the Rule: The WVDA has clarified 61-CSR-8 to state that the WVDA shall collect and transport the samples, and perform the testing specifically required by the test of this rule at no cost to the farmer. Additional analytical testing that may be required by the producer's HACCP plan would have to be paid for by the farmer. The WVDA does not anticipate much if any additional testing will be necessary by the farmer.

Comment 3: Two commenters state that distance requirements for locating aquaculture water sources or aquaculture production facilities near potential sources of contamination are excessive. (Federal Hill Farm) (WV Aquaculture Association)

Agency response to Comment 3: The WVDA believes the 200 foot distance requirement in 61-CSR-23-4.6 for separation of aquaculture production areas and aquaculture water sources from septic systems is sound. This is the distance many health authorities require separation of private wells and

septic systems for the prevention of fecal and other contamination. There is an exception for tanks and other production systems with impervious barriers. Aquaculture producers bear the responsibility of providing proper setbacks of their operations from their property lines.

Agency Change of the Rule: The WVDA has reconsidered the 500 foot distance requirement and has revised the rule to conform with Best Management Practices for fertilizers and Manures (61-22B-4.1.c) and reduced the distance requirement of the rule under 61-23-4.7 to 50 feet.

Agency change to the Rule: The WVDA has reconsidered the 500 foot distance requirements in 61-CSR-23-6.2 and altered the distance requirement to at least a 100 foot separation for land application of pesticides not registered for use on fish for human consumption. A 500 foot distance is maintained for aerial applications of pesticides not registered for use on fish for human consumption.

Comment 4: One commenter stated 61-CSR-23-2.1, 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-23-6.8.a and 61-CSR-23-6.9.a. 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 stated concerns with 61-CSR-23-8.2 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 5: The WVDA strongly believes that in this rapidly changing area of agriculture, the commissioner must have the authority approved by the U.S. Food and Drug Administration. This authority will ensure that this rapidly developing cooperative program will be successful in Wet Virginia.

Comment 6: 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 6: The commenter is right the farmers 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 aquaculture farms. The WVDA has a draft of a farm inspection report and is moving forward with this program. These

standards will be promulgated well in advance of any inspection activities conducted by WVDA.

Comment 7: Two commenters suggest fish hatcheries operated by the State of West Virginia and the United States Government which are exempted by 61-CSR-12-1.a and 61-CSR-23-13.3 be subject to inspection by the WVDA.(Federal Hill Farm, Inc.)(WV Aquaculture Association)

Agency response to comment 7: 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) or a federal agency(US Fish and Wildlife Service).

Comment 8: One commenter suggest adding to 61-CSR-23-12, Powers and Duties of the Commissioner, a section requiring the commissioner to provide new information and/or guidance and supply feedback t assist fish farmers improve the quality of operation.(Federal Hill Trout Farm, Inc.) Another commenter asks about 61-CSR-23-2 and the development of HACCP plans, record keeping, and providing training for producers.(WV Aquaculture Association)

Agency Change to the Rule: The WVDA has every intention of assisting farmers comply with the HACCP system by providing them with information and assistance and arranging training for the industry. The WVDA is also involved with developing a model aquaculture farm HACCP plan including the record keeping system. The WVDA has revised 61-CSR-23-12 formally adding to the commissioner's duties to assist farmers by providing assistance and information as necessary to comply with HACCP regulations, and development of a model HACCP plan.

Agency Change to the Rule: To better provide feedback to the industry, WVDA has amended 61-CSR-23-12 to provide for the commissioner to appoint an Aquaculture Committee for the purpose of coordinating WVDA efforts with the aquaculture industry.

Comment 8: One commenter strongly opposes section 61-CSR-13.4. The commenter also opposes the inspection schedule, 61-CSR-13 for small producers, and protests that the costs and manpower required by inspections.(WV Aquaculture Association)

Agency response to comment 8: 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. HACCP at the processor level will require some guarantee from the farmer regarding the safety and quality of his/her fish. The direct monetary cost to the farmer of WVDA aquaculture farm inspections will be \$0. The farmer or his/her representative would in all probability want 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 4 hours or less to complete. After the initial implementation of a HACCP plan, it would require only a few extra minutes a day for record keeping. Due to the serious nature of food safety concerns today, the aquaculture industry, even the small producers, would in all actuality benefit more from inspection, barring any violations, than the time of inspection would hinder them. Since the stated intention of this rule is to provide a level playing field for all aquaculture producers in the state, providing an exception for operations of 10,000 pounds production a year or less, would go against this objective. These comments underscore the need for education and training of the industry.

Agency Change to the Rule: Due to the need for education and training the WVDA has reconsidered and has revised 61-CSR-23-13.4, to allow for a 3 year grace period after the issuance of the final rule to fully comply with 61-CSR-3 and a 2 year grace period to fully comply with all other sections of the rule.

Comment 9: One commenter states WVDA intends for the rules to provide a level playing field for all aquaculture producers in West Virginia, the regulations should clearly indicate WVDA does intend to inspect fish raised outside the state of West Virginia. The commenter cites 61-CSR-23-3-1, 61-CSR-23-7-1, and 61-CSR-23-12-1.a.(Smith)

Agency response to comment 9: All fish in the United States will soon be processed under a HACCP plan due to the U.S. Food and Drug Administration's Proposal to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products. It is the intention of WVDA to be proactive and provide a head start for West Virginia's aquaculture industry, rather than lag behind. The WVDA believes it has the authority to promulgate rules for the regulation of aquaculture within the confines of West Virginia. Production of Nontraditional Agriculture Products Law states the commissioner shall promulgate rules, in accordance with Chapter 19 Article 29-1 et seq. of this code for the promotion, marketing, and regulation of nontraditional agriculture. Chapter 19 Article 29-4 et seq. further states the commissioner shall promulgate rules, in accordance with 29-1-1 et seq of this code, to include inspection of the meat from nontraditional agriculture intended for sale in commercial outlets.

Comment 10: One commenter states the request for records must be made in writing, dated, with the time requested indicated in writing. The commenter asks in what manner the firm would make the records available for the commissioner to inspect, or delivered to Charleston.(Smith)

Agency response to comment 9: The HACCP inspection system hinges upon the inspector having access to all HACCP records during an inspection. Due to the integral nature of records in a HACCP inspection program, the records are reviewed on site by the inspector, during the inspection.

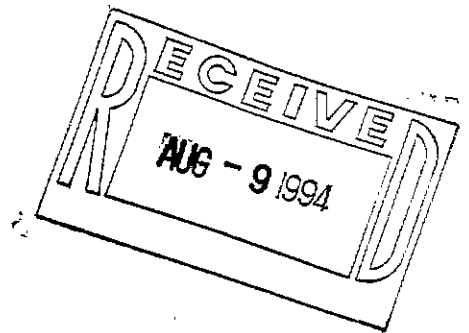
Agency Change to the Rule: The WVDA has rewritten 61-CSR-23-12.1.f., to require producers to make records available for the commissioner's review during the inspection.

Comment 11: One commenter states 61-CSR-23-12.1.1 conflicts with 61-CSR-23-10.1.a. (Smith)

Agency Change to the Rule: The WVDA has corrected 61-CSR-23-12.1.1 to agree with 61-CSR-23-10.1.a.

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 sec61-23-1 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 5 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,

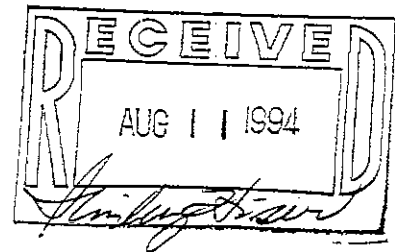


Ron Widmyer, President
Federal Hill Farm Inc

cc Aggy Spice, Est Service



Barbara J. Smith
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Charleston, WV 25314
304-342-1755



August 9, 1994

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

RE: Proposed WV Aquaculture Farm Rules (61CSR23)

Dear John,

I have reviewed the proposed "WV Aquaculture Farm Rules" and appreciate the opportunity to comment on them.

Scope of the rules You state in the fiscal note that these rules provide a level playing field for all aquaculture producers in this state. The name of the rule also implies that the rule applies to farming operations.

Yet the scope of the regulation is not limited to aquaculture producers in the text. In fact, the text of the regulation indicates that the intent is to inspect all fish sold in this state - no matter what the source of the fish. The only exemption is in 61CSR23-13.3, for consumption of the producer, their non-paying guests, etc.

Some examples of text where the inspection of all fish (no matter where it was raised) is indicated:

3.1 All producers of fish for human consumption shall...[have a plan] for each location where fish are grown

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

12.1.a. [The Commissioner may] enter and inspect... any location, [except for state and federal hatcheries] where fish are produced, sold, stored or transported for human consumption...

Page Two
Proposed WV Aquaculture Farm Rules (61CSR23)
August 9, 1994

These rules must clearly state that only fish raised by aquaculture within the state of West Virginia is covered by these rules.

Grading system The criteria for the inspection grading system must be specified (see 13.1). 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.

Adulteration The definition of "adulteration" (61CSR23-2.1) needs to be more specific. Surely there are standards and criteria that will 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 61CSR23-6.8 and 6.9 for chemicals and drugs. What standards would be used if chemicals or drugs not on this list are found? I suggest that sections 40CFR185, 21CFR556 and 21CFR109.30 be specifically referenced to make this definition more specific.

Laboratory Methods Allowing the commissioner to approve methods, (see 61CSR23-8.2) 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 that 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.

Section 61CSR23-12.1.f. The request for records needs to be in writing to the firm, and dated, with the time requested indicated in writing. In what manner would the firm make the records available, at their firm for the commissioner to inspect, or delivered to his office in Charleston? How would computer records be made available (what if the firm uses a software that they cannot make available to the commissioner)?

Section 61CSR23-12.1.i. This section is in conflict with section 61CSR23-10.1.a.

Thank you again for the opportunity to comment on this rules. Good luck in the development of this new program.

Sincerely,



Barbara J. Smith

West Virginia Aquaculture Association, Inc.

201 Henry Avenue
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Phone (304) 636-2455

August 14, 1994

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

Dear John,

On behalf of the West Virginia Aquaculture Association, I am contacting you with respect to the proposed WVDA aquaculture farm rules. During our quarterly meeting, yesterday August 13, the members shared the following comments with respect to these rules:

First, we applaud the actions of the WVDA with respect to providing increased assistance to the aquaculture industry in West Virginia. We, as aquaculture producers, know well the importance of providing a safe and wholesome product to the marketplace. Any assistance that WVDA can give us in terms of water and product testing and suggestions for improving our production facilities is welcomed. However, we remind WVDA that the aquaculture industry in West Virginia is very young and very small. Excessive regulation at this point in our development will impact the industry in such a way that economic benefits to the state of West Virginia from the growth of aquaculture will be lost. With this caution in mind we offer the following comments on the proposed West Virginia Aquaculture Farm Rules:

We suggest that the inspection schedule noted in the Enforcement Policy Section 13 be amended to read that small aquaculture operations of 10,000 pounds per year production or less be inspected on a bi-yearly basis after receiving a grade of A. The inspection schedule as it now stands is excessive and will require a great deal of manpower and cost to conduct these many inspections, even for a small industry. Ultimately the cost of these inspections and tests is not one which the industry can be made to bear. In addition, the annual inspection schedule for Section 13 .1 and testing schedule listed for water sources in Section 4 also are excessive in terms of time and cost. Aquaculture sources which are tested as satisfactory should not be retested on an annual basis unless modifications to the facility, the watershed or water source or consumer complaints raise questions about the quality of the water source. A five year testing schedule might be more realistic. We also question who will assume the cost of repeated water testing.

In Section 2 concerning the development of individual HACCP plans and record keeping, who will be responsible for the development of the required record keeping system, and who will provide training for all the producers in the use of this record keeping system?

Also in Section 4, with respect to distance requirements for septic systems and manure and fertilizer applications, these distance requirements are excessive. In addition, what measures are there to protect the aquaculture producer, whose neighbor builds a septic system or uses manure or fertilizer, if property lines end less than the required 200 or 500 feet from an aquaculture system? Some measures of protection for aquaculture producers must be enacted with respect to contamination of upstream water sources by industrial or farming operations over which the aquaculture producer has no control. If water source testing confirms a water quality problem, especially for existing aquaculture facilities, all efforts must be made to find the source of the contamination and remove it. Who will assume the cost or liability to the producer in this situation? Perhaps the HACCP plan for an individual aquaculture facility could be modified to explain some deviations from the distance requirements in situations where property lines interfere with the proposed regulations, without substantial and costly modifications to existing aquaculture facilities, especially if the water source tests satisfactorily.

WVAA strongly opposes Section 13.4 as it is now written which allows little time for existing aquaculture facilities to phase in a HACCP plan, especially if extensive and expensive modifications to the facility must be made. WVAA strongly suggest a five year phase in period for HACCP plans for existing systems. In addition, because so many of our current producers are small, hobby level aquaculture producers, there must be some flexibility to allow non-industrial focused producers to move forward into the industry and expand their production without cost prohibitive regulatory requirements. A small industry cannot start out with HACCP requirements tailored to large aquaculture production facilities. Perhaps some leniency in the compliance schedule could be adopted so that small producers would not be reviewed as frequently as large producers, but should be required to have a HACCP plan and be working toward full compliance within a reasonable period of time.

Our final comments concern Section 12.1 denoting the power and authority of the Commissioner of Agriculture. Fish produced in state and federal hatcheries are in large part caught and consumed by the general public. If state and federal hatcheries are not to be included in HACCP planning and the testing and inspection services rendered to the aquaculture industry, then these fish are not determined to be free from contamination. Therefore, wild caught fish are not deemed to be safe and wholesome food products and the public must be informed of this inherent danger. Public announcements at recreational fishing areas must be posted to warn

consumers that these fish are not inspected, and as such are not for human consumption. WVAA feels that excluding state and federally raised fish from the HACCP process will reflect negatively on the recreational industry, and as such our state and federal hatcheries should be required to implement HACCP plans to protect consumers, unless they are willing to post that wild caught fish are not to be used for consumption. WVAA realizes that this is a very serious issue, but for the good of the public health we feel it is one which we must comment on very strongly. WVAA understands the necessity of regulation for fish raised for human consumption and the need to provide the public with security in eating fish and seafood products.

We thank you for this opportunity to offer industry input into the development of the industry regulations, and for your willingness to assist us in making sure that we can increase consumer confidence, and ultimately sales of our aquaculture products.

Sincerely,


Aggy Vanderpool Spicer
Secretary, WVAA