United States Environmental Protection Agency
Region 10
1200 Sixth Avenue
Seattle, Washington 98101

Authorization to Discharge under the National Pollutant Discharge Elimination System (NPDES)

In compliance with the provisions of the Clean Water Act, 33 U.S.C. §1251 *et seq*., as amended by the Water Quality Act of 1987, P.L. 100-4, the "Act,"

Federal Aquaculture Facilities and Aquaculture Facilities Located in Indian Country

Within the boundaries of the State of Washington

which are described in Part I of this general NPDES permit are authorized to discharge to Waters of the United States, in accordance with discharge points, effluent limitations, monitoring requirements and other conditions set forth herein.

A copy of this General Permit must be kept at all times at the facility where discharges occur, if feasible. Otherwise, it must be in the possession of staff whenever working at the facility.

This General Permit will become effective: **August 1, 2016**

This General Permit and the authorization to discharge will expire: **July 31, 2021**

Each Permittee must apply for reauthorization to discharge on or before **February 2, 2021** if it intends to continue operations and discharge from the facility beyond the term of this permit.

Signed this 9th day of June, 2016

_____/S/_____

Daniel D. Opalski, Director
Office of Water and Watersheds

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I. SCHEDULE OF SUBMISSIONS

The following is a summary of the items the Permittee must complete and/or submit to EPA during the term of this permit:

Item	**Due Date**
1. Initial Notice of Intent (NOI)	Existing dischargers: no additional NOI submittal necessary at this time. New dischargers: at least 180 days before initiation of discharge. (§III.A.) Authorization to discharge must be obtained from the EPA and the Spokane Tribe (as appropriate) prior to commencement of a discharge.
2. Discharge Monitoring Reports (DMRs)	Facilities must submit DMRs monthly by the 20th day of the month. See §VI.C for instructions on submitting DMRs.
3. Surface Water Monitoring Report	Due with the DMR for the month in which the monitoring is conducted. (§IV.C.)
4. Monitoring Records	Monitoring records must be retained for a period of at least five years. (§VI.)
5. Quality Assurance Plan (QA Plan)	New dischargers: Provide written notification to the EPA and to the Lummi, Spokane, Swinomish, or Tulalip Tribes (as appropriate) that the QA Plan has been developed and implemented within 90 days after receiving authorization to discharge under this Permit (§IV.F). Existing dischargers: Modify the QA Plan as necessary and submit written notice to the EPA and to the Lummi, Spokane, Swinomish, or Tulalip Tribes (as appropriate) that the Plan has been modified and implemented within 90 days of the effective date of this General Permit. The QA Plan must be kept on-site and made available to the EPA upon request.

Item	Due Date
6. Best Management Practices (BMP) Plan	New dischargers: Provide written notification to the EPA and to the Lummi, Spokane, Swinomish, or Tulalip Tribes (as appropriate) that the BMP Plan has been developed and implemented within 90 days after authorization to discharge under this Permit (§IV.G). Existing dischargers: Modify the Plan as necessary and submit written notice to the EPA and to the Lummi, Spokane, Swinomish, or Tulalip Tribes (as appropriate) that the Plan has been modified and implemented within 90 days of the effective date of this General Permit. The Plan must be kept on-site and made available to the EPA upon request.
7. Anticipated INAD Study Participation or Extralabel Drug Use	Written notification to the EPA within 7 days of signing up for an INAD study or receiving a prescription for extralabel drug use if the drug was not previously listed on an NOI or if the drug is being used at a higher dosage than previously approved by Food and Drug Administration (FDA) for this or a different species or disease. (Appendix D)
8. INAD Use, Extralabel Drug Use, or First Use of Low Regulatory Priority Drugs or Potassium Permanganate	Oral notification to the EPA and the Spokane Tribe (as appropriate) within 7 days of beginning use and written notification to the EPA within 30 days of beginning use if the drug was not previously listed on an NOI or if the drug is being used at a higher dosage than previously approved by Food and Drug Administration (FDA) for this or a different species or disease. (Appendix D)
9. Structural failure or damage notification	Oral notification to the EPA within 24 hours of becoming aware of structural damage or failure that caused a release of pollutants to waters of the U.S. Written notification to the EPA within 5 days of becoming aware of such damage or failure. (§V.D)
10. Notification of spills of feed, drugs, pesticides, or other chemicals notification	Oral notification to the EPA and to the Spokane Tribe (as appropriate) within 24 hours of becoming aware of a spill that caused a release of pollutants to waters of the U.S. Written notification to the EPA within 5 days of becoming aware of such a spill. (§V.E.1)
11. Oil or hazardous materials	The Permittee must report immediately to the EPA at 1-800-424-8802 any spills of oil or hazardous materials to waters of the U.S. The Permittee must report any spills of oil or hazardous materials to the appropriate Tribe or Ecology regional office. (§V.E.2)
12. Annual Report	By January 20 each year. (§V.G)

Item	**Due Date**
13. Non-Compliance Report	Oral notification to the EPA and to the Spokane Tribe (as appropriate) within 24 hours of becoming aware of an unanticipated bypass of treatment facilities or an upset that result in exceedance of effluent limits, or any exceedance of an applicable maximum daily limit for total residual chlorine. Written notification to the EPA within 5 days. (§VI.G.)
14. Submittal of subsequent NOI	The NOI to be covered under a subsequent General Permit must be submitted to the EPA at least 180 days before the expiration date of this permit. (§III.A.)
15. Notice of Termination of Discharge	Facilities must request permit termination from the EPA in writing. The EPA will respond with a written determination on the request, in accordance with 40 CFR 122.64. (§III.E.)

II. Permit Coverage

A. EPA Authorization Required

1. ***Authorization to discharge under this General Permit requires written notification from the U.S. Environmental Protection Agency (EPA) that coverage has been granted and that a specific permit number has been assigned to the facility.***

2. The EPA may notify a discharger that it is covered under the General Permit even if the discharger has not submitted a Notice of Intent (NOI) to be covered.

B. Eligible Facilities

1. Facilities eligible for coverage under this permit include the following, within the boundaries of the State of Washington:

a) Federally owned or operated fish hatcheries, fish farms, or other such facilities;

b) Fish hatcheries, fish farms, or other such facilities, regardless of type of ownership, that are located in Indian country, as defined in 18 U.S.C. 1151.

2. To be eligible for coverage under this General Permit, a fish hatchery, fish farm, or other such facility must contain, grow, or hold cold water species of fin-fish in ponds, raceways, or similar structures, which discharge to fresh or marine waters within the State of Washington from a federal facility or from such a facility located in Indian country.

3. The General Permit applies only to those upland facilities that discharge for at least 30 days per year except facilities which produce less than 9,000 harvest weight kilograms (approximately 20,000 pounds) of aquatic animals per year and facilities which feed less than 2,272 kilograms (approximately 5,000 pounds) of food during the calendar month of maximum feeding. The EPA may designate a smaller facility as a significant contributor of pollution to Waters of the United States based on the considerations, such as those listed below [40 CFR §122.24(c)]. Under such circumstances, the designated facility is subject to the limitations and conditions of this permit. Considerations include:

a. The location and quality of the receiving waters;

b. The holding, feeding, and production capacities of the facility;

c. The quantity and nature of the pollutants reaching waters of the United States; and

d. Any other relevant factors.

C. New Sources

Aquaculture facilities that produce 100,000 pounds or more of aquatic animals per year in flow-through or recirculating systems that are constructed after September 22, 2004, are *new sources*, as defined in 40 CFR §§122.2, and 122.29. A facility is a *new source* if (1) the facility is constructed at a site where no other facility is located, (2) the facility totally replaces the process or production equipment that causes the discharge of pollutants at the existing facility, or (3) the facility processes are substantially independent of an existing facility at the same site. See 40 CFR §122.29(b) and (c). A facility smaller than 100,000 pounds of annual production is not a *new source* for these purposes and is not subject to these *new source* requirements.

Pursuant to Section 511(c) of the Clean Water Act, 33 U.S.C. 1371(c), National Environmental Policy Act (NEPA) compliance is required for NPDES permits for the discharge of any pollutant by a "new source."

In accordance with 40 CFR §§ 6.300 and 6.301, the *new source* facility must prepare and submit to the EPA, along with its NOI, an Environmental Information Document or a draft Environmental Assessment (EA) and supporting documents.

New sources may be required to apply for an individual permit.

D. Authorized Discharges

The General Permit authorizes discharges to Waters of the United States. During the effective period of the permit, authorized discharges are subject to the requirements and conditions set forth in this permit. The General Permit does not authorize the discharge of any waste streams, including spills and other unintentional or non-routine discharges of pollutants, that are not part of the normal operation of the facility, as disclosed in the Permittee's NOI, or any pollutants that are not ordinarily present in such waste streams.

E. Discharges Not Authorized

1. The General Permit does not automatically apply to discharges from aquaculture facilities which produce less than 9,000 harvest weight kilograms (approximately 20,000 pounds) of aquatic animals per year or to facilities which feed less than 2,272 kilograms (approximately 5,000 pounds) of food during the calendar month of maximum feeding. Facilities below the thresholds for permit coverage may voluntarily submit the information required in a Notice of Intent with a request in a cover letter to be included or excluded from coverage.

2. The General Permit does not apply to net pens.

3. The General Permit does not automatically apply to discharges from facilities where an individual NPDES permit has been terminated or denied for cause nor where coverage has been denied under this or any other General Permit. The EPA will review such facilities for coverage on a case by case basis.

4. The General Permit does not apply to discharges that may contribute to a violation of an applicable water quality standard.

5. The General Permit does not apply to discharges to (a) *impaired waters*, designated pursuant to Section 303(d) of the Clean Water Act (CWA), which are water-quality limited for a pollutant of concern evaluated in the development of this permit (BOD_5, total suspended solids, settleable solids, nutrients, ammonia, chlorine), unless a wasteload allocation has been assigned to the discharge and is applied in this permit, or to (b) receiving waters that are one mile or less upstream from an impaired water that is designated as such pursuant to Section 303(d) of the CWA, unless a specific effluent limit based on a WLA has been applied in this permit.

If a waterbody to which an existing Permittee discharges becomes impaired during the next permit cycle, the Permittee may submit information to the EPA that demonstrates that the discharge is not expected to cause or contribute to an exceedance of water quality standards. Then, the EPA will determine 1) whether the discharge would cause or contribute to an exceedance or impairment, and 2) whether the facility may remain covered under this General Permit in future permit cycles or if an individual permit is needed. New dischargers to impaired waterbodies are not eligible under this General Permit, and must seek permit coverage under an individual permit.

6. The General Permit does not apply to any discharges that include copper or copper compounds.

7. The General Permit does not apply to discharges from processes not associated with fish hatcheries or farms nor to discharges from fish hatchery or farm processes where the EPA determines at the time a discharger seeks coverage that the General Permit does not adequately address the environmental concerns associated with the discharge.

8. The General Permit does not apply to discharges to land or to publicly owned treatment works.

9. The General Permit does not apply to facilities that discharge one mile or less upstream from waters that constitute an outstanding national resource.[1]

10. The General Permit does not apply to facilities that discharge to waters that constitute special resource tribal waters.

F. Permit Expiration

This General Permit will expire five years after its effective date, as specified on the cover page of the permit. In accordance with 40 CFR §122.6, if the permit is not reissued by the expiration date, the conditions of the General Permit will continue in force and effect until a

[1] As part of an antidegradation policy, Tier 3 maintains and protects water quality in outstanding national resource waters. Except for certain temporary changes, water quality cannot be lowered in such waters. States and authorized Indian Tribes decide which water bodies qualify for this type of protection. As of the date of this permit, no outstanding national resource waters have been designated within the boundaries of Washington State.

new General Permit is issued. Only those facilities authorized to discharge under the expiring General Permit and who submit an NOI at least 180 days prior to the expiration date of the General Permit will remain authorized to discharge under the administratively continued permit conditions.

III. Obtaining Authorization to Discharge under this General Permit

A. Submitting a Notice of Intent

Owners or operators seeking coverage under this General Permit must submit to the EPA Region 10 a timely and complete Notice of Intent (NOI) to be covered by the General Permit. The owner/operator must submit the information indicated in Appendix A (Notice of Intent Contents) of this General Permit. ***A copy of the NOI must be retained on-site***. If lack of suitable storage area makes on-site storage impossible, the NOI must be in the possession of staff whenever they are working on-site.

1. Submittal Address

a. To the EPA

The NOI must be submitted to the EPA at the following address:

USEPA Region 10
Washington Hatchery NOI, OWW-191
1200 Sixth Avenue, Suite 900
Seattle, WA 98101-3140

b. To the Lummi Nation

As per the Tribe's CWA Section 401 certification, each operator of a facility that discharges to Lummi Nation waters shall be responsible for achieving compliance with the Water Quality Standards for Surface Waters of the Lummi Indian Reservation. The NOI for dischargers to waters of the Lummi Nation must also be submitted to the Lummi Nation at the following address at the same time the NOI is submitted to the EPA:

Lummi Natural Resources Department
ATTN: Water Resources Manager
Lummi Natural Resources Department
2665 Kwina Road
Bellingham, WA 98226

c. To the Spokane Tribe

As per the Tribe's CWA Section 401 certification, the NOI for dischargers to waters of the Spokane Tribe must also be submitted to the Spokane Tribe Water Control Board at the following address:

Water Control Board

c/o Brian Crossley
PO Box 480
Wellpinit WA 99040

d. To the Swinomish Indian Tribal Community

As per the Tribe's CWA Section 401 certification, the NOI for dischargers to waters of the Swinomish Tribe must also be submitted to the Tribe at the following address:

Department of Environmental Protection
11430 Moorage Way
LaConner, WA 98257

e. To the Tulalip Tribes

As per the Tribe's CWA Section 401 certification, the NOI for dischargers to waters of the Tulalip Tribes should include the location and extent of action area, list the federally-listed threatened or endangered species or designated critical habitat likely to occur in the action area, and list the potential pollutants (if they are new dischargers). The Tulalip Tribes may require additional Tribal Endangered Species Act consultation. Any permit related discharge that may have a potential adverse effect on historic properties should be reported to Richard Young, of the Tulalip Tribe's Cultural Resources Department. His contact information is (360) 716-2652 and ryoung@tulaliptribes-nsn.gov. The NOI for dischargers to waters of the Tulalip Tribes must also be submitted to the Tulalip Tribes' Natural and Cultural Resources Department at the following address:

Kurt Nelson
Environmental Division Manager
Tulalip Tribes Natural and Cultural Resources Department
6406 Marine Dr.
Tulalip, WA 98271

Tulalip Tribal Hatchery NPDES questions should be directed to:

Mike Crewson
QA Program Manager
6406 Marine Drive
Tulalip, WA 98271
Telephone: 360-716-4626

2. A Permittee authorized to discharge under this General Permit must submit to the EPA (and applicable tribe) an updated and/or amended NOI when there is any material change in the information submitted within its original NOI. A material change may include, but is not limited to, changes in the operator/owner of the facility, a modification

in the treatment train, the introduction of new pollutants not identified in the original NOI, or increases in pollutants above the presently authorized levels.

3. When an aquaculture facility is owned by one person or company, and is operated by another person or company, it is the operator's responsibility to apply for and obtain permit coverage. For owners/operators of multiple facilities, a separate NOI must be completed for each site or facility.

4. Deadlines for Submittal

a. Existing facilities with coverage under this permit are ***not*** required to reapply to be covered by this General Permit upon reissuance. In order to remain covered by the General Permit after this permit expires (i.e., five years from issuance), existing dischargers must submit an NOI at least 180 days before the expiration of this permit. See Appendix A of this General Permit for NOI requirements.

b. Existing facilities without permit coverage that increase their production levels and/or feed levels to exceed both the thresholds in §II.B.3, above, must submit an NOI within 30 days of knowing they will exceed or have exceeded both thresholds.

c. New dischargers must submit NOIs at least 180 days prior to initiation of new discharges.

5. Signatory Requirement

The NOI must be signed and certified in accordance with 40 CFR §122.22, as required by Section VIII.E (Signatory Requirements) of this permit.

B. When the Permittee is Authorized to Discharge

A discharger will be authorized to discharge beginning on the date it receives written notification from the EPA that grants coverage under the General Permit and assigns an individual number under this General Permit.

C. Individual Permit Alternative

1. EPA Requirement for Individual Permit.

The Director may require any discharger requesting coverage under this General Permit to apply for and obtain an individual NPDES permit in accordance with 40 CFR 122.28(b)(3)(i). In this case, the Permittee will be notified in writing that an individual permit is required and be given a brief explanation of the reasons for the decision. Individual permits may be appropriate if:

a. Whenever the Permittee is not in compliance with the conditions of this General Permit;

b. Whenever a change has occurred in the availability of demonstrated technology or practices for the control or abatement of pollutants applicable to the point source, therefore causing limitations of the General Permit to not be appropriate for the control or abatement of pollutants from the point source(s);

c. If a water quality management plan, including a Total Maximum Daily Load (TMDL), containing requirements applicable to the point source is approved after the effective date of the General Permit;

d. If the discharge(s) is a significant contributor of pollution;

e. If circumstances have changed since the time of NOI submittal, so that the Permittee is no longer appropriately controlled under the General Permit, or either a temporary or permanent reduction or elimination of the discharge is necessary.

D. Permittee's Request to be Excluded from Coverage under the General Permit

Applying for an Individual Permit.

Any owner or operator authorized by this General Permit may request to be excluded from the coverage under the General Permit by applying for an individual permit. The Permittee must submit an individual permit application with reasons supporting the request to the Director no later than 90 days after the publication by EPA of the General Permit in the Federal Register. The request shall be granted by issuing of any individual permit if the reasons cited by the owner or operator are adequate to support the request. Coverage under this General Permit will be automatically terminated on the effective date of the individual permit. 40 CFR 122.28(b)(3)(ii-iii).

E. Notice of Termination of Discharge

The Permittee must notify the EPA and any affected tribe within 30 days of discharge termination. The Permittee is required to submit DMRs until the effective date of Permit termination.

1. Requests to terminate coverage under this Permit must be in writing and submitted to EPA at the following address:

United States Environmental Protection Agency, Region 10
Unit Manager, NPDES Permits Unit
1200 Sixth Avenue, Suite 900 OWW-191
Seattle, WA 98101

2. Coverage under this Permit may be terminated in accordance with 40 CFR 122.64 if the EPA determines in writing that the entire discharge is permanently terminated, either by elimination of the flow or by connection to a publicly owned treatment works (POTW). Termination of coverage will become effective 30 days after the written determination is sent to the Permittee by the EPA, unless the Permittee objects within that time.

3. Any Permittee whose production and/or feed levels drop below and are expected to remain below the thresholds in §II.B.3, above, may request termination of coverage under this permit in accordance with this Part. The Permittee must include information on projected levels of production and feed for the following five years.

4. Under all circumstances, a Permittee must be covered under this Permit until it has properly disposed of wastewater or solids that were generated at the facility or collected in a raceway or settling basin or held in storage, and until the facility is no longer discharging to waters of the U.S.

IV. Effluent Limitations and Monitoring Requirements

A. Effluent Limitations

1. Prohibited Discharges

a. The Permittee must not discharge to waters of the U.S. from the hatchery complex:

(1) Atlantic salmon *(Salmo salar).*

(2) Solids, including sludge and grit that accumulate in raceways or ponds, in off-line or full-flow settling basins, or in other components of the production facility in excess of the applicable limits in this permit.

(3) Hazardous substances, unless authorized by this permit.

(4) Untreated cleaning wastewater (e.g., obtained from a vacuum or standpipe bottom drain system or rearing/holding unit disinfection).

(5) Visible foam or floating, suspended or submerged matter, including fish mortalities, kill spawning, processing wastes, and leachate from these materials, in amounts causing, or contributing to, a nuisance or objectionable condition in the receiving water or that may impair designated beneficial uses in the receiving water. This does not apply to approved nutrient enhancement efforts.

(6) Disease control chemicals and drugs except those approved by the Food and Drug Administration and/or the EPA for hatchery use or those reported to the EPA in accordance with Section V (Aquaculture specific reporting requirements).

(7) Toxic substances, including drugs, pesticides, or other chemicals, in toxic amounts that may impair designated uses or violate water quality standards of the receiving water.

2. Prohibited Practices

The Permittee is prohibited from engaging in any of the following practices or otherwise facilitating prohibited discharges described in §IV.A.1, above:

a. Practices that allow accumulated solids in excess of the limits to be discharged to waters of the United States from the permitted facility (*e.g.*, the removal of dam boards in raceways or ponds, the cleaning of settling basins, etc.);

b. Sweeping, raking, or otherwise intentionally discharging accumulated solids from raceways, ponds, or settling basins to waters of the United States; and/or

c. Containing, growing or holding fish within an off-line or in-line settling basin.

3. Discharge Limits

a. Permitted Discharges. During the effective period of the Permittee's authorization to discharge, the Permittee is authorized to discharge pollutants from the outfall(s) specified in its NOI within the limits and subject to the conditions set forth in this permit. This permit authorizes the discharge of only those pollutants resulting from facility processes, waste streams, and operations that have been clearly identified in the NOI, including non-production facilities, such as incubators, laboratories, tagging operations, etc. It does not authorize the discharge of any waste streams, including spills and other unintentional or non-routine discharges of pollutants, that are not part of the normal operation of the facility as disclosed in the Permittee's NOI nor does it authorize the discharge of any pollutants that are not ordinarily present in such waste streams.

b. Discharge Limits. The Permittee must limit discharges from all outfalls authorized under this permit as specified in Tables 1 and 2, below, as applicable. The limits in Table 1 apply to all hatchery discharges except those from separate off-line settling basin outfalls and rearing pond discharges during drawdown, limits for which are listed in Table 2. All limits represent maximum effluent limits, unless otherwise indicated. The Permittee must comply with the applicable effluent limits in the tables at all times, unless otherwise indicated, regardless of the frequency of monitoring or reporting.

Table 1
Effluent Limitations for Hatchery Discharges[1]

Pollutant	Average Monthly Limit	Maximum Daily Limit	Instantaneous Maximum
Net **Total Suspended Solids**[2]	5 mg/L	---	15 mg/L
Net **Settleable Solids**[2]	0.1 ml/L	---	---
Total Residual Chlorine[3] – into fresh water	9.0 µg/L	18.0 µg/L	---
Total Residual Chlorine[3] – into marine water	6.1 µg/L	12.3 µg/L	---

[1] Excluding discharges from separate off-line settling basins (OLSBs) and from raceways or pond systems during drawdown; see Table 2 for limits on those discharges.

[2] Net concentration = effluent concentration – influent concentration. Net TSS and settleable solids determinations will require influent analysis in addition to effluent analysis unless the permittee chooses to assume that the pollutant concentration in the influent is zero. Influent samples must be collected prior to collection of effluent samples; and net TSS and settleable solids will be determined by subtracting the influent concentrations from the effluent concentrations: see Appendix B. The EPA may require additional sampling to prove substantial similarity between influent and effluent solids, where indicated. All influent and effluent samples and flow measurements must be taken on the same day.

[3] Chlorine limits only apply when chlorine or Chloramine-T is being used. The Permittee will be in compliance with the effluent limits for total residual chlorine, provided the total residual chlorine residual levels are at or below the compliance evaluation level of 50 µg/L. Chlorine monitoring is not required if chlorine is allowed to dry at the location of use.

c. Discharge Limits for Off-Line Settling Basins (OLSBs) and for Raceways or Rearing Ponds during drawdown for fish release. These limits apply to any discharge to waters of the U.S. from an OLSB in addition to limitations listed in Table 1, above, for the total hatchery flow. These limits apply to raceways or pond systems during drawdown for fish release in lieu of the TSS and settleable solids limits in Table 1, above. See Table 2, below. The total residual chlorine limits set forth in Table 1, above, still apply to raceways or pond systems during drawdown for fish release.

Table 2

Effluent Limits for Discharges from Off-line Settling Basins[1] and from Raceways or Rearing Ponds during Drawdown for Fish Release

Pollutant	Maximum Daily Limit
Total Suspended Solids	100 mg/L
Settleable Solids	1.0 ml/L

[1] These limits apply to only those OLSB effluents that discharge directly to waters of the U.S.

4. Rearing Vessel Disinfection Water

When rearing vessels are disinfected with chlorine, the total residual chlorine effluent limits in Table 1, above, apply.

B. Effluent Monitoring Requirements

1. Hatchery Monitoring

Discharges authorized by this permit from fish hatcheries must be monitored at each outfall described in the NOI. Monitoring in Table 3, below, must be performed before the effluent is discharged to the receiving water. Monitoring results must be submitted to the EPA as directed in §VI.B.

Table 3
Hatchery Effluent Monitoring Requirements

Parameter	Units	Sample Type	Sample Frequency	Sample Location
Effluent Flow[1]	Gallons per day	Flow meter, calibrated weir, or other approved method	Monthly[2]	Effluent[3,4]
Net Total Suspended Solids[5]	mg/L	Composite[6]	Monthly[2]	Influent[5] & Effluent[3]
Net Settleable Solids[5]	ml/L	Grab	Monthly[2]	Influent[5] & Effluent[3]
Total Residual Chlorine (including when Chloramine-T is in use)[7]	µg/L	Grab	Monthly[2]	Effluent[3]
Temperature (facilities that discharge to waters impaired for temperature)	°C	Meter	Continuous (2 years)	Upstream & Effluent[3]

[1] All influent and effluent samples and flow measurements must be taken on the same day.

[2] Monthly monitoring must begin in the first full calendar month of permit coverage; quarterly monitoring must begin in the first full calendar quarter of permit coverage.

[3] Effluent samples must be collected from the effluent stream after the last unit prior to discharge into the receiving waters or to subsequent mixing with other water flows. If off-line settling basin effluent combines with raceway flows, at least one quarter of the grab samples that go into a composite sample must be collected when the OLSB is discharging.

[4] If the facility is operating in a steady state (no drawdown nor filling up), the flow may be monitored at the influent or the effluent.

[5] Net concentration = effluent concentration – influent concentration. Net TSS and settleable solids determinations will require influent analysis in addition to effluent analysis unless the permittee chooses to assume that the pollutant concentration in the influent is zero. Influent samples must be collected prior to collection of effluent samples; and net TSS and settleable solids will be determined by subtracting the influent concentrations from the effluent concentrations: see Appendix B. The EPA may require additional sampling to prove substantial similarity between influent and effluent solids, where indicated.

[6] Composite samples must consist of four or more discrete samples taken at one-half hour intervals or greater over a 24-hour period; for facilities that clean raceways periodically, at least one fourth of the samples must be taken during quiescent zone or raceway cleaning. Facilities with multiple effluent discharge points and/or influent points must composite samples from all points proportionally to their respective flows. Only the composite sample must be analyzed.

[7] Total residual chlorine must be monitored only when being used, giving consideration to retention times in the facility. Monitoring for must be conducted during each calendar quarter if the chemical used at any time during the quarter but sampling does not need to occur more than once a quarter. Chlorine monitoring is not necessary if chlorine is allowed to dry at the location of use.

Temperature

The following facilities covered by this General Permit discharge to water bodies impaired for temperature and are required to monitor for temperature:

1. Makah National Fish Hatchery (USFWS)
2. Quilcene National Fish Hatchery (USFWS)
3. House of Salmon (Lower Elwha Klallam Tribe)
4. Chief Joseph Hatchery on the Columbia (Confederated Tribes of the Colville Reservation).
5. Skookum Creek Fish Hatchery (Lummi Nation)

Continuous temperature monitoring must begin within one year of the effective date of this Permit. Permittees must monitor for two (not necessarily consecutive) calendar years. Permittees must monitor their effluent, as well as the receiving water immediately upstream of the facility. Upstream and effluent temperature monitoring must occur simultaneously. If a facility has more than one outfall, the Permittee must perform temperature monitoring on the outfall that is most representative of the facility's flow.

Temperature data must be recorded using a micro-recording temperature devices known as a thermistor. Set the recording device to record at one-hour intervals. Collect the following data: monthly instantaneous maximum, maximum daily average, and a seven-day running average of the daily instantaneous maximum.

Use the temperature device manufacturer's software to generate (export) an Excel text or electronic ASCII text file. The text file and placement log must be submitted to the EPA with the annual report for the 2020 calendar year. The placement logs should include the following information for both thermistor deployment and retrieval: date, time, temperature device manufacturer ID, location, depth, whether it measured air or water temperature, and any other details that may explain data anomalies.

2. Off-line Settling Basin (OLSB) Effluent Monitoring

Discharges to waters of the U.S. from OLSBs must be monitored as required in Table 4, below. OLSB discharges must be monitored 12 months out of the year if there is a discharge, regardless of pounds of fish at the facility.

Table 4
Off-Line Settling Basin
Effluent Monitoring Requirements[1]

Parameter	Units	Sample Type	Sample Frequency	Sample Location
Effluent Flow[2]	Gallons per day	Flow meter, calibrated weir, or other approved method	Monthly[3]	Effluent[4]
Total Suspended Solids	mg/L	Grab[5]	Monthly[3]	Effluent[4]
Settleable Solids	ml/L	Grab[5]	Monthly[3]	Effluent[4]
Ammonia[6]	mg/L	Grab[5]	Quarterly[3]	Effluent[4]
Temperature[7]	° C.	Meter	Weekly when OLSB is discharging	Effluent[4]
pH[8]	Standard Units	Meter	Quarterly[3]	Effluent[4]

[1] Only direct discharges to waters of the U.S. need to be monitored; if the discharge combines with other process wastewaters, these additional OLSB monitoring requirements do not apply.

[2] All effluent samples and flow measurements must be taken on the same day.

[3] Monthly monitoring must begin in the first full calendar month of permit coverage; quarterly monitoring must begin in the first full calendar quarter of permit coverage.

[4] Effluent samples must be collected from the effluent stream after the last unit prior to discharge into the receiving waters or to subsequent mixing with other water flows.

[5] Facilities with multiple effluent discharge points must composite grab samples from all points proportionally to their respective flows. Only the composite sample must be analyzed.

[6] Ammonia monitoring is required only for those facilities with OLSBs discharging directly to receiving waters.

[7] Temperature monitoring must be taken concurrently with each grab sample for the composite ammonia sample and the results averaged and reported on the discharge monitoring report (DMR).

[8] pH monitoring must be taken concurrently with each grab sample for the composite ammonia sample and the range of results reported on the discharge monitoring report (DMR).

3. Monitoring Discharges of Rearing Pond and Raceway Drawdowns for Fish Release

Samples for rearing pond and raceway drawdowns for fish release must be collected regardless of amount of fish in the facility. See Table 5, below.

Table 5

Monitoring Requirements for Discharges from Rearing Pond or Raceway Drawdowns for Fish Release

Parameter	Sample Point	Sampling Frequency	Type of Sample
Settleable Solids (mL/L)	Effluent	1/Drawdown[1]	Grab
Total Suspended Solids (mg/L)	Effluent	1/Drawdown[1]	Grab

[1] Drawdown samples must be collected during the last quarter of each drawdown event. If the drawdown is a continuous event that involves more than one rearing pond or raceway discharging directly to waters of the US, the Permittee may composite grab samples from each rearing pond or raceway proportionally to their respective flows, each taken in the last quarter of its drawdown; the combined sample may be analyzed instead of separately analyzing grab samples from each of the rearing ponds or raceways. If the discharge is to a settling pond, the facility must estimate when the final ¼ of the discharge is being released to the settling pond, delay the monitoring by the residence time calculated for the pond, and then monitor as the effluent discharges from the pond to the receiving water. If multiple drawdown events are sequential or on different days, a separate grab sample must be analyzed for each event.

4. Monitoring Discharges of Rearing Vessel Disinfection Water

Rearing vessel disinfection water that has been treated with chlorine must be tested before it is allowed to be discharged to waters of the United States; see Table 6, below. Chlorine monitoring is not required if rearing vessels are allowed to dry completely and there is no discharge of chlorine.

Table 6
Monitoring Requirement for Discharges of Rearing Vessel Disinfection Water

Parameter	Sample Point	Sampling Frequency	Type of Sample
Total Residual Chlorine (mg/L)	Effluent	1/Discharge	Grab

C. Surface Water Monitoring

a. Ammonia, Temperature, and pH Monitoring. All Permittees that have off-line settling basins that discharge **directly** to surface waters must conduct surface water monitoring quarterly for ammonia, pH, and temperature immediately upstream, outside the influence of the discharge.

b. Sample Collection. All surface water samples must be grab samples and must be collected at approximately the same time as the effluent samples.

c. Minimum Levels. All samples must be analyzed for the parameters listed in Table 7 to achieve minimum levels (MLs) that are equivalent to or less than those listed in Table 8. The Permittee may request different MLs if its results have consistently been above the required MLs. Such a request must be in writing and must be approved by the EPA before the Permittee may use the revised MLs.

d. Reporting Surface Water Monitoring Results. All surface water monitoring results must be submitted to the EPA and to applicable tribes with the DMRs for the month when the monitoring is conducted. The report must include all information required below, and a summary and evaluation of the analytical results.

Table 7
Surface Water Monitoring Requirements[1]

Parameter	Units
Ammonia Nitrogen as N	mg/L
pH	standard units
Temperature	^{o}C

[1] Surface water monitoring is only required for Permittees that have off-line settling basins that discharge **directly** to surface waters

D. PCB Monitoring for Facilities in the Spokane Watershed

All facilities that discharge to waters in WRIA 54 (Lower Spokane) and WRIA 57 (Middle Spokane) must monitor their effluent for PCB congeners. As of the date of permit issuance, these permit provision applies to two facilities that discharge within these WRIAs: Ford State Fish Hatchery and Spokane Tribal Hatchery.

The EPA is requiring the use of EPA Method 1668C. Permittees must report the total concentration of "dioxin-like" PCB congeners (see Table 8). A complete congener analysis must also be submitted as an attachment to the DMR. PCB monitoring must take place annually, during the calendar quarter of maximum feeding. For any analysis of PCB congeners using EPA Method 1668, the permittee must target MDLs no greater than the MDLs listed in Table 2 of EPA Method 1668 Revision C (EPA-820-R-10-005) and must analyze for each of the 209 individual congeners.

Permittees must follow the Spokane River Regional Toxics Task Force Quality Assurance Project Plan with respect to data validation and blank censoring. The Task Force QAPP addresses this issue in Section 4.2.2, on Pages 40 and 41. Analytes found in samples at concentrations less than 3 times the associated blank concentration will be flagged with a "B" qualifier. The Task Force QAPP states that "all qualified data will be reported with validation qualifiers, however B flagged data will not be used in congener summations for total PCB" (Page 41). See http://srrttf.org/wp-content/uploads/2013/05/QAPP_FINAL_081114.pdf.

Table 8. Dioxin-Like PCB Congeners

Dioxin-Like PCBs IUPAC #	Homolog Group	Substitution Group	IUPAC Name
non-*ortho* substituted PCBs			
77	tetra-CB	non-ortho	3,3',4,4'-tetra-CB
81	tetra-CB	non-ortho	3,4,4',5-tetra-CB
126	penta-CB	non-ortho	3,3',4,4',5-penta-CB
169	hexa-CB	non-ortho	3,3',4,4',5,5'-hexa-CB
mono-*ortho* substituted PCBs			
105	penta-CB	mono-ortho	2,3,3',4,4'-penta-CB
114	penta-CB	mono-ortho	2,3,4,4',5-penta-CB
118	penta-CB	mono-ortho	2,3',4,4',5-penta-CB
123	penta-CB	mono-ortho	2,3',4,4',5-penta-CB
156	hexa-CB	mono-ortho	2,3,3',4,4',5-hexa-CB
157	hexa-CB	mono-ortho	2,3,3',4,4',5'-hexa-CB
167	hexa-CB	mono-ortho	2,3',4,4',5,5'-hexa-CB
189	hepta-CB	mono-ortho	2,3,3',4,4',5,5'-hepta-

In addition to the BMP requirements of the General Permit, Permittees in WRIAs 54 and 57 must use any available product testing data to preferentially purchase paint and caulk with the lowest practicable total PCB concentrations.

Facilities in the Spokane River area must also request PCB content information from fish food suppliers and include documentation of that request in their files.

E. Minimum Levels (MLs)

For all effluent monitoring, the Permittee must use a sufficiently sensitive analytical method which meets the following:

a) Parameters with an effluent limit: The method must achieve a minimum level (ML) less than the effluent limitation unless otherwise specified in Table 1 Effluent Limitations and Monitoring Requirements.

b) Parameters that do not have effluent limitations: The Permittee must use a method that detects and quantifies the level of the pollutant, or the Permittee must use a method that can achieve a maximum ML less than or equal to those specified in Table 8.

c) Minimum Levels: For parameters that do not have an effluent limit, the Permittee may request different MLs. The request must be in writing and must be approved by the EPA. See also Part VI.B. Monitoring Procedures.

For purposes of reporting on the DMR for a single sample, if a value is less than the Method Detection Limit (MDL), the Permittee must report "less than {numeric value of the MDL}" and if a value is less than the ML, the Permittee must report "less than

{numeric value of the ML}."

For purposes of calculating monthly averages, zero may be assigned for values less than the MDL, and the {numeric value of the MDL} may be assigned for values between the MDL and the ML. If the average value is less than the MDL, the Permittee must report "less than {numeric value of the MDL}" and if the average value is less than the ML, the Permittee must report "less than {numeric value of the ML}." If a value is equal to or greater than the ML, the Permittee must report and use the actual value. The resulting average value must be compared to the compliance level, the ML, in assessing compliance.

Table 9
Minimum Levels

Parameter	Minimum Level (ML)
Total Suspended Solids	5 mg/L
Ammonia Nitrogen as N	50 µg/L
pH	NA
Temperature	0.2° C
Total Residual Chlorine	50 µg/L

F. Quality Assurance (QA) Plan

a. Plan Development.

The Permittee must develop a quality assurance plan (QA Plan) for all monitoring required by this permit to assist in planning for the collection and analysis of effluent and receiving water samples in support of the permit and in explaining data anomalies when they occur. The plan must be developed and implemented within 90 days after receiving authorization to discharge under this permit. Any existing QA Plans may be modified to meet this requirement.

Existing Permittees must review and update their QA Plans within 90 days of the reissuance of this General Permit.

b. Required Submittal

(1) To the EPA

A Permittee must certify that a QA Plan has been developed and is being implemented and must submit the certification, which includes the information specified in Appendix C, to EPA within 90 days after receiving authorization to discharge under this permit. The submittal address for the EPA is set forth in

§III.A.1, above. A new Permittee must submit the certification with the NOI to be covered under this permit.

(2) To the Lummi Nation

As a requirement of the Tribe's 401 Certification, any Permittee that discharges to waters of the Lummi Nation must submit its QA Plan to the Lummi Nation address listed in §III.A.1, at the same time it is submitted to the EPA.

(3) To the Spokane Tribe

As a requirement of the Tribe's 401 Certification, any Permittee that discharges to waters of the Spokane Tribe must submit its QA Plan to the Spokane Tribe address listed in §III.A.1 within 90 days after receiving authorization to discharge under this permit.

(4) To the Swinomish Indian Tribal Community

As a requirement of the Tribe's 401 Certification, any Permittee that seeks coverage under this Permit who intends to discharge to Swinomish waters must submit a copy of the QA Plan to the Department of Environmental Protection at the address listed in §III.A.1.

(5) To the Tulalip Tribes

As a requirement of the Tribes' 401 Certification, any Permittee that discharges to waters of the Tulalip Tribes must submit or make available to the Tribes its QA Plan.

c. Conformity with EPA procedures

Throughout all sample collection and analysis activities, the Permittee must use the EPA-approved quality assurance and quality control (QA/QC) and chain-of-custody procedures described in Requirements for Quality Assurance Project Plans (EPA/QA/R-5)[2] and Guidance for Quality Assurance Project Plans (EPA/QA/G-5)[3]. The QA Plan must be prepared in the format that is specified in these documents.

d. Plan contents

At a minimum, the QA Plan must include the following:

(1) Details on the number of samples, type of sample containers, preservation of samples, holding times, analytical methods, analytical detection and quantification limits for each parameter, type and number of quality assurance field samples, precision and accuracy requirements, sample preparation requirements, and sample shipping methods. See §VI. for additional requirements regarding monitoring.

(2) Description of flow measuring devices used to measure influent and/or effluent flow at each point, calibration procedures, and calculations used to

[2] http://www.epa.gov/quality/qs-docs/r5-final.pdf
[3] http://www.epa.gov/quality/qs-docs/g5-final.pdf

convert to flow units. Facilities with multiple effluent discharge points and/or influent points must describe their method of compositing samples from all points proportionally to their respective flows;

(3) Maps indicating the location of each sampling point;

(4) Qualification and training of personnel; and

(5) Name, address and telephone number of the laboratory used by or proposed to be used by the Permittee.

e. Modifications required

The Permittee must amend the QA Plan whenever there is a modification in sample collection, sample analysis, or other procedure addressed by the QA Plan and must update it whenever there is a change in ownership or operator.

f. Copies required on-site

Copies of the QA Plan must be kept on site and made available to the EPA upon request. If lack of suitable storage area makes on-site storage impossible, the QA Plan must be in the possession of staff whenever they are working on-site.

G. Best Management Practices Plan

1. Purpose

Through implementation of the best management practices (BMP) plan, the Permittee must prevent or minimize the generation and discharge of wastes and pollutants from the facility to waters of the United States to meet water quality standards and permit requirements; the Permittee must also ensure that disposal or land application of wastes is carried out in such a way as to minimize negative environmental impact and, if applicable, to comply with Washington State solid waste disposal regulations.

2. Development and Implementation Deadline

The Permittee must develop and implement a BMP Plan that meets the specific requirements listed in Part III.C.5, below. An existing BMP Plan may be modified for use under this section. The Permittee must implement the provisions of the BMP Plan as conditions of this permit within 90 days of receiving authorization to discharge under this permit.

Existing Permittees must review and update their BMP Plans within 90 days of the reissuance of this General Permit.

3. Required Submittal

a. To the EPA

A Permittee must certify that a BMP Plan has been developed and is being implemented. The certification must be submitted to the EPA and must include the information specified in Appendix C. An existing discharger must submit the

certification within 90 days after receiving the authorization to discharge under this permit. A new Permittee must submit the certification with the written NOI to be covered under this permit.

b. To the Lummi Nation

As a requirement of the Tribe's 401 Certification, any Permittee that discharges to waters of the Lummi Nation must submit its BMP Plan to the Lummi Nation at the same time it is submitted to the EPA.

c. To the Spokane Tribe

As a requirement of the Tribe's 401 Certification, any Permittee that discharges to waters of the Spokane Tribe must submit its BMP Plan to the Spokane Tribe within 90 days after receiving authorization to discharge under this permit.

d. To the Swinomish Indian Tribal Community

As a requirement of the Tribe's 401 Certification, any Permittee that discharges to waters of the Swinomish Tribe must submit or make available to the Tribe its BMP Plan.

e. To the Tulalip Tribes

As a requirement of the Tribes' 401 Certification, any Permittee that discharges to waters of the Tulalip Tribes must submit or make available to the Tribes its BMP Plan.

4. Annual Review

a. The Permittee must review the BMP Plan annually.

b. A certified statement that the annual review has been completed and that the BMP Plan fulfills the requirements set forth in this permit must be submitted to the EPA in the Annual Report of Operations, due by January 20 each year. See Appendix E.

5. Requirements of the BMP Plan

The BMP Plan must include, at a minimum, the following BMPs. Where a particular practice below is infeasible, the Permittee will substitute another practice to achieve the same end.

a. Materials Storage

(1) Ensure proper storage of drugs and other chemicals to prevent spills that may result in the discharge to waters of the United States.

(2) Implement procedures for properly containing, cleaning, and disposing of any spilled materials.

b. Structural Maintenance

(1) Routinely inspect rearing and holding units and waste collection and containment systems to identify and promptly repair damage.

(2) Regularly conduct maintenance of rearing and holding units and waste collection and containment systems to ensure their proper function.

c. Record keeping

(1) Document feed amounts and numbers and weights of aquatic animals to calculate feed conversion ratios.

(2) Document the frequency of cleanings, inspections, maintenance, and repairs.

(3) Maintain records of all medicinal and therapeutic chemical usage for each treatment at the facility. Include the information required in the Chemical Log Sheet in Appendix D and in the Annual Reports in Appendix E.

(4) A copy of the label (with treatment application requirements) and the Material Safety Data Sheet (MSDS) must be maintained in the facility's records for each drug or chemical used at the facility.

(5) In order to show how the maximum concentrations of chlorine and/or Chloramine-T were derived (see Table 3 for monitoring requirements), facilities must maintain records by chemical and by outfall of the approach/analyses used to determine the elapsed time from its application to its maximum (peak) effluent concentration, giving consideration to retention times within the facility.

(6) Permittees must keep the records necessary to provide the water-borne treatment/calculations information required on page 7 of the revised Annual Report (see Appendix E).

d. Training Requirements

(1) Train all relevant personnel in spill prevention and how to respond in the event of a spill to ensure proper clean-up and disposal of spilled materials.

(2) Train personnel on proper structural inspection and maintenance of rearing and holding units and waste collection and containment systems.

e. Operational Requirements

(1) Raceways and ponds must be cleaned at such a frequency and in such a manner that minimizes accumulated solids discharged to waters of the U.S.

(2) Fish feeding must be conducted in such a manner as to minimize the discharge of unconsumed food.

(3) Fish grading, harvesting, egg taking, and other activities within ponds or raceways must be conducted in such a way as to minimize the discharge of accumulated solids and blood wastes.

(4) Animal mortalities must be removed and disposed of on a regular basis to the greatest extent feasible.

(5) Water used in the rearing and holding units or hauling trucks that is disinfected with chlorine or other chemicals must be treated before it is discharged to waters of the U.S.

(6) Treatment equipment used to control the discharge of floating, suspended or submerged matter must be cleaned and maintained at a frequency sufficient to minimize overflow or bypass of the treatment unit by floating, suspended, or submerged matter; turbulent flow must be minimized to avoid entrainment of solids.

(7) Procedures must be implemented to prevent fish from entering quiescent zones, full-flow, and off-line settling basins. Fish that have entered quiescent zones or basins must be removed as soon as practicable.

(8) Procedures must be implemented to minimize the release of diseased fish from the facility.

(9) All drugs and pesticides must be used in accordance with applicable label directions (FIFRA or FDA), except under the following conditions, both of which must be reported to the EPA in accordance with §V, below:

(a) Participation in Investigational New Animal Drug (INAD) studies, using established protocols; or

(b) Extralabel drug use, as prescribed by a veterinarian.

(10) Procedures must be identified and implemented to collect, store, and dispose of wastes, such as biological wastes. Such wastes include fish mortalities and other processing solid wastes from aquaculture operations.

(11) Facilities must dispose of excess/unused disinfectants in a way that does not allow them to enter waters of the U.S.

(12) Facilities must implement procedures to eliminate the release of Polychlorinated Biphenyls (PCBs) from any known sources in the facility-including paint, caulk, or feed. If removing paint or caulk that was applied prior to 1980, refer to the EPA guidance (abatement steps 1-4) at http://www.epa.gov/epawaste/hazard/tsd/pcbs/pubs/caulk/guide/guide-sect4a.htm. Any future application of paint or caulk must be below the allowable TSCA level of 50 ppm. Facilities must implement purchasing procedures that give preference for fish food that contains the lowest amount of PCBs that is economically and practically feasible.

6. Documentation

The Permittee must maintain a copy of the BMP Plan at the facility and make it available to the EPA, the Spokane Tribe (if on the Spokane Reservation), or an authorized representative upon request. If lack of a suitable storage area makes on-site storage

impossible, the BMP Plan must be in the possession of staff whenever they are working on-site.

7. BMP Plan Modification

The Permittee must amend the BMP Plan whenever there is a change in the facility or in the operation of the facility which materially increases the generation of pollutants or their release or potential release to surface waters. With any change in operator, the BMP Plan must be reviewed and modified, if necessary. The new operator must submit a certification in accordance (see Appendix C).

V. Aquaculture Specific Reporting Requirements

A. Drug and Other Chemical Use and Reporting Requirements

The following requirements apply to disease control chemicals that are used in such a way that they will be or may be discharged to waters of the United States.

B. Use of Drugs, Pesticides, and Other Chemicals

a. Only disease control chemicals and drugs approved for aquaculture use by the U.S. Food and Drug Administration (FDA) or by the EPA may be used.

b. The following drugs may also be used:

(1) Investigational New Animal Drugs (INADs) for which the FDA has authorized use on a case-by-case basis.

(2) Extralabel drug use of approved animal and human drugs by, or on the order of, a licensed veterinarian.

(3) Low Regulatory Priority (LRP) compounds in accordance with conditions included on the list in the FDA policy 1240.4200: *Enforcement Priorities for Drug Use in Aquaculture* (08/09/2002; 4/26/07 minor revisions)[4] p.13--15. (See Appendix F of this permit.)

(4) Potassium permanganate, a deferred regulatory priority drug.

c. All drugs, pesticides and other chemicals must be applied in accordance with label directions (with the exception of INAD, extralabel drug use, LRP compounds, or potassium permanganate, as described above).

d. Records of all applications of drugs, pesticides, and other chemicals must be maintained and must, at a minimum, include the information specified in Appendix D. This information must also be summarized in the Annual Report.

C. Reporting Drug Usage

a. <u>INADs and Extralabel Drug Use</u>

[4] http://www.fda.gov/cvm/Policy_Procedures/4200.pdf

The following written and oral reports must be provided to the EPA and to the Spokane Tribe (if on the Spokane Reservation) when an INAD or extralabel drug is used for the first time at a facility and when an INAD or extralabel drug is used at a higher dosage than previously approved by the FDA for this or a different animal species or disease. The Permittee must include descriptions of all disease control chemicals used during the past year on the Annual Report.

The following INAD and extralabel drug use reporting requirements only apply if the Permittee did not list the disease treatment chemical on its NOI:

(1) Anticipated INAD Study Participation and Extralabel Drug Usage

Written Report: A Permittee must provide a written report to the EPA and to the Spokane Tribe (if on the Spokane Reservation) within seven days of agreeing or signing up to participate in an INAD drug study or receiving a prescription for extralabel drug use. The report must include the information specified in Appendix D.

(2) Actual Use of INADs or Extralabel Drug Use

(a) Oral Report:

For INAD and extralabel drug uses, the Permittee must provide an oral report to the EPA (206-553-1846) and to the Spokane Tribe (if on the Spokane Reservation) (509-626-4409) as soon as possible during business hours, preferably in advance of use, but no later than 7 days after initiating use of the drug. The report must include the drug(s) used, the method of application, and the reason for the drug(s).

(b) Written Report:

For INADs and extralabel drug uses, the Permittee must provide to the EPA and to the Spokane Tribe (if on the Spokane Reservation) a written report within 30 days after initiating use of the drug. The report must include the information specified in Appendix D. This information must also be included in the Annual Report.

b. First Use of Low Regulatory Priority (LRP) Drugs or Potassium Permanganate

(1) Oral Report:

For first use of an LRP drug or potassium permanganate (only if it was not listed in the NOI), the Permittee must provide an oral report to the EPA (206-553-1846) and to the Spokane Tribe (if on the Spokane Reservation) (509-626-4409) as soon as possible during business hours, preferably in advance of use, but no later than 7 days after initiating use of the drug. The report must include the information specified in Appendix D.

(2) Written Report:

For first use of an LRP drug or potassium permanganate (only if it was not listed in the NOI), the Permittee must provide to the EPA and to the Spokane Tribe (if on the Spokane Reservation) a written report within 30 days after initiating use of the drug. The report must include the information specified in Appendix D. This information must also be included in the Annual Report.

D. Structural Failure or Damage to the Facility

Structural failure or damage to the facility must be reported to the EPA orally within 24 hours and in writing within five days when there is a resulting discharge of pollutants to waters of the U.S. Reports must include the identity and quantity of pollutants released. (See Representative Sampling and Noncompliance Reporting in §VI.A. and §VI.H.)

E. Spills of Drugs, Pesticides or Other Chemicals

1. Drugs, Pesticides or Other Chemicals

The Permittee must monitor and report to the EPA and to applicable tribes any spills of drugs, pesticides, or other chemicals that result in a discharge to waters of the United States; these must be reported orally within 24 hours and in writing within five days. Reports must include the identity and quantity of pollutants released. (See Representative Sampling and Noncompliance Reporting in §VI.).

2. Oil or Hazardous Materials

a. <u>To the EPA</u>

The Permittee must report immediately to the EPA at 1-800-424-8802 any spills of oil or hazardous materials to waters of the U.S.

b. <u>To Washington Department of Ecology</u>

The Permittee must report any spills of oil or hazardous materials to waters of the State of Washington to Ecology at 1-800-258-5990 or 1-800-OILS-911 and to the appropriate Ecology regional office:

Northwest Region	Island, King, Kitsap, San Juan, Skagit, Snohomish, & Whatcom counties	425-649-7000
Southwest Region	Clallam, Clark, Cowlitz, Grays Harbor, Jefferson, Mason, Lewis, Pacific, Pierce, Skamania, Thurston, & Wahkiakum counties	360-407-6300
Central Region	Benton, Chelan, Douglas, Kittitas, Klickitat, Okanogan, & Yakima counties	509-575-2490

Eastern Region	Adams, Asotin, Columbia, Ferry, Franklin, Garfield, Grant, Lincoln, Pend Oreille, Spokane, Stevens, Walla Walla, & Whitman counties	509-329-3400

c. To the Lummi Nation

As a requirement of the Tribe's 401 Certification, any operator of a facility on Lummi lands must report immediately any spills of oil or hazardous materials to waters of the Lummi Nation to the Lummi Natural Resources Department Director at 360-410-1706.

d. To the Spokane Tribe

As a requirement of the Tribe's 401 Certification, any operator of a facility on the Spokane Reservation must report immediately any spills of hazardous materials to waters of the Spokane Tribe to the Spokane Tribe Water Control Board at 509-626-4409.

e. To the Swinomish Indian Tribal Community

As a requirement of the Tribe's 401 Certification, any operator of a facility that discharges to Swinomish waters must report immediately any spills of drugs, pesticides, oil, or hazardous materials to the Department of Environmental Protection at 360-466-7280 and to the Swinomish Police Department.

f. To the Tulalip Tribes

As a requirement of the Tribes' 401 Certification, any operator of a facility on the Tulalip Reservation must report immediately any spills of drugs, pesticides, oil, or hazardous materials to waters of the Tulalip Tribes at 360-716-5911.

F. Records of Fish Mortalities

1. Maintenance of Records. Records of routine and mass mortalities must be maintained on site for at least three years.

2. Annual Reporting. Summaries of mortality data must be included in annual reports.

G. Annual Report of Operations

During the term of this permit, the Permittee must prepare and submit an annual report of the previous year's operations by January 20th of each year. A copy of the annual report and the data used to compile it must be available to the EPA upon request and during inspections. The report must include the information specified in Appendix E.

1. To the EPA:

A Permittee must submit the annual report to the EPA at the address in §III.A.1.

2. To the Lummi Nation:

A Permittee that discharges to waters of the Lummi Nation must submit the annual report to the Lummi Nation at the address in §III.A.1.

3. To the Spokane Tribe:

A Permittee that discharges to waters of the Spokane Tribe must submit the annual report to the Spokane Tribe at the address in §III.A.1.

4. To the Swinomish Indian Tribal Community:

A Permittee that discharges to waters of the Swinomish Tribe must submit the annual report or make it available to the Department of Environmental Protection at the address in §III.A.1

5. To the Tulalip Tribes:

A Permittee that discharges to waters of the Tulalip Tribes must submit the annual report to the Tulalip Tribes at the address in §III.A.1

VI. Standard Monitoring, Recordkeeping, and Reporting Requirements

A. Representative Sampling (Routine and Non-Routine Discharges)

Samples and measurements must be representative of the volume and nature of the monitored discharge or source water.

In order to ensure that the effluent limits set forth in this permit are not violated at times other than when routine samples are taken, the Permittee must collect additional samples at the appropriate outfall whenever any discharge occurs that may reasonably be expected to cause or contribute to a violation that is unlikely to be detected by a routine sample. The Permittee must analyze the additional samples for those parameters limited in §IV.A ("Effluent Limitations") that are likely to be affected by the discharge.

The Permittee must collect such additional samples as soon as the spill, discharge, or bypassed effluent reaches the outfall. The samples must be analyzed in accordance with §VI.B ("Monitoring Procedures"). The Permittee must report all additional monitoring in accordance with §VI.D ("Additional Monitoring by Permittee").

B. Monitoring Procedures

The Permittee must conduct monitoring according to test procedures approved under 40 CFR 136, unless another method is required under 40 CFR subchapters N or O, or other test procedures have been specified in this Permit or approved by the EPA as an alternative test procedure under 40 CFR 136.5.

C. Reporting of Monitoring Results

The Permittee must summarize monthly monitoring results on the DMR. Monitoring data must be submitted electronically using NetDMR. NetDMR is described in more detail below. If additional monitoring of any pollutant is performed more frequently than required by the permit, the results must be included in the DMR.

The Permittee is not required to monitor when the facility is not discharging. However, the DMR must indicate the facility is not discharging and must be submitted as described below. The Permittee must submit a monthly DMR even if a discharge has not occurred, unless permit coverage has been terminated in accordance with §III.E. of this permit.

An annual report of raw monitoring data in a spreadsheet or text-format electronic file must be submitted to the EPA and to the Lummi, Spokane, Swinomish, or Tulalip Tribes (as appropriate) with the January DMR each year.

During the period between the effective date of the Permit and six months from the effective date, the Permittee must either submit monitoring data and other reports in paper form, or must report electronically using NetDMR.

1. Paper Copy Submissions

Prior to switching to NetDMR, all required monitoring data must be submitted using the DMR form (EPA No. 3320-1) or the equivalent and must be postmarked by the 20th day of the month following the end of the reporting period.

The Permittee must submit the legible originals of required documents as follows:

a. <u>To the EPA:</u>

The Permittee must submit the legible originals of these documents to the EPA Region 10 Director, Office of Compliance and Enforcement, at the address below:

USEPA Region 10
Attn: ICIS Data Entry Team
1200 Sixth Avenue, Suite 900, OCE-133
Seattle, Washington 98101-3140

b. <u>To the Lummi Nation:</u>

As a requirement of the Tribe's 401 Certification, any operator of a facility that discharges to Lummi Nation Waters must submit copies of DMRs, surface water monitoring reports, annual reports, notices of intent, BMP and QA Plans and certifications, spill reports, and any Non-compliance reports to the address below:

Lummi Natural Resources Department
ATTN: Water Resources Manager

2616 Kwina Road
Bellingham, WA 98226

c. To the Spokane Tribe

As a requirement of the Tribe's 401 Certification, any Permittee that discharges to Spokane Tribe waters must submit copies of DMRs, surface water monitoring reports, annual reports, notices of intent, BMP and QA Plans and certifications, spill reports, and any Non-compliance reports to the address below:

Water Control Board
c/o Brian Crossley
PO Box 480
Wellpinit, WA 99040

d. To the Swinomish Indian Tribal Community

As a requirement of the Tribe's 401 Certification, any Permittee that discharges to Swinomish Tribal waters must submit or make available to the Department of Environmental Protection monitoring records, notices, QA and BMP plans and reports authorized by this Permit to the address below:

Department of Environmental Protection
11430 Moorage Way
LaConner, WA 98257

e. To the Tulalip Tribes

As a requirement of the Tribes' 401 Certification, any Permittee that discharges to Tulalip Tribal waters must submit, or make available to the Tribes, copies of DMRs, surface water monitoring reports, annual reports, notices of intent, BMP and QA Plans and certifications, spill reports, and any Non-compliance reports to the address below:

Kurt Nelson
Environmental Division Manager
Tulalip Tribes Natural and Cultural Resources Department
6406 Marine Dr.
Tulalip, WA 98271

2. Electronic submissions

All required monitoring data must be submitted electronically to EPA no later than the 20th day of the month following the end of the reporting period.

All reports required under this Permit must be submitted to EPA as a legible electronic attachment to the DMR.

Once a Permittee begins submitting reports using NetDMR, it will no longer be required to submit paper copies of DMRs to EPA and to the Lummi, Spokane, Swinomish, and/or Tulalip Tribes, as appropriate.

After the first six (6) months of the effective date of the Permit, the Permittee must submit monitoring data and other reports electronically using NetDMR. The Permittee may use NetDMR after requesting and receiving permission from U.S. EPA Region 10. NetDMR is accessed from https://netdmr.epa.gov/netdmr/public/home.htm.

D. Additional Monitoring by the Permittee

If the Permittee monitors any pollutant more frequently than required by this permit, using test procedures approved under 40 CFR §136 or as specified in this permit or approved by the Regional Administrator, the results of this monitoring must be included in the calculation and reporting of the data submitted in DMRs.

Upon request by the EPA, the Permittee must submit results of any other sampling, regardless of the test method used.

E. Records Contents

Records of monitoring information must include:

1. The date, exact place, and time of sampling or measurements,
2. Names of the individual(s) who performed the sampling or measurements,
3. The date(s) analyses were performed,
4. Name of the individual(s) who performed the analyses**,**
5. The analytical techniques or methods used, and
6. The results of such analyses.

F. Retention of Records

The Permittee must retain records of all monitoring information, including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation, copies of all reports required by this Permit, and records of all data used to complete the NOI to become authorized to discharge under this permit, for a period of at least five years from the date of the sample, measurement, report, or NOI. This period may be extended by request of the EPA at any time. Data collected on-site, copies of DMRs and Annual Reports, and a copy of this NPDES permit and the NOI must be maintained on site during the duration of activity at the permitted location or in the possession of staff when working on-site. A copy of this Permit must be readily available for reference by applicable tribal inspectors.

G. Twenty-four Hour Notice of Noncompliance Reporting

1. The Permittee must report the following occurrences of noncompliance by telephone to the EPA (206-553-1846). For Lummi Nation dischargers, Permittees must also report to the Lummi Natural Resources Department Director (360-410-1706); for Spokane Tribe dischargers, to the Water Control Board (509-626-4409); for Tulalip Tribes' dischargers, to the Tulalip Tribes' Natural Resources Department (360-716-5911), as soon as possible, but no later than 24 hours from the time the Permittee becomes aware of the circumstances:

a. Any unanticipated bypass that exceeds an effluent limitation in the Permit;

b. Any upset that exceeds an effluent limitation in the permit;

c. Violation of an applicable maximum daily discharge limitation for total residual chlorine.

2. A written report must also be submitted within 5 days after the Permittee becomes aware of the circumstances. The written submission must contain:

a. Description of the noncompliance and its cause;

b. The period of noncompliance, including exact dates and times;

c. If the noncompliance has not been corrected, the anticipated time it is expected to continue; and

d. Steps taken or planned to reduce, eliminate, and prevent recurrence of the noncompliance.

3. The written report must be submitted, as follows:

a. to the EPA at the address in §III.A.1., above.

b. for Lummi Nation dischargers, the report must also be submitted to the address in §III.A.1., above.

c. for Spokane Tribe dischargers, the report must also be submitted to the address in §III.A.1., above.

4. The EPA may waive the requirement for a written report of non-compliance on a case-by-case basis, if an oral report has been received within 24 hours by telephone at 206-553-1846.

H. Other Noncompliance Reporting

The Permittee must report all instances of noncompliance, not required to be reported within 24 hours, at the time that monitoring reports for §VI.C ("Reporting of Monitoring Results") are submitted. The report must contain the information listed in §VI.G of this permit ("Twenty-four Hour Notice of Noncompliance Reporting").

VII. Compliance Responsibilities

A. Duty to Comply

The Permittee must comply with all conditions of this permit. Any permit noncompliance constitutes a violation of the Clean Water Act (the Act) and is grounds for enforcement action, for termination of the authorization to discharge, or for denial of coverage after submittal of a Notice of Intent.

B. Penalties for Violations of Permit Conditions

1. **Civil Penalties.** Pursuant to 40 CFR §19 and the Act, any person who violates section 301, 302, 306, 307, 308, 318 or 405 of the Act, or any permit condition or limitation implementing any such sections in a permit issued under section 402, or any requirement imposed in a pretreatment program approved under sections 402(a)(3) or 402(b)(8) of the Act, is subject to a civil penalty not to exceed the maximum amounts authorized by Section 309(d) of the Act and the Federal Civil Penalties Inflation Adjustment Act (28 U.S.C. §2461 note) as amended by the Debt Collection Improvement Act (31 U.S.C. §3701 note) (currently $37,500 per day for each violation).

2. **Administrative Penalties.** Any person may be assessed an administrative penalty by the Administrator for violating section 301, 302, 306, 307, 308, 318 or 405 of this Act, or any permit condition or limitation implementing any of such sections in a permit issued under section 402 of this Act. Pursuant to 40 CFR §19 and the Act, administrative penalties for Class I violations are not to exceed the maximum amounts authorized by Section 309(g)(2)(A) of the Act and the Federal Civil Penalties Inflation Adjustment Act (28 U.S.C. §2461 note) as amended by the Debt Collection Improvement Act (31 U.S.C. §3701 note) (currently $16,000 per violation, with the maximum amount of any Class I penalty assessed not to exceed $37,500). Pursuant to 40 CFR §19 and the Act, penalties for Class II violations are not to exceed the maximum amounts authorized by Section 309(g)(2)(B) of the Act and the Federal Civil Penalties Inflation Adjustment Act (28 U.S.C. §2461 note) as amended by the Debt Collection Improvement Act (31 U.S.C. §3701 note) (currently $16,000 per day for each day during which the violation continues, with the maximum amount of any Class II penalty not to exceed $177,500).

3. **Criminal Penalties:**

a. Negligent Violations. The Act provides that any person who negligently violates sections 301, 302, 306, 307, 308, 318, or 405 of the Act, or any condition or limitation implementing any of such sections in a permit issued under section 402 of the Act, or any requirement imposed in a pretreatment program approved under section 402(a)(3) or 402(b)(8) of the Act, is subject to criminal penalties of $2,500 to $25,000 per day of violation, or imprisonment of not more than 1 year, or both. In the case of a second or subsequent conviction for a negligent violation, a person shall be subject to criminal penalties of not more than $50,000 per day of violation, or by imprisonment of not more than 2 years, or both.

b. Knowing Violations. Any person who knowingly violates such sections, or such conditions or limitations is subject to criminal penalties of $5,000 to $50,000 per day of violation, or imprisonment for not more than 3 years, or both. In the case of a second or subsequent conviction for a knowing violation, a person shall be subject to criminal penalties of not more than $100,000 per day of violation, or imprisonment of not more than 6 years, or both.

c. Knowing Endangerment. Any person who knowingly violates section 301, 302, 303, 306, 307, 308, 318 or 405 of the Act, or any permit condition or limitation implementing any of such sections in a permit issued under section 402 of the Act, and who knows at that time that he thereby places another person in imminent danger of death or serious bodily injury, shall, upon conviction, be subject to a fine of not more than $250,000 or imprisonment of not more than 15 years, or both. In the case of a second or subsequent conviction for a knowing endangerment violation, a person shall be subject to a fine of not more than $500,000 or by imprisonment of not more than 30 years, or both. An organization, as defined in section 309(c)(3)(B)(iii) of the Act, shall, upon conviction of violating the imminent danger provision, be subject to a fine of not more than $1,000,000 and can be fined up to $2,000,000 for second or subsequent convictions.

d. False Statements. The Act provides that any person who falsifies, tampers with, or knowingly renders inaccurate any monitoring device or method required to be maintained under this permit shall, upon conviction, be punished by a fine of not more than $10,000, or by imprisonment for not more than 2 years, or both. If a conviction of a person is for a violation committed after a first conviction of such person under this paragraph, punishment is a fine of not more than $20,000 per day of violation, or by imprisonment of not more than 4 years, or both. The Act further provides that any person who knowingly makes any false statement, representation, or certification in any record or other document submitted or required to be maintained under this permit, including monitoring reports or reports of compliance or non-compliance shall, upon conviction, be punished by a fine of not more than $10,000 per violation, or by imprisonment for not more than 6 months per violation, or by both.

C. Need to Halt or Reduce Activity Not a Defense

It shall not be a defense for the Permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.

D. Duty to Mitigate

The Permittee shall take all reasonable steps to minimize or prevent any discharge in violation of this permit which has a reasonable likelihood of adversely affecting human health or the environment.

E. Proper Operation and Maintenance

The Permittee must at all times properly operate and maintain all facilities and systems of treatment and control (and related appurtenances) which are installed or used by the Permittee to achieve compliance with the conditions of this permit. Proper operation and maintenance also includes adequate laboratory controls and appropriate quality assurance procedures. This provision requires the operation of back-up or auxiliary facilities or similar systems only when the operation is necessary to achieve compliance with the conditions of this permit.

F. Bypass of Treatment Facilities

1. **Bypass not exceeding limitations.** The Permittee may allow any bypass to occur which does not cause effluent limitations to be exceeded, but only if it also is for essential maintenance to assure efficient operation. These bypasses are not subject to the provisions of paragraphs b and c of this section.

Notice:

a. Anticipated bypass. If the Permittee knows in advance of the need for a bypass, it shall submit prior notice, if possible at least 10 days before the date of the bypass.

b. Unanticipated bypass. The Permittee shall submit notice of an unanticipated bypass as required under permit §VI.G (Twenty-four Hour Notice of Noncompliance Reporting).

2. **Prohibition of bypass.** Bypass is prohibited and the EPA may take enforcement action against the Permittee for a bypass, unless:

a. The bypass was unavoidable to prevent loss of life, personal injury, or severe property damage;

b. There were no feasible alternatives to the bypass, such as the use of auxiliary treatment facilities, retention of untreated wastes, or maintenance during normal periods of equipment downtime. This condition is not satisfied if adequate back-up equipment should have been installed in the exercise of reasonable engineering judgment to prevent a bypass which occurred during normal periods of equipment downtime or preventive maintenance; and

c. The Permittee submitted notices as required under §VII.F.2, above.

3. The Director of the Office of Compliance and Enforcement may approve an anticipated bypass, after considering its adverse effects, if the Director determines that it will meet the three conditions listed above.

G. Upset Conditions

1. **Effect of an upset.** An upset constitutes an affirmative defense to an action brought for noncompliance with technology based permit effluent limitations, if the requirements of §VII.G.2, below, are met. No determination made during administrative review of

claims that noncompliance was caused by upset, and before an action for noncompliance, is final administrative action subject to judicial review.

2. **Conditions necessary to demonstrate an upset.** To establish the affirmative defense of upset, the Permittee shall demonstrate, through properly signed, contemporaneous operating logs, or other relevant evidence, that:

a. An upset occurred and that the Permittee can identify the cause(s) of the upset;

b. The permitted facility was at the time being properly operated;

c. The Permittee submitted notice of the upset as required under §VI.G (Twenty-four Hour Notice of Noncompliance Reporting); and

d. The Permittee complied with any remedial measures required under §VII.D (Duty to Mitigate).

3. **Burden of proof.** In any enforcement proceeding, the Permittee seeking to establish the occurrence of an upset has the burden of proof.

H. Toxic Pollutants

The Permittee must comply with effluent standards or prohibitions established under Section 307(a) of the Act for toxic pollutants within the time provided in the regulations that establish those standards or prohibitions, even if the permit has not yet been modified to incorporate the requirement.

I. Planned Changes

The Permittee must give notice to the EPA as soon as possible of any planned physical alterations or additions to the permitted facility whenever:

1. The alteration or addition to a permitted facility may meet one of the criteria for determining whether a facility is a new source as determined in 40 CFR §122.29 (b); or

2. The alteration or addition could significantly change the nature or increase the quantity of pollutants discharged. This notification applies to pollutants that are not subject to effluent limitations in the permit.

J. Anticipated Noncompliance

The Permittee must give advance notice to the EPA of any planned changes in the permitted facility or activity that may result in noncompliance with this permit.

VIII. General Provisions

A. Permit Actions

This permit or coverage under this permit may be modified, revoked and reissued, or terminated for cause as specified in 40 CFR §§ 122.62, 122.64, or 124.5. The filing of a request by the Permittee for a permit modification, revocation and reissuance, termination, or

a notification of planned changes or anticipated noncompliance does not stay any permit condition.

B. Duty to Reapply

If the Permittee intends to continue an activity regulated by this permit after the expiration date of this permit, the Permittee must submit a Notice of Intent. In accordance with 40 CFR §122.28(b)(2)(iii), the Permittee must submit a new Notice of Intent at least 180 days before the expiration date of this permit, unless the Regional Administrator has granted permission to submit the Notice of Intent at a later date in accordance with 40 CFR §122.21(d). If the NOI is received by the applicable deadline, even if the permit is not reissued before the expiration date, the conditions of the permit will continue in force until the effective date of the subsequently reissued permit. If the facility is no longer operating but still has a potential to discharge when the permit is due to expire, the Permittee must reapply for coverage.

C. Duty to Provide Information

The Permittee must furnish to the EPA and, within the time specified in the request, any information that the EPA may request to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit, or to determine compliance with this permit. The Permittee must also furnish to the EPA, upon request, copies of records required to be kept by this permit.

D. Other Information

When the Permittee becomes aware that it failed to submit any relevant facts in a permit application, or that it submitted incorrect information in a notice of intent or any report to the EPA, it must promptly submit the omitted facts or corrected information.

E. Signatory Requirements

All Notices of Intent, reports, or information submitted to the EPA must be signed and certified as follows.

1. All Notices of Intent must be signed as follows:

   a. For a corporation: by a responsible corporate officer.

   b. For a partnership or sole proprietorship: by a general partner or the proprietor, respectively.

   c. For a municipality, state, federal, Indian tribe, or other public agency: by either a principal executive officer or ranking elected official.

2. All reports required by the permit and other information requested by the EPA must be signed by a person described above or by a duly authorized representative of that person. A person is a duly authorized representative only if:

   a. The authorization is made in writing by a person described above;

   b. The authorization specifies either an individual or a position having responsibility for the overall operation of the regulated facility or activity, such as the

position of plant manager, operator of a well or a well field, superintendent, position of equivalent responsibility, or an individual or position having overall responsibility for environmental matters for the company; and

c. The written authorization is submitted to the EPA.

3. **Changes to authorization.** If an authorization is no longer accurate because a different individual or position has responsibility for the overall operation of the facility, a new authorization satisfying the requirements of §VII.E.2 must be submitted to the EPA prior to or together with any reports, information, or applications to be signed by an authorized representative.

4. **Certification.** Any person signing a document under this Part must make the following certification:

"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

F. Availability of Reports

In accordance with 40 CFR §2, information submitted to the EPA pursuant to this permit may be claimed as confidential by the Permittee. In accordance with the Act, permit applications, permits and effluent data are not considered confidential. Any confidentiality claim must be asserted at the time of submission by stamping the words "confidential business information" on each page containing such information. If no claim is made at the time of submission, the EPA may make the information available to the public without further notice to the Permittee. If a claim is asserted, the information will be treated in accordance with the procedures in 40 CFR §2, Subpart B (Public Information) and 41 Fed. Reg. 36902 through 36924 (September 1, 1976), as amended.

G. Inspection and Entry

The Permittee must allow the EPA, an authorized EPA representative (including an authorized contractor acting as a representative of the Administrator), and, in the case of Permittees discharging to waters of the Spokane Tribe, an authorized representative of the Tribal Water Control Board or its designee, upon the presentation of credentials and other documents as may be required by law, to:

1. Enter upon the Permittee's premises where a regulated facility or activity is located or conducted, or where records must be kept under the conditions of this permit;

2. Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;

3. Inspect at reasonable times any facilities, equipment (including monitoring and control equipment), practices, or operations regulated or required under this permit; and

4. Sample or monitor at reasonable times, for the purpose of assuring permit compliance or as otherwise authorized by the Act, any substances or parameters at any location.

The Tulalip Tribes may conduct an inspection of any facility covered by the permit under Tulalip jurisdiction to ensure compliance with tribal water quality standards and enforce its certification conditions.

H. Property Rights

The issuance of this permit does not convey any property rights of any sort, or any exclusive privileges, nor does it authorize any injury to persons or property or invasion of other private rights, nor any infringement of federal, tribal, state or local laws or regulations.

I. Transfer

Authorization to discharge under this permit may be automatically transferred to a new Permittee on the date specified in the agreement only if:

1. The current Permittee notifies the Director of the Office of Water and Watersheds at least 30 days in advance of the proposed transfer date;

2. The notice includes a written agreement between the existing and new Permittees containing a specific date for transfer of permit responsibility and liability between them; and

3. The Director does not notify the existing and new permittees of the intent to revoke and reissue the authorization to discharge.

J. State Laws

Nothing in this permit shall be construed to preclude the institution of any legal action or relieve the Permittee from any responsibilities, liabilities, or penalties established pursuant to any applicable state law or regulation under authority preserved by Section 510 of the Act.

IX. Definitions and Acronyms

The Act - The Clean Water Act, codified at 33 U.S.C. §1251 et seq.

Administrator - The Administrator of the United States Environmental Protection Agency, or an authorized representative (40 CFR §122.2).

Aquaculture facility - A hatchery, fish farm, or other facility which contains, grows, or holds fish for later harvest (or process) and sale or for release.

Average monthly limit - The maximum allowable average of "daily discharges" over a monitoring month, calculated as the sum of all "daily discharges" measured during a monitoring month divided by the number of "daily discharges" measured during that month. It may also be referred to as the "monthly average discharge"(40 CFR §122.2).

Background - The biological, physical, or chemical condition of waters measured at a point immediately upstream of the influence of the discharge.

BAT - Best available technology economically achievable.

BCT - Best conventional pollutant control technology.

Beneficial use - A desirable use of a water resource, such as recreation (fishing, boating, swimming) and water supply.

Best Management Practices (BMPs) - Schedules of activities, prohibitions of practices, maintenance procedures, and other management practices to prevent or reduce the pollution of Waters of the United States. BMPs also include treatment requirements, operating procedures, and practices to control plant site runoff, spillage or leaks, sludge or waste disposal, or drainage from raw material storage. (40 CFR §122.2)

BOD (Biochemical oxygen demand) - The measure of the oxygen required to break down organic materials in water. Higher organic loads require larger amounts of oxygen and may reduce the amount of oxygen available for fish and aquatic life below acceptable levels. Unless otherwise specified, this term means the 5-day BOD incubated at 20º C. (BOD_5)

BPJ - Best professional judgment.

BPT - Best practicable control technology currently available.

Bypass - The intentional diversion of waste streams from any portion of a treatment facility. (40 CFR §122.41 (m))

CAAP - Concentrated aquatic animal production; At 40 CFR §122.24, the EPA defines concentrated aquatic animal production (CAAP) facilities as point sources subject to the National

Pollutant Discharge Elimination System (NPDES) permit program including those upland facilities that discharge for at least 30 days per year and contain, grow, or hold cold water fish species or other cold water aquatic animals except in facilities which produce less than 9,0000 harvest weight kilograms (approximately 20,000 pounds) of aquatic animals per year and facilities which feed less than 2,272 kilograms (approximately 5,000 pounds) of food during the calendar month of maximum feeding.

CFR - Code of Federal Regulations, the body of federal regulations. Title 40 of the Code of Federal Regulations, Parts 1 - 1499 contains regulations of the Environmental Protection Agency.

cfs - Cubic feet per second.

Chemical - Any substance that is added to the facility to maintain or restore water quality for aquatic animal production and that may be discharged to Waters of the United States.

Clean Water Act - Formerly referred to as the Federal Water Pollution Control Act of 1972, codified at 33 U.S.C. §1251 et seq.

Cold water species - Cold water aquatic animals include, but are not limited to, the Salmonidae family of fish, e.g. trout and salmon.

Composite sample - A combination of four or more discrete samples taken at on-half hour intervals or greater over a 24-hour period; at least one fourth of the samples must be taken while cleaning. Facilities with multiple effluent discharge points and/or influent points must composite samples from all points proportionally to their respective flows.

Core rearing - A designated use of a water body where there is moderate to high density use by salmonid species, usually in the middle to upper reaches of a river system.

Critical Habitat - The geographical area occupied by a threatened or endangered species. See 16 U.S.C. §1532 (the Endangered Species Act of 1973) for a complete definition.

CWA - The Clean Water Act, 33 U.S.C. §1251 *et seq.*

DMR - Discharge monitoring report.

Director - The Director of the EPA Region 10 Office of Water and Watersheds.

Discharge of a pollutant-
(a) Any addition of any "pollutant" or combination of pollutants to "waters of the United States" from any "point source," or (b) Any addition of any pollutant or combination of pollutants to the waters of the "contiguous zone" or the ocean from any point source other than a vessel or other floating craft which is being used as a means of transportation.

This definition includes additions of pollutants into waters of the United States from: surface runoff which is collected or channeled by humans; discharges through pipes, sewers, or other conveyances owned by a State, municipality, or other person which do not lead to a treatment works; and discharges through pipes, sewers, or other conveyances, leading into privately owned

treatment works. This term does not include an addition of pollutants by any "indirect discharger" (40 CFR §122.2).

Disinfectant - Any chemical used to reduce pathogenic or objectionable organisms, including but not limited to algicides, fungicides, and pesticides.

Ecology - The Washington Department of Ecology.

Effluent - Wastewater discharged from a point source, such as a pipe.

Effluent limitation - Any restriction imposed by the Director on quantities, discharge rates, and concentrations of "pollutants" which are "discharged" from "point sources" into "waters of the United States," the waters of the "contiguous zone," or the ocean (40 CFR §122.2).

ELGs (effluent limitations guidelines) - Regulations published by the Administrator under Section 304(b) of CWA to adopt or revise "effluent limitations." (40 CFR §122.2).

EPA - The United States Environmental Protection Agency.

Extralabel Drug Use - A drug approved under the Federal Food, Drug, and Cosmetic Act that is not used in accordance with the approved label directions; see 21 CFR 530. (40 CFR §451.2(f))

FR (or Fed.Reg.) - The Federal Register, the official daily publication for rules, proposed rules, and notices of Federal agencies and organizations, as well as executive orders and other presidential documents.

Flow-through System - A system designed for continuous water flow to waters of the United States through chambers used to produce aquatic animals. Flow-through systems typically use either raceways or tank systems. Water is transported from nearby rivers or springs to raceways which are typically long, rectangular chambers at or below grade, constructed of earth, concrete, plastic, or metal. Tanks systems are similarly supplied with water and concentrate aquatic animals in circular or rectangular tanks above grade. The term "flow through system" does not include net pens.

General Permit - An NPDES permit issued in accordance with 40 CFR §122.28, authorizing a category of discharges under the CWA within a geographical area. (40 CFR §122.2)

Grab Samples - A discrete volume of water collected, by hand or machine, during one short sampling period (less than 15 minutes).

Hatchery - Culture or rearing unit such as a raceway, pond, tank, net or other structure used to contain, hold or produce aquatic animals. The containment system includes structures designed to hold sediments and other materials that are part of a wastewater treatment system.(40 CFR §451.2 (c))

Hazardous Substance - Any substance designated under 40 CFR part 116, pursuant to Section 311 of the CWA.

Impaired Waters - Waters identified by Ecology pursuant to Section 303(d) of the Clean Water Act for which effluent limitations guidelines are not stringent enough to implement all applicable water quality standards.

INAD - Investigational New Animal Drug, a drug for which there is a valid exemption in effect under section 512(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.360b(j), to conduct experiments. (40 CFR §451.2(h))

Indian Country - "all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and, including rights-of-way running through the reservation, (b) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a state, and (c) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same." (18 USC §1151)

Influent - The water entering a facility or part of a facility.

Listed Endangered or Threatened Species - Species that are in danger of extinction throughout all or a significant portion of their range or that are likely to become endangered species within the foreseeable future. See 16 U.S.C. §1532 (the Endangered Species Act of 1973) for a complete definition.

mg/L - Milligrams of solute per liter of solution, equivalent to parts per million, assuming unit density.

Minimum level (ML) - The concentration at which the entire analytical system must give a recognizable signal and an acceptable calibration point. The ML is the concentration in a sample that is equivalent to the concentration of the lowest calibration standard analyzed by a specific analytical procedure, assuming that all the method-specified sample weights, volumes and processing steps have been followed (40 CFR §136).

Monthly average - The average of "daily discharges" over a monitoring month, calculated as the sum of all "daily discharges" measured during a monitoring month divided by the number of "daily discharges" measured during that month (40 CFR §122.2).

NPDES (National Pollutant Discharge Elimination System) - The national program for issuing, modifying, revoking and reissuing, terminating, monitoring and enforcing permits, and imposing and enforcing pretreatment requirements, under sections 307, 402, 318, and 405 of CWA (40 CFR §122.2).

Net - The difference between effluent concentration and influent concentration (or loads).

Net Pen - A stationary, suspended, or floating system of nets or screens in open marine, lake, or estuarine waters of the United States. Net pen systems are typically located along a shore or pier or may be anchored and floating offshore. Net pens and cages rely on tides or currents to provide a continual supply of high quality water.

New Source - Any building, structure, facility, or installation from which there is or may be a discharge of pollutants, the construction of which commenced:

(a) After promulgation of standards of performance under Section 306 of the CWA, which are applicable to such source, or

(b) After proposal of standards of performance in accordance with Section 306 of the CWA, which are applicable to such source, but only if the standards are promulgated in accordance with Section 306 within 120 days of their proposal. (40 CFR §122.2)

NOI (Notice of Intent) - A written application form submitted to the permitting authority (i.e. EPA) seeking authorization to discharge under a General Permit.

NPDES - The National Pollutant Discharge Elimination System, the national program for issuing, modifying, revoking and reissuing, terminating, monitoring, and enforcing [wastewater discharge] permits, and imposing and enforcing pretreatment requirements, under Sections 307, 402, 318, and 405 of the CWA. (40 CFR §122.2)

Off-line Settling Basin - A constructed retention basin that receives wastewater from cleaning of aquaculture facility rearing or holding units and/or quiescent zones for the retention and treatment of the wastewater through settling of solids.

Outfall – A discrete point or outlet where the discharge is released to the receiving water.

Outstanding National Resource - A state park, game sanctuary or refuge; a national park, preserve, or monument; a national wildlife refuge; a national wilderness area; or a river designated as *wild* or *scenic* under the Wild and Scenic Rivers Act.

Permittee - An individual, association, partnership, corporation, municipality, Indian Tribe or authorized Indian tribal organization, State or Federal agency, or an agent or employee thereof, who is authorized by the EPA to discharge in accordance with the requirements of the General Permit.

Point Source - Any discernible, confined, and discrete conveyance from which pollutants are or may be discharged.

Pollutant - Chemical wastes, biological materials, … industrial waste discharge into water. (40 CFR §122.2)

Production - The act of harvesting, processing or releasing fish, or the harvest weight of fish contained, grown, or held in a CAAP facility. (40 CFR §122, Appx. C)

Publicly Owned Treatment Works (POTW) - Devices and systems, owned by a state or municipality, used in storage, treatment, recycling, and reclamation of municipal sewage or liquid industrial wastes, including sewers that convey wastewater to a POTW treatment plant. (40 CFR §403.3)

QA - Quality assurance, an integrated system of management activities involving planning, implementation, documentation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed to meet the performance criteria.

Recirculating System - A system that filters and reuses water in which the aquatic animals are produced prior to discharge; recirculating systems typically use tanks, biological or mechanical

filtration, and mechanical support equipment to maintain high quality water to produce aquatic animals.

Regional Administrator - The Administrator of Region 10 of the United States Environmental Protection Agency, or an authorized representative.

Severe property damage - Substantial physical damage to property, damage to the treatment facilities which causes them to become inoperable, or substantial and permanent loss of natural resources which can reasonably be expected to occur in the absence of a bypass. Severe property damage does not mean economic loss caused by delays in production. (40 CFR § 122.41(m)(ii))

Special Resource Tribal Waters - Waters that comprise a special and/or a unique resource to the Tribe, as determined by the appropriate tribal authority at the time a discharger seeks coverage under this General Permit

TSS - Total Suspended Solids.

Tier II water - Waters of a higher quality than the criteria assigned that may not be degraded unless such lowering of water quality is necessary and in the overriding public interest.

Toxic pollutants - Those pollutants, or combinations of pollutants, including disease-causing agents, which, after discharge and upon exposure, ingestion, inhalation or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will, on the basis of information available to the Administrator, cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction) or physical deformation in such organisms or their offspring. (CWA §502(13))

Toxic substances ... Substances that when discharged above natural background levels in waters of the state have the potential either singularly or cumulatively to adversely affect characteristic water uses, cause acute or chronic toxicity to the most sensitive biota dependent upon those waters, or adversely affect public health, as determined by the Department of Ecology.

TSD - Technical Support Document for water quality-based toxics control (EPA 1991).

TSS - Total suspended solids, of which the concentration in water is measured in mg/L.

Upland hatchery - A hatchery not located within the waters of the State (or, by extension, the U.S.) where fish are hatched, fed, nurtured, held, maintained, or reared to reach the size of release or for market sale. (WAC 173-221A-030)

Upset - An exceptional incident in which there is unintentional and temporary noncompliance with technology-based permit effluent limitations because of factors beyond the reasonable control of the Permittee. An upset does not include noncompliance to the extent caused by operational error, improperly designed treatment facilities, inadequate treatment facilities, lack of preventative maintenance, or careless or improper operation. (40 CFR §122.41(n)(1)).

WAC - Washington Administrative Code.

WQBEL (Water quality-based effluent limitation) - An effluent limitation that is applied to a discharger when technology-based limitations would cause violations of water quality standards.

WET (Whole effluent toxicity) - The aggregate toxic effect of an effluent measured directly by a toxicity test (40 CFR §122.2).

WLA - Wasteload allocation, the amount of pollutant assigned to a specific discharger in a TMDL or, in the absence of a TMDL, calculated by the permitting authority to comply with water quality standards in the receiving water.

Warm water species - Fish that include, but are not limited to, the *Ameiuride*, *Centrarchidae* and *Cyprinidae* families of fish, e.g., respectively, catfish, sunfish and minnows.

Waters of the United States (40 CFR §122.2) -

(a) All waters which are currently used, were used in the past, or may be susceptible to use in interstate or foreign commerce, including all waters which are subject to the ebb and flow of the tide;

(b) All interstate waters, including interstate wetlands;

(c) All other waters such as intrastate lakes, rivers, streams (including intermittent streams), mudflats, sandflats, wetlands, sloughs, prairie potholes, wet meadows, playa lakes, or natural ponds, the use, degradation, or destruction of which would affect or could affect interstate or foreign commerce including any such waters:

(1) Which are or could be used by interstate or foreign travelers for recreational or other purposes;

(2) From which fish or shellfish are or could be taken and sold in interstate or foreign commerce; or

(3) Which are or could be used for industrial purposes by industries in interstate commerce;

(d) All impoundments of waters otherwise defined as Waters of the United States under this definition;

(e) Tributaries of waters identified in paragraphs (a) through (d) of this definition;

(f) The territorial sea; and

(g) Wetlands adjacent to waters (other than waters that are themselves wetlands) identified in paragraphs (a) through (f) of this definition.

Appendix A

Notice of Intent Contents

A Notice of Intent (NOI) to discharge under the General Permit,
supplying the information indicated in this appendix,
and must be submitted to the EPA Region 10
in order to obtain authorization for the discharge(s).
See §II.A of this permit.

NOI

Notice of Intent to be Covered Under EPA's NPDES Permit for Federal Aquaculture Facilities and Aquaculture Facilities Located in Indian Country within the Boundaries of the State of Washington

General Permit WAG130000

In addition to the requirements in the following pages, a complete application must also include the following:

☐ 1) An area map showing regional context

☐ 2) A sketch, aerial photograph, or map of the existing or proposed facility with the following clearly marked (include scale):

- ☐ Approximate overall dimensions of the facility
- ☐ All raceways and rearing ponds
- ☐ All water sources and water flow rates
- ☐ Any settling ponds, including dimensions and volume
- ☐ All discharge points and receiving waters
- ☐ All water flow paths
- ☐ Sludge disposal areas
- ☐ Water conditioning units
- ☐ Water treatment units (such as off-line settling basins)
- ☐ Holding tanks
- ☐ Locations where flows are measured
- ☐ Points of chemical and therapeutic drug addition
- ☐ Points of feed addition
- ☐ Painted or caulked surfaces in contact with water

☐ 3) A sketch, aerial photograph, or map of all satellite facilities that are part of your hatchery program, in relation to the facility for which you are seeking NPDES permit coverage

☐ 4) A map to accompany driving directions to the facility (if address is not posted or visible on-site)

☐ 5) A completed signature page

Notice of Intent

To comply with NPDES General Permit No. WAG130000 for Federal Aquaculture Facilities and Aquaculture Facilities Located in Indian Country within the Boundaries of the State of Washington

Permit Number for your facility (if already enrolled in this permit):
Other permit number(s), date, and issuing agency:

Section 1. Owner/Operator Information

Owner Name:	Title:
Phone:	Fax:
Email:	

Owner Mailing Address

Line 1:		
Line 2:		
City:	State:	Zip:

Operator Information

Owner Name:	Title:
Phone:	Fax:
Email:	

Operator Mailing Address

Line 1:		
Line 2:		
City:	State:	Zip:

Section 2. Facility Information

Facility Name:
Tribal or Federal Facility? ☐ Tribal ☐ Federal ☐ Other _____
Is the facility located in Indian Country? ☐ Yes ☐ No Notes:

Facility Mailing Address

Line 1:		
Line 2:		
City:	State:	Zip:

Facility Physical Address

Line 1:		
Line 2:		
City:	State:	Zip:
County/Reservation:		

Please provide driving directions to the facility from the nearest town or city. Attach a separate page if needed. Include a map to accompany these directions if the address is not posted or visible on-site.

Is there a locked gate or barrier that prevents access via car to the facility? ☐ Yes ☐ No

Notes:

Section 2. Facility Information (cont'd)

Is this an existing facility? ☐ Yes ☐ No Date of first discharge:	
Is this a planned/proposed facility? ☐ Yes ☐ No	
If yes, estimated construction start date:	Estimated construction end date:
Date(s) facility remodeled, expanded, or upgraded (MM/DD/YYYY):	
Have there been any changes or additions to the facility that will increase it to more than 100,000 lbs of annual production since the last permit application? ☐ Yes ☐ No Describe:	
Are there any planned remodels, additions, or expansions that will increase annual production to over 100,000 lbs during the next 5 years? ☐ Yes ☐ No Describe:	

Section 2. Facility Information (cont'd) Satellite Facilities

Please describe any satellite facilities that operate in tandem with the NPDES-permitted facility as part of the hatchery program. This may include off-site acclimation ponds, net pens, other hatcheries that fish are transported to or from, facilities from which eggs are delivered, etc.

Attach a sketch, aerial photograph, or map to show where any satellite facilities are located in relation to the facility for which you are seeking NPDES coverage in this application.

Submit additional pages as necessary to cover all additional facilities.
Label additional pages: Satellite Facilities/Hatchery Program

Name of facility:
Describe the function of satellite facility and how it relates to the facility for which this NOI is requesting NPDES coverage. Include the species raised and life stage for each facility that is part of the hatchery program.

Satellite Facility Physical Address

Line 1:		
Line 2:		
City:	State:	Zip:
County/Reservation:		

Satellite Facility Operator Information

Agency/Tribe/Entity:	Name of Facility Manager:
Phone:	
Email:	

Satellite Facility Operator Mailing Address

Line 1:		
Line 2:		
City:	State:	Zip:

Section 3. Operations and Production

Is the production system best described as:

☐ Flow through ☐ Recirculating ☐ Pond system ☐ Other_____

Does the facility operate year-round? ☐ Yes ☐ No
If not, please indicate which months the facility holds fish or eggs:

Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec

List the species grown or held at your facility and estimate the annual production of each in gross harvestable weight. If fish are released rather than harvested, list the estimated weight at time of release. The estimate can be a range over the next 5 years, if appropriate.

Species	Fish Produced	Receiving Water to which Fish are Released	Month Released/ Spawned

Fill in the table below with the highest production numbers expected for the next 5 years. List the maximum amount of fish on-site and the maximum amount of food **per month** for the year of maximum production. For **new facilities**, provide information for the year of highest anticipated production within the next 5 years.

Month	Total Fish (lbs)	Fish Feed (lbs)	Month	Total Fish (lbs)	Fish Feed (lbs)
January			July		
February			August		
March			September		
April			October		
May			November		
June			December		

From what year are these data? _____

Note: If you operate for 30 or more days per year and exceed the production (20,000 lbs) and feed thresholds (5,000 lbs of food during the month of maximum feeding) for even a brief period of time, your facility is required to apply for NPDES permit coverage.

Section 3. Operations and Production (cont'd)

Does this facility process fish for market at this location? ☐ Yes ☐ No
Are fish spawned on-site? ☐ Yes ☐ No During which months are fish spawned on-site?
Describe wastes generated as a result of on-site spawning (e.g., blood, anesthetics, disinfectants, carcasses):
Describe how spawning wastes are disposed of and to which outfall (if any):

Provide the percentage of fish released from the facility <u>directly</u> to a lake, river, or other location.		
☐ Lake _____ % Approximate lbs fish: Location/Receiving water name:	☐ River _____ % Approximate lbs fish: Location/Receiving water name:	☐ Other _____ % Approximate lbs fish: Location/Receiving water name:
Provide the percentage of fish <u>hauled off-site</u> to a lake, river, or other location.		
☐ Lake _____ % Approximate lbs fish: Location/Receiving water name:	☐ River _____ % Approximate lbs fish: Location/Receiving water name:	☐ Other _____ % Approximate lbs fish: Location/Receiving water name:

Are fish held on-site for broodstock? ☐ Yes ☐ No Describe the species, where obtained, quantity, and where held (i.e., raceway or pond):

Section 4. Source Waters (Intakes)

Describe the facility's water sources. Attach additional pages as necessary.

Source No. 1	Source Water Name:	Max Flow	Min Flow	Avg Flow	Units (cfs or gpm)
Source Water Treatment:					
Are solids removed from influent water? ☐ Yes ☐ No Describe:					
Source No. 2	Source Water Name:	Max Flow	Min Flow	Avg Flow	Units (cfs or gpm)
Source Water Treatment:					
Are solids removed from influent water? ☐ Yes ☐ No Describe:					
Source No. 3	Source Water Name:	Max Flow	Min Flow	Avg Flow	Units (cfs or gpm)
Source Water Treatment:					
Are solids removed from influent water? ☐ Yes ☐ No Describe:					
Source No. 4	Source Water Name:	Max Flow	Min Flow	Avg Flow	Units (cfs or gpm)
Source Water Treatment:					
Are solids removed from influent water? ☐ Yes ☐ No Describe:					
Source No. 5	Source Water Name:	Max Flow	Min Flow	Avg Flow	Units (cfs or gpm)
Source Water Treatment:					
Are solids removed from influent water? ☐ Yes ☐ No Describe:					

Section 5. Receiving Waters

Do the receiving waters primarily consist of: ☐ Fresh water ☐ Salt/Brackish water ☐ Other (Describe below)
Notes:

- Indicate if a receiving water is listed as impaired, in accordance with Section 303(d) of the Clean Water Act.
- Indicate the pollutants for which the water body is impaired and any wasteload allocations that have been assigned to the facility.
- Indicate if the discharge is to waters in Indian Country located within one mile upstream of a waterbody listed as impaired.
- Refer to the 303(d) list of impaired waters at http://www.ecy.wa.gov/programs/Wq/303d/index.html.
- If there is an applicable Total Maximum Daily Load (TMDL) with a Wasteload Allocation assigned to the facility, include that information here.

Receiving Water			
Receiving Water	Pollutant for which impaired	Wasteload Allocations	TMDL document the WLA

Additional Notes:

Section 6. Wastewater

Wastewater Discharges						
Outfall	Location of Outfall				Notes: Include source (where in the facility the wastewater is generated), frequency, duration & volume (cfs or gpm) of discharge)	Name of Receiving Water
		Degrees	Minutes	Seconds		
001	Latitude					
	Longitude					
002	Latitude					
	Longitude					
003	Latitude					
	Longitude					
004	Latitude					
	Longitude					
005	Latitude					
	Longitude					
006	Latitude					
	Longitude					
007	Latitude					
	Longitude					
008	Latitude					
	Longitude					
009	Latitude					
	Longitude					
010	Latitude					
	Longitude					

Section 6. Wastewater (cont'd)

Indicate the type(s) of wastewater treatment provided at this facility.

In-line Settling Basin

Do any rearing units discharge through an in-line settling basin? ☐ Yes ☐ No Describe in-line settling basin (length, volume, retention time, etc.): Which rearing units discharge to the in-line settling basin, and when?

Off-line Settling Basin

Does the facility use an off-line settling basin? ☐ Yes ☐ No Number of off-line settling basins:	
Which rearing units discharge to the off-line settling basin, and when/under what circumstances?	
Does the off-line settling basin discharge directly to surface water? ☐ Yes ☐ No Describe:	
Basin size:	Retention time:
Water volume of off-line settling basin:	
Estimate the number of discharges from the off-line settling basin per year:	
How often is the off-line settling basin cleaned/excavated?	
If an off-line settling basin is used for cleaning wastes, is there a quiescent zone at the end of the last raceway or rearing pond in each series? ☐ Yes ☐ No Describe:	
Is there a mechanism to block discharges of floating material? ☐ Yes ☐ No Describe:	
Does the facility discharge to the ground? ☐ Yes ☐ No Describe:	
Does the facility have unlined structures? ☐ Yes ☐ No	
Material:	Quantity:
Describe:	

Section 6. Wastewater (cont'd)

Construction of Off-line Settling Basin (if known)	
Liner Material	Thickness
Concrete	Inches
Asphalt	Inches
Clay or earthen	Inches
Plastic PVC/HDPE/other Describe:	mils

Pond and Raceway Cleaning

How frequently are the ponds and/or raceways cleaned (specify which)?
Notes:

Methods of cleaning: ☐ Vacuum ☐ Manually ☐ Other _____

What is done with the removed solids?

Are ponds cleaned prior to fish release? ☐ Yes ☐ No

Are any liquid or solid wastes discharged to the ground? ☐ Yes ☐ No
If yes, describe:

Are any wastes (other than domestic sewage) discharged to a septic system? ☐ Yes ☐ No
If yes, describe:

Are any solids or wastes (other than domestic waste) discharged to a publicly owned treatment works?
☐ Yes ☐ No
If yes, name of facility:

Describe waste:

Are wastes discharged to any other waste treatment system? ☐ Yes ☐ No
If yes, describe:

Section 7. Solid Waste Disposal

Describe annual quantities of solids (including fish mortalities) disposed and location of disposal.

Type of Solid Disposed	Date Disposed	Location Disposed
Notes:		

Section 8. Aquaculture Drugs and Chemicals

Please indicate which drugs or chemicals you plan to use at the facility during the next 5 years.

Plan to use in the next 5 years?	Investigational New Animal Drug (INAD)?	Drug or Chemical
☐ Yes ☐ No	☐ Yes ☐ No	Azithromyicin
☐ Yes ☐ No	☐ Yes ☐ No	Chloramine-T
☐ Yes ☐ No	☐ Yes ☐ No	Chlorine
☐ Yes ☐ No	☐ Yes ☐ No	Draxxin
☐ Yes ☐ No	☐ Yes ☐ No	Erythromycin - injectable
☐ Yes ☐ No	☐ Yes ☐ No	Erythromycin - medicated feed
☐ Yes ☐ No	☐ Yes ☐ No	Florfenicol (Aquaflor)
☐ Yes ☐ No	☐ Yes ☐ No	Formalin - 37% formaldehyde
☐ Yes ☐ No	☐ Yes ☐ No	Herbicide - describe:
☐ Yes ☐ No	☐ Yes ☐ No	Hormone - describe:
☐ Yes ☐ No	☐ Yes ☐ No	Hydrogen Peroxide
☐ Yes ☐ No	☐ Yes ☐ No	Iodine
☐ Yes ☐ No	☐ Yes ☐ No	Oxytetracycline
☐ Yes ☐ No	☐ Yes ☐ No	Potassium Permanganate
☐ Yes ☐ No	☐ Yes ☐ No	Romet
☐ Yes ☐ No	☐ Yes ☐ No	SLICE (emamectin benzoate)
☐ Yes ☐ No	☐ Yes ☐ No	Sodium Chloride - salt
☐ Yes ☐ No	☐ Yes ☐ No	Vibrio vaccine
☐ Yes ☐ No	☐ Yes ☐ No	Other:
☐ Yes ☐ No	☐ Yes ☐ No	Other:
☐ Yes ☐ No	☐ Yes ☐ No	Other:

Section 9. Painted or Caulked Surfaces

Describe all painted and caulked surfaces that are in regular contact with water that is discharged to waters of the U.S.

Location of such surfaces should appear in the drawing required as part of the checklist on page 1.

Type of Paint/Caulk	Where applied (including area)	Amount applied	Date applied	Reason for application
Notes:				

Section 10. Other Information/Changes

Describe any changes to the facility or operations since the last permit application. Disregard this section if this is a new or proposed facility.

Section 11. Signature and Certification

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly evaluate and gather the information submitted. Based on my inquiry of the person or persons, who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

Printed name of person signing	Title
Applicant Signature	Date Signed

All permit applications must be signed as follows:

a. For a corporation: by a responsible corporate officer.

b. For a partnership or sole proprietorship: by a general partner or the proprietor, respectively.

c. For a municipality, state, federal, Indian tribe, or other public agency: by either a principal executive officer or ranking elected official.

Section 12. Submittal Information

Send the complete, signed information, along with required attachments, to the following address:

U.S. EPA Region 10, OWW-191

Washington Hatchery NOI

1200 Sixth Avenue, Suite 900

Seattle, WA 98101-3140

Appendix B

Effluent Calculations

Guidance on Calculating Effluent Values

Calculating "Net" Effluent Values

Pollutant Concentrations for Total Suspended Solids and Settleable Solids are measured at both influent and effluent monitoring locations. The net concentration is the difference between the two measurements and can either be positive or negative since the pollutant concentration may either increase or decrease as the water passes through the facility. It is calculated as follows:

Effluent concentration (mg/L) -- influent concentration (mg/L) =

Net concentration (mg/L)

Appendix C

Quality Assurance Plan &
Best Management Practices Plan
Certification

Quality Assurance Plan
(QA Plan)
Certification

Facility Name:_____

NPDES Permit Number:_____

The QA Plan is complete and is available upon request to the EPA.

The QA Plan is being implemented by trained employees.

The QA Plan has been reviewed and endorsed by the facility manager.

The individuals responsible for implementation of the QA Plan have been properly trained.

"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

Signature:	**Title/Company:**
Print Name:	**Date:**

An existing discharger must submit this certification within 90 days of the effective date of this permit. For a new Permittee, this certification must be submitted no later than the written Notice of Intent to be covered under this permit. The certification must be submitted to the EPA.

Best Management Practices Plan
(BMP Plan)
Certification

Facility Name:_____

NPDES Permit Number:_____

The BMP Plan is complete and is available upon request to the EPA.

The BMP Plan is being implemented by trained employees.

The BMP Plan has been reviewed and endorsed by the facility manager.

The individuals responsible for implementation of the BMP Plan have been properly trained.

"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

Signature:	**Title/Company:**
Print Name:	**Date:**

An existing discharger must submit this certification within 90 days of the effective date of this permit. For a new Permittee, this certification must be submitted no later than the written Notice of Intent to be covered under this permit. The certification must be submitted to the EPA.

Appendix D

Drug and Chemical Use
Report Contents

CHECKLIST FOR ORAL REPORT FOR INVESTIGATIONAL NEW ANIMAL DRUG (INAD) USE, EXTRALABEL DRUG USE, AND FIRST USE OF LOW REGULATORY PRIORITY DRUGS AND POTASSIUM PERMANGANATE

(Provide an oral report to the EPA: 206-553-1846 and to Ecology (where applicable) within 7 days after initiating use of the drug)

(First row is an example.)

Name of Drug (INAD & Extralabel) Used & Reason for Use	Method of Application	First Date of Drug Use	Date Oral Report to EPA	Person reporting
Extralabel: Erythromycin Treat bacterial infections	*Injection*	*09/09/04*	*09/10/04*	*MJ*

WRITTEN REPORT FOR AGREEING TO PARTICIPATE IN AN INAD STUDY

(Submit a written report to the EPA and Ecology within 7 days of agreeing or signing up to participate in an INAD study)

Facility Name:_____NPDES Permit Number:_____

Name of person submitting this report:_____

Date of agreement to participate in INAD study: _____

Date this written report will be submitted:_____

The first row is an example.

Expected Dates of Use	Name of INAD Used	Disease or Condition Intended to Treat	Method of Application	Dosage
09/09/04	*Oxytetracycline*	*For controlling columnaris in trout*	☑ *Medicated feed* ☐ *Injection* ☐ *Bath treatment* ☐ *Other:* _____	
			☐ Medicated feed ☐ Injection ☐ Bath treatment ☐ Other: _____	
			☐ Medicated feed ☐ Injection ☐ Bath treatment ☐ Other: _____	
			☐ Medicated feed ☐ Injection ☐ Bath treatment ☐ Other: _____	

WRITTEN REPORT FOR INAD AND EXTRALABEL DRUG USE AND FIRST USE OF LOW REGULATORY PRIORITY DRUGS AND POTASSIUM PERMANGANATE

(Submit a written report to the EPA and Ecology within 30 days after initiating use of the drug)

Facility Name:_____NPDES Permit Number:_____

Name of person submitting this report:_____

Date this written report will be submitted to the EPA:_____

For Extralabel Drug Use, include the **name of the prescribing veterinarian** and **date of the prescription** in a footnote.

The first row is an example.

Name of Drug & Reason for Use	**Date and Time of Application (start & end)**	**Duration**	**Method of Application**	**Total Amount of Active Ingredient Added**	**Total Amount of Medicated Feed Added***
Oxytetracycline *For control of columnaris in walleye*	*09/09/04 10:00 AM* *09/13/04 10:00 AM*	*5 consecutive days*	☑ *Medicated feed* ☐ *Injection* ☐ *Bath treatment* ☐ *Other:* _____	*1 g/lb as sole ration*	*50 lbs*
			☐ Medicated feed ☐ Injection ☐ Bath treatment ☐ Other: _____		
			☐ Medicated feed ☐ Injection ☐ Bath treatment ☐ Other: _____		
			☐ Medicated feed ☐ Injection ☐ Bath treatment ☐ Other: _____		

* Applies only to drugs applied through medicated feed.

CHEMICAL LOG SHEET (FOR WATER-BORNE TREATMENTS)

SEE ALSO THE REQUIREMENTS IN THE ANNUAL REPORT

Facility Name:_____ NPDES Permit Number:_____

Date	Raceway Treated	Chemical Name[1]	Active Ingredient	Amount Applied	Units	Duration of Treatment	Treatment Type[2]	Flow Treated (cfs)	Total Effluent Flow (cfs)	Effluent Conc. (ppb)	Person reporting

[1] Both a copy of the label with application requirements and the Material Safety Data Sheet (MSDS) must be kept in your records.
[2] Treatment type means, for example, static or flush bath, injection or feed.

Appendix E

Annual Report Contents

Annual Report of Operations for Year _____

To comply with NPDES General Permit No. WAG130000 for Federal Aquaculture Facilities and Aquaculture Facilities Located in Indian Country within the Boundaries of the State of Washington

NPDES # for your Facility:

Facility & Owner Information

Facility Name:	
Operator Name (Permittee):	
Address:	
Email:	Phone:
Owner Name (if different from operator):	
Email:	Phone:

Best Management Practices (BMP) Plan

Has the BMP Plan been reviewed this year? ☐ Yes ☐ No

Does the BMP Plan fulfill the requirements of the General Permit? ☐ Yes ☐ No

Summarize any changes to the BMP Plan since the last annual report. Attach additional pages if necessary.

Operations and Production

Total harvestable weight produced in the past calendar year in pounds (lbs): Pounds of food fed to fish during the maximum month:

List the species grown or held at your facility and the annual production of each in gross harvestable weight. If fish were released rather than harvested, list the weight at time of release.

Species	Fish Produced	Receiving Water(s) to which Fish were Released	Month Released/ Spawned

Fill in the table below with production numbers from the past year. List the **maximum** amount of fish on-site and the maximum amount of food fed **per month**.

Month	Total Fish (lbs)	Fish Feed (lbs)	Month	Total Fish (lbs)	Fish Feed (lbs)
January			July		
February			August		
March			September		
April			October		
May			November		
June			December		

Additional Comments:

Solid Waste Disposal

Describe the solid waste disposed of during the calendar year (including fish mortalities).

Type of Solid Disposed	Date Disposed	Location Disposed
Additional Comments:		

Fish Mortalities

Include a description and the dates of mass mortalities in the past year (more than 5% per week). Attach additional pages, if necessary. Include total mortalities from all causes.

Date	Cause of Deaths	Steps Taken to Correct Problem	Pounds of Fish
Additional Comments:			

Noncompliance Summary

Include a description and the dates of noncompliance events (including spills), the reasons for the incidents, and the steps taken to correct the problems. Attach additional pages, if necessary.

Inspections & Repairs for Production & Wastewater Treatment Systems

Date Inspected	Date Repaired	Description of System Inspected and/or Repaired

Aquaculture Drugs and Chemicals

Please indicate whether you used each drug/chemical **during the past calendar year**.
Describe the use of each drug/chemical in more detail on the following pages.

Used in the past year?	Drug or Chemical
☐ Yes ☐ No	Azithromycin
☐ Yes ☐ No	Chloramine-T: ***See additional reporting requirements on page 7***
☐ Yes ☐ No	Chlorine
☐ Yes ☐ No	Draxxin
☐ Yes ☐ No	Erythromycin - injectable
☐ Yes ☐ No	Erythromycin - medicated feed
☐ Yes ☐ No	Florfenicol (Aquaflor)
☐ Yes ☐ No	Formalin - 37% formaldehyde: ***See additional reporting requirements on page 7***
☐ Yes ☐ No	Herbicide - describe:
☐ Yes ☐ No	Hormone - describe:
☐ Yes ☐ No	Hydrogen Peroxide: ***See additional reporting requirements on page 7***
☐ Yes ☐ No	Iodine: ***See additional reporting requirements on page 7***
☐ Yes ☐ No	Oxytetracycline
☐ Yes ☐ No	Potassium Permanganate: ***See additional reporting requirements on page 7***
☐ Yes ☐ No	Romet
☐ Yes ☐ No	SLICE (emamectin benzoate)
☐ Yes ☐ No	Sodium Chloride - salt
☐ Yes ☐ No	Vibrio vaccine
☐ Yes ☐ No	Other:
☐ Yes ☐ No	Other:

Aquaculture Drugs and Chemicals (cont'd)

Describe all drug and/or chemical treatments that occurred during the year. Fill out the information below for each drug or chemical, plus page 7 for water-borne treatments. Attach additional pages as necessary.

Brand Name:		Generic Name:	
Reason for use:			
☐ Preventative/Prophylactic ☐ As-needed	Total quantity of formulated product per treatment (specify units):	Total quantity of formulated product used in past year (specify units):	
Date(s) of treatment:			Total number of treatments in past year:
Maximum daily volume of treated water:	Treatment concentration (specify units):	Duration and frequency of treatment(s):	
Method of application:	☐ Static Bath ☐ Flow-through	☐ Medicated Feed ☐ Other (describe):	
Location in facility chemical was used (check all that apply):	☐ Raceways ☐ Incubation building	☐ Ponds ☐ Off-line settling basin	☐ Other (describe):
Where did water treated with this chemical go? (check all that apply):	☐ Discharged w/o treatment ☐ Settling basin	☐ Septic System ☐ Publicly owned treatment works	☐ Other (describe):
Provide any additional information about how this chemical was used and/or special pollution prevention practices during use:			

Brand Name:		Generic Name:	
Reason for use:			
☐ Preventative/Prophylactic ☐ As-needed	Total quantity of formulated product per treatment:	Total quantity of formulated product used in past year (specify units):	
Date(s) of treatment:			Total number of treatments in past year:
Maximum daily volume of treated water:	Treatment concentration (specify units):	Duration and frequency of treatment(s):	
Method of application:	☐ Static Bath ☐ Flow-through	☐ Medicated Feed ☐ Other (describe):	
Location in facility chemical was used (check all that apply):	☐ Raceways ☐ Incubation building	☐ Ponds ☐ Off-line settling basin	☐ Other (describe):
Where did water treated with this chemical go? (check all that apply):	☐ Discharged w/o treatment ☐ Settling basin	☐ Septic System ☐ Publicly owned treatment works	☐ Other (describe):
Provide any additional information about how this chemical was used and/or special pollution prevention practices during use:			

Aquaculture Drugs and Chemicals (cont'd)

Additional Reporting Requirements for Water-Borne Treatments

- If a water-borne treatment was used during the calendar year, Permittees must include detailed records/calculations as an attachment to this Annual Report in order to demonstrate how the maximum effluent concentrations of solution and active ingredient were calculated for each chemical.
- EPA recognizes that water-borne treatments may vary in the volume of the vessels treated, concentration, quantity of product, etc. Permittees must provide the information listed in the following tables for a reasonable worst case (i.e., maximum effluent concentration) scenario, not for each individual treatment.
- Permittees must submit this information and calculate the maximum effluent concentration for each water-borne chemical used during the past calendar year.
- See also Appendix D for the Chemical Log Sheet.

Static Bath Treatments	
Tank Volume	Liters
Desired Static Bath Treatment Concentration	µg/L
Volume of Product Needed	Liters Product
Maximum Effluent Concentration of: 1) Solution and 2) Active Ingredient	Solution: Active Ingredient: Specify Units
Minimum Volume of Total (treated + untreated) Water Discharged from the Facility per day	Specify Units
Maximum % of Facility Discharge Treated	% of Total Discharge

Flow-Through Treatments	
Tank Volume	Liters
Calculated Flow Rate	Liters/Minute
Duration of Treatment	Minutes
Desired Flow-Through Treatment Concentration of Product	µg/L
Amount of Product to Add Initially	Liters Product
Amount of Product to Add During Treatment	mL/Minute
Total Volume of Product Needed	Liters Product
Maximum Effluent Concentration of: 1) Solution and 2) Active Ingredient	Solution: Active Ingredient: Specify Units
Minimum Volume of Total (treated + untreated) Water Discharged from the Facility per day	Specify Units
Maximum % of Facility Discharge Treated	% of Total Discharge

Changes to the Facility or Operations

Describe any changes to the facility or operations since the last annual report.

Signature and Certification

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly evaluate and gather the information submitted. Based on my inquiry of the person or persons, who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

Printed name of person signing	Title
Applicant Signature	Date Signed

Submittal Information

Send the complete, signed information, along with any attachments, to the following address:

U.S. EPA Region 10, OWW-191

Washington Hatchery Annual Report

1200 Sixth Avenue, Suite 900

Seattle, WA 98101-3140

Appendix F

Food and Drug Administration Policy:

Enforcement Priorities for Drug Use in Aquaculture

ENFORCEMENT PRIORITIES FOR DRUG USE IN AQUACULTURE

PART A

ENFORCEMENT PRIORITIES FOR DRUG USE IN NON-FOOD FISH

I. Purpose

This document describes enforcement priorities that apply to drugs for use in aquaculture nonfood species/populations.

II. Definitions

Non-food fish - An aquaculture species is presumed to be a non-food species if it is reasonably likely that a) no significant percentage of the species population will be consumed directly or indirectly by humans for food, or b) the fish species is not known to be consumed by an identifiable human population. The following definitions are provided for categories of non-food fish.

Ornamental and aquarium fish - In general, ornamental and aquarium species are nonfood species. Ornamental and aquarium fish are defined as: fish that are produced and maintained solely for exhibit purposes in home or public aquaria, or in ornamental garden ponds. (Policy and Procedures (P&P) PPM 1240.4260).

Baitfish – Fish commercially raised to be used as bait in sport or commercial fishing e.g., fathead minnows, golden shiners and goldfish. A baitfish species will be considered a food fish if humans will consume any significant part of the species directly or indirectly.

Home aquarium - An aquarium in a private residence or exhibited in a business for hobby or decorative purposes.

Ornamental garden pond - Pond on the property of a private residence or for display in a business for hobby or decorative purposes.

Commercial pond – Pond/ raceway where the fish are grown ultimately to be sold

to individuals at pet stores or for some other commercial use.

III. Regulation of Drug Use in Non-Food Species

When CVM personnel in Division of Compliance are asked questions or receive inquiries regarding the use of compounds in non-food fish they need to:

A. Determine which Agency or Food and Drug Administration (FDA) Center has jurisdiction for the regulation of the product based on the following categories:

1. The compound is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal; and intended to affect the structure or any function of the body of man or other animals. The compound is a drug and is under the jurisdiction of FDA, Center for Veterinary Medicine (CVM). [Federal Food, Drug and Cosmetic Act (FFDCA), 201(g).] [Go to Section III B]. If the compound is determined to be a drug under FFDCA it is a drug even if it has pesticide, biologic, food or color additive properties or claims.

2. The compound is any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant. [Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)] The compound is a **pesticide** and is under the jurisdiction of the Environmental Protection Agency (EPA). Contact EPA, Office of Pesticides.

3. The compound is a virus, serum, toxin (excluding substances that are selectively toxic to microorganisms, e.g., antibiotics), or analogous product at any stage of production, shipment, distribution, or sale, which is intended for use in the treatment of animals and which acts primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response. (9 CFR 101.2) The compound is a **biologic** and is under the jurisdiction of USDA, Animal and Plant Health Inspection Service (APHIS), Center for Veterinary Biologics (CVB). Contact USDA APHIS CVB.

4. The compound is a substance with the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component of, or otherwise affecting the characteristics of any food for man or animals. (FFDCA 201 (s)) The compound is a **food additive** and is under the jurisdiction of the FDA CVM. Contact FDA, CVM, Division of Animal Feeds.

5. The compound is a substance which is capable of coloring food, and its use or intended use is not for a purpose other than coloring. (FFDCA

201 (t)) The compound is a **color additive** and is under the jurisdiction of the FDA Center for Food Safety and Applied Nutrition (CFSAN). Contact FDA CFSAN.

B. Decide the regulatory status. CVM will use the following categories to determine the regulatory status of a drug:

1. **Approved new animal drug** - An approved New Animal Drug Application (NADA) exists for this indication. Refer to 21 Code of Federal Regulations (CFR) Part 514. Product is used according to label directions.
2. **Investigational New Animal Drug (INAD)** - A potential sponsor may request an INAD exemption for collecting data to support a new animal drug approval. Contact the CVM Aquaculture Drugs Team, HFV-131.
3. **Extra-label use drug - Use of an FDA** - approved drug under the provisions of Animal Medicinal Drug Use Clarification Act (AMDUCA). See 21 CFR 530.
4. **Extra-label use of medicated feeds** -Provisions for the use of approved medicated feeds for minor species are explained in the Compliance Policy Guide (CPG) for Extra-label Use of Medicated Feeds for Minor Species. Compliance Policy Guide, Chapter 6, Section 615.115.
5. **Regulatory discretion** - Drugs that have been evaluated for regulatory discretion as low priority for enforcement action (INADs/NADAs will not be required). See Low Regulatory Priority (LRP) list in Part C of this document. For others not on the list go to Part A, Section IV of this document.

IV. Factors to Consider for Regulatory Discretion

Division of Compliance evaluates the potential for regulatory discretion. Drugs will be categorized at CVM's initiative or on request of an interested party. In the latter case, the requestor will be asked to provide available data and information that the Center can use to determine enforcement priority. The criteria used in this determination are as follows:

A. The safety status of the compound including:

1. User safety – Contact the Division of Human Food Safety, HFV-150.

High priorities are:

a. known or suspected carcinogens;

b. known serious toxicological hazards;

c. and suspected serious toxicological hazards believed to have substantial use in aquaculture.

2. Environmental safety – Contact the Environmental Assessment Team, HFV-145. Considerations include:

a. potential public or ecological safety issues including:

(1) potential for surface or groundwater contamination;
(2) known serious human toxicological hazard; and
(3) known serious toxicological hazard to aquatic organisms including fish, insects, and birds.

b. compliance with applicable Federal, State, and local environmental laws.

B. Extent of data available for enforcement priority determinations

In general, only published peer-reviewed studies or literature will be reviewed for the purpose of making enforcement priority determinations. However, unpublished data may be reviewed for enforcement priority determinations on a case-by-case basis. Areas to be reviewed include:

1. Human Food Safety;
2. Target animal safety and effectiveness;
3. Environmental safety; and
4. Human user and occupational safety.

V. Factors to Consider for Enforcement Priorities

A. In general, regulatory action may be considered in any case where a high enforcement priority drug (see section V.C.) is found. In addition, high enforcement priority drugs may be the subjects of special assignments to the Field. Other drugs will be subject to regulatory action on a case-by-case basis, based on the factors listed below.

1. Jurisdiction – (see Part A, Section III A of this document)

2. Approval status of the active ingredient

a. If FDA has withdrawn the approval of the active ingredient for reasons other than human food safety, priority will be determined on a case-by-case basis.

b. If an approved animal drug product containing the same active

ingredient is available, the drug will ordinarily not be considered a low enforcement priority to protect the marketing of the approved product.

3. Approval or LRP status of drugs with different active ingredients but similar uses

   a. If an approved animal drug product containing a different active ingredient but for a similar use is available, then the drug will ordinarily not be considered a low enforcement priority to protect the marketing of the approved product.

   b. If an animal drug product containing a different active ingredient but for a similar use as a drug is included on the LRP list (see Part C of this guide), then the drug under consideration will ordinarily not be considered a low enforcement priority.

4. The presence or absence of any significant safety or effectiveness concern as established by the available data will determine the enforcement priority. These data will include information about the active ingredient, formulation, and proposed conditions of use.

5. Products with a known potential for diversion, either directly to humans (e.g., anabolic steroids) or to food-producing species should be considered for high priority.

6. Regulatory considerations include:

   a. potential effect on public health;
   b. availability of expert support for a court case;
   c. availability of agency resources to support a regulatory action;
   d. egregiousness of the violative action; and
   e. availability of the required evidence.

B. Enforcement Priorities by Segment of Industry

II. Priorities for Regulation of Drug Use in Food Species/Populations:

A. Enforcement Priorities by Segment of Industry.

1. Drug Manufacturers:

   a Primary focus among drug manufacturers and distributors will be on firms that specialize in manufacturing for, and distributing to, the aquaculture industry. Special attention should be given to:

   (1) distribution of high priority drugs;

(2) possible diversion and abuse situations, e.g., promotion for food species use of drugs labeled for nonfood species; and packaging of "nonfood fish" drugs in commercial pond-size containers.

b. If intended drug use of a multi-purpose chemical is not established by labeling, or by overt acts by the vendor (e.g., promotion), enforcement actions against the vendor would have to be based on case-by-case analysis. See 21 CFR 201.128.

c. All products granted low enforcement priority must:

(1) be labeled “For Non-food Fish Only” in a prominent place on the label;
(2) have adequate directions for use: and
(3) be drug listed per 21 CFR 207.

d. Manufacturers must:

(1) be registered: and
(2) follow Current Good Manufacturing Practices (CGMPs) per 21 CFR 210 & 211.

2. Feed Manufacturers:

Priorities will be determined on a case-by-case basis. For firms required to be licensed to manufacture medicated feeds and veterinary feed directive drugs, inspections and enforcement actions will be handled according to relevant compliance guidelines.

Extra-label use of medicated feeds is prohibited under the Animal Medicinal Drug Use Clarification Act. See 21 CFR 530. However, regulatory discretion is allowed for extra-label use of medicated feeds in minor species, including fish, under a Compliance Policy Guide. See CPG 615-115. Note that for extra-label use in aquatic species, the medicated feed must already be approved for use in another aquatic species and may not be reformulated.

3. Producers:

Primary objective with producers will be on education with emphasis on proper drug usage, e.g., which drugs are permitted and under what conditions. There will be no routine inspections for enforcement purposes. This will not preclude "for-cause" inspections or surveys to determine usage patterns for drugs, sources of the drugs, etc.

"For cause" inspection assignments will encompass either individual producers, or

could be more broadly based. Such inspections might include, for example, a situation in which there is reason to believe that producers might be holding significant quantities of a drug of high enforcement priority (such as malachite green) and regulation at the manufacturer/distributor level is not feasible.

PART B

ENFORCEMENT PRIORITIES FOR DRUG USE IN FOOD, FISH AND SHELFISH

I. Purpose

This part of this document describes enforcement priorities that apply to drugs for use in aquaculture food species, fin fish or shellfish.

II. Definitions

Food fish and shellfish for human consumption - An aquaculture species is presumed to be a food species if it is reasonably likely that a) a significant percentage of the species population will be consumed directly or indirectly by humans for food, or b) the species is consumed by an identifiable human population.

Food fish and shellfish for animal feed - fish used in whole or in part as a component of any animal feed will be considered a food fish species.

III. Regulation of Drug Use in Food Species, both fin fish and shellfish

When CVM personnel in Division of Compliance are faced with inquiries regarding the use of compounds in food fish (fin fish and shellfish) they need to:

A. Determine which Agency or Food and Drug Administration (FDA) Center has jurisdiction for the regulation of the product based on the following categories:

1. The compound is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal; and intended to affect the structure or any function of the body of man or other animals. The compound is a **drug** and is under the jurisdiction of FDA, CVM. [Federal Food, Drug and Cosmetic Act (FFDCA), 201(g).] [Go to Section III B]. If the compound is determined to be a drug under FFDCA it is a drug even if it has pesticide, biologic, food or color additive properties or claims.

2. The compound is any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or any substance or mixture of substances intended for use as a plant regulator, defoliant, or

3. Desiccant. [Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)] The compound is a **pesticide** and is under the jurisdiction of the Environmental Protection Agency (EPA). Contact EPA, Office of Pesticides.

4. The compound is a virus, serum, toxin (excluding substances that are selectively toxic to microorganisms, e.g., antibiotics), or analogous product at any stage of production, shipment, distribution, or sale, which is intended for use in the treatment of animals and which acts primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response. (9 CFR 101.2) The compound is a **biologic** and is under the jurisdiction of USDA, Animal and Plant Health Inspection Service (APHIS), Center for Veterinary Biologics (CVB). Contact USDA APHIS CVB.

5. The compound is a substance with the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component of, or otherwise affecting the characteristics of any food for humans or animals. (FFDCA 201 (s)) The compound is a **food additive** and is under the jurisdiction of the FDA, CVM. Contact FDA CVM, Division of Animal Feeds.

6. The compound is a substance which is capable of coloring food, and its use or intended use is not for a purpose other than coloring. (FFDCA 201 (t)) The compound is a **color additive** and is under the jurisdiction of the FDA Center for Food Safety and Applied Nutrition (CFSAN). Contact FDA CFSAN.

B. Decide the regulatory status. CVM will use the following categories to determine the regulatory status of a drug:

1. **Approved new animal drug** - An approved New Animal Drug Application (NADA) exists for this indication. Refer to 21 Code of Federal Regulations (CFR) Part 514. Product is used according to label directions.

2. **Investigational New Animal Drug (INAD)** - A potential sponsor may request an INAD exemption for collecting data to support a new animal drug approval. Contact the CVM Aquaculture Drugs Team, HFV-131.

3. **Extra-label use drug -**Use of an FDA-approved drug under the provisions of Animal Medicinal Drug Use Clarification Act (AMDUCA). See 21 CFR 530.

4. **Extra-label use of medicated feeds** - Provisions for the use of

approved medicated feeds for minor species are explained in the Compliance Policy Guide (CPG) for Extra-label Use of Medicated Feeds for Minor Species. Compliance Policy Guide, Chapter 6, Section 615.115.

5. **Regulatory discretion** - Drugs that have been evaluated for regulatory discretion as low priority for enforcement action (INADs/NADAs will not be required). See Low Regulatory Priority (LRP) list in Part C of this document. For others not on the list, go to Part A, Section IV of this document.

IV. Factors to Consider for Regulatory Discretion

Division of Compliance evaluates the potential for regulatory discretion. Drugs will be categorized at CVM's initiative or on request of an interested party. In the latter case, the requestor will be asked to provide available data and information that the Center can use to determine enforcement priority. The criteria used in this determination are as follows:

A. The safety status of the compound including:

1. Human Food Safety – Contact the Division of Human Food Safety, HFV-150. High priority are:

   a. known or suspected carcinogens;
   b. known serious toxicological hazards;
   c. suspected serious toxicological hazards believed to have substantial use in aquaculture; and
   d. antimicrobials likely to confer bacterial resistance to drugs used in human medicine.

2. User safety – Contact the Division of Human Food Safety, HFV-150. High priority are:

   a. known or suspected carcinogens;
   b. known serious toxicological hazards; and
   c. suspected serious toxicological hazards believed to have substantial use in aquaculture.

3. Environmental safety – Contact the Environmental Assessment Team, HFV-145. Considerations include:

   a. potential public or ecological safety issues including:

      (1) potential for surface or groundwater contamination;
      (2) known serious human toxicological hazard; and
      (3) known serious toxicological hazard to aquatic organisms

including fish, insects, and birds.

b. compliance with applicable Federal, State, and local environmental laws.

B. Extent of data available for enforcement priority determinations

In general, only published peer-reviewed studies or literature will be reviewed for the purpose of making enforcement priority determinations. However, unpublished data may be reviewed for enforcement priority determinations on a case-by-case basis. Areas to be reviewed include:

1. Human food safety;
2. Target animal safety and effectiveness;
3. Environmental safety; and
4. Human user and occupational safety.

V. Factors to Consider for Enforcement Priorities

A. In general, regulatory action may be considered in any case where a high enforcement priority drug (see section V.C.) is found. In addition, high enforcement priority drugs may be the subjects of special assignments to the Field. Other drugs will be subject to regulatory action on a case-by-case basis, based on the factors listed below.

1. Jurisdiction – (see Part A, Section III A of this document)
2. Approval status of the active ingredient -
   a. If FDA has withdrawn the approval of the active ingredient for human food safety reasons regulatory discretion will not normally be granted.

   b. If FDA has withdrawn the approval of the active ingredient for reasons other than food safety reasons regulatory discretion will be determined on a case-by-case basis.

   c. If an approved animal drug product containing the same active ingredient is available, the drug will ordinarily not be considered a low enforcement priority to protect the marketing of the approved product.

3. Approval or LRP status of drugs with different active ingredients but similar uses

   a. If an approved animal drug product containing a different active ingredient but for a similar use is available, then the drug will ordinarily not be considered a low enforcement priority to

protect the marketing of the approved product.

b. If an animal drug product containing a different active ingredient but for a similar use as a drug is included on the LRP list (see Part C of this document), then the drug under consideration will ordinarily not be considered a low enforcement priority.

4. If the treated fish are intended for use in animal feed, then there is a higher concern if the feed is to be used for food-producing animals. The method of feed preparation should also be considered, e.g., rendering vs. fish or fish parts.

5. The presence or absence of any significant safety or effectiveness concern as established by the available data will determine the enforcement priority. These data will include information about the active ingredient, formulation, and proposed conditions of use.

6. Regulatory considerations include:

a. potential effect on public health;
b. availability of expert support for a court case;
c. availability of agency resources to support a regulatory action;
d. egregiousness of the violative action; and
e. availability of the required evidence.

B. Enforcement Priorities by Segment of Industry

1. Drug Manufacturers

a. Primary focus among drug manufacturers and distributors will be on firms that specialize in manufacturing for, and distributing to, the aquaculture industry. Special attention should be given to:
(1) distribution of high priority drugs; and
(2) abuse situations, e.g., promotion for food species use of drugs labeled for nonfood species and packaging of "non-food fish" drugs in commercial pond-size containers.

b. If intended drug use of a multi-purpose chemical is not established by labeling, or by overt acts by the vendor (e.g., promotion), enforcement actions against the vendor should be based on case-by-case analysis. See 21 CFR 201.128.

c. All products granted low enforcement priority must:

(1) have adequate directions for use; and
(2) be drug listed per 21 CFR 207.

d. Manufacturers must:

(1) be registered;
(2) be drug listed per 21 CFR 207; and
(3) follow Current Good Manufacturing Practices (CGMPs) per 21 CFR 210 & 211.

2. Feed Manufacturers

For firms required to be licensed to manufacture medicated feeds and veterinary feed directive drugs, inspections and enforcement actions will be handled according to relevant compliance guides.

Extra-label use of medicated feeds is prohibited under the Animal Medicinal Drug Use Clarification Act. See 21 CFR 530. However, regulatory discretion is allowed for extra-label use of medicated feeds in minor species, including fish, under a Compliance Policy Guide. See CPG 615-115. Note that for extra-label use in an aquatic species, the medicated feed must already be approved for use in another aquatic species and may not be reformulated.

3. Producers

Primary emphasis with producers will be on education with emphasis on proper drug usage, e.g., which drugs are permitted and under what conditions. There will be no routine inspections for enforcement purposes. This will not preclude "for-cause" inspections or surveys to determine usage patterns for drugs, sources of the drugs, etc.

"For cause" inspection assignments will encompass either individual producers, or could be more broadly based. Such inspections might include, for example, a situation in which there is reason to believe that producers might be holding significant quantities of a drug of high enforcement priority (such as malachite green) and regulation at the manufacturer/distributor level is not feasible.

PART C

ENFORCEMENT PRIORITIES

I. LOW REGULATORY PRIORITY AQUACULTURE DRUGS

The following compounds have undergone review by the Food and Drug Administration and have been determined to be new animal drugs of low regulatory priority.

ACETIC ACID - 1000 to 2000 ppm dip for 1 to 10 minutes as a parasiticide for fish.

CALCIUM CHLORIDE - Used to increase water calcium concentration to ensure proper egg hardening. Dosages used would be those necessary to raise calcium concentration to 10-20 ppm CaC03.

- Used up to 150 ppm indefinitely to increase the hardness of water for holding and transporting fish in order to enable fish to maintain osmotic balance.

CALCIUM OXIDE - Used as an external protozoacide for fingerlings to adult fish at a concentration of 2000 mg/L for 5 seconds.

CARBON DIOXIDE GAS - For anesthetic purposes in cold, cool, and warm water fish.

FULLER'S EARTH - Used to reduce the adhesiveness of fish eggs to improve hatchability.

GARLIC (Whole Form) - Used for control of helminth and sea lice infestations of marine salmonids at all life stages.

ICE - Used to reduce metabolic rate of fish during transport.

MAGNESIUM SULFATE - Used to treat external monogenic trematode infestations and external crustacean infestations in fish at all life stages. Used in all freshwater species. Fish are immersed in a 30,000 mg $MgS0_4$/L and 7000 mg NaCl/L solutions for 5 to 10 minutes.

ONION (Whole Form) - Used to treat external crustacean parasites, and to deter sea lice from infesting external surface of salmonids at all life stages.

PAPAIN - Use of a 0.2% solution in removing the gelatinous matrix of fish egg masses in order to improve hatchability and decrease the incidence of disease.

POTASSIUM CHLORIDE - Used as an aid in osmoregulation; relieves stress and prevents shock. Dosages used would be those necessary to increase chloride ion concentration to 10-2000 mg/L.

POVIDONE IODINE - 100 ppm solution for 10 minutes as an egg surface disinfectant during and after water hardening.

SODIUM BICARBONATE - 142-642 ppm for 5 minutes as a means of introducing carbon dioxide into the water to anesthetize fish.

SODIUM CHLORIDE - 0.5% to 1.0% solution for an indefinite period as an osmoregulatory aid for the relief of stress and prevention of shock; and 3% solution for 10 to 30 minutes as a parasiticide.

SODIUM SULFITE – 1.5% solution for 5 to 8 minutes to treat eggs in order to improve their hatchability.

THIAMINE HYDROCHLORIDE - Used to prevent or treat thiamine deficiency in salmonids. Eggs are immersed in an aqueous solution of up to 100 ppm for up to four hours during water

hardening. Sac fry are immersed in an aqueous solution of up to 1,000 ppm for up to one hour.

UREA and TANNIC ACID - Used to denature the adhesive component of fish eggs at concentrations of 15g urea and 20g NaCl/5 liters of water for approximately 6 minutes, followed by a separate solution of 0.75g tannic acid/5 liters of water for an additional 6 minutes. These amounts will treat approximately 400,000 eggs.

The Agency is unlikely to object to the use of these substances if the following conditions are met:

(1) The substances are used for these indications;
(2) The substances are used at the prescribed levels;
(3) The substances are used according to good management practices;
(4) The product is of an appropriate grade for use in food animals, and
(5) There is not likely to be an adverse effect on the environment.

The Agency's enforcement position on the use of these substances should not be considered an approval nor an affirmation of their safety and effectiveness. Based on the information available at some time in the future, the Agency may take a different position on the use of any or all of these substances.

Classification of these substances as new animal drugs of low regulatory priority does not exempt facilities from complying with other Federal, State, and local environmental requirements. For example, facilities using these substances would still be required to comply with National Pollutant Discharge Elimination System (NPDES) requirements.

NOTE: The primary long range goals in enforcement prioritization will be to protect public health and encourage submission of INADs and NADAs with a view toward obtaining approvals to meet therapeutic and production needs in aquaculture.

(6) Labeling and GMPs for Low Priority Drugs.

a. Labeling for low priority use will not be required for a chemical that is commonly used for nondrug purposes even if the manufacturer or distributor promotes the chemical for the permitted low priority use.

b. However, a chemical that has significant animal or human drug uses in addition to the low priority aquaculture use will be required to be labeled for the low priority uses if the manufacturer or distributor establishes the intended low priority use for its product by promotion or other means.

c. Where labeling is required, all other provisions of the Act pertaining to drugs except the approval requirement will apply. This includes registration, drug listing and Current Good Manufacturing Practices (CGMPs), etc.

d. Low regulatory priority compounds may be marketed for aquaculture use with

drug claims (the claims permitted for such compounds) but must be of an appropriate quality for use in food animals.

e. If drug claims appear on the product label, in product catalogs, or in promotional material, the following conditions must be met:

The product must have been manufactured according to CGMPs as defined in 21 CFR 210 & 211;

The product manufacturer must be registered with the FDA; and

The product must be drug-listed with FDA.

Material deviations in labeling or promotion from the permitted low priority claims might cause a particular product to be removed from the low priority category.

II. SPECIAL CATEGORY

Products found not to be low regulatory priority but regulatory action deferred pending further study:

Copper sulfate

Potassium permanganate

III. EXAMPLES OF DRUGS WITH HIGH ENFORCEMENT PRIORITY

Chloramphenicol Nitrofurans Fluoroquinolones and Quinolones Malachite Green Steroid Hormones

HISTORY

July 26, 2011 – Typo was found on page 15, under compounds - SODIUM SULFITE. Changed from 15% to 1.5% solution