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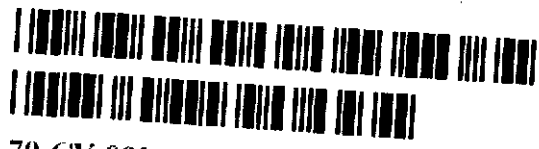
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Hon. Edward Rafeedie

By Deputy *[Signature]* CLERK U.S. DISTRICT COURT
BY WESTERN DISTRICT OF WASHINGTON DEPUTY

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70-CV-09213-ORD

MAY 04 1994

BY *[Signature]* CLERK U.S. DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON DEPUTY

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA, et al.,)	No. 9213
)	Subproceeding 89-3
Plaintiffs,)	
)	
vs.)	CONSENT DECREE
)	REGARDING SHELLFISH
STATE OF WASHINGTON, et al.,)	SANITATION ISSUES
)	
Defendants.)	

I. PARTIES

A. This Consent Decree is entered into by and between the plaintiffs United States of America, Hoh Tribe, Jamestown S'Klallam Tribe, Lower Elwha S'Klallam Tribe, Lummi Nation, Makah Tribe, Muckleshoot Tribe, Nisqually Tribe, Nooksack Tribe, Port Gamble S'Klallam Tribe, Puyallup Tribe, Quileute Tribe, Quinault Indian Nation, Skokomish Tribe, Squaxin Island Tribe, Suquamish Tribe, Swinomish Indian tribal Community, Tulalip Tribes, Upper Skagit Tribe, and Yakama Indian Nation, defendant the State of Washington and defendant state officers ("the state defendants"), all of whom,

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11304

1 plaintiff and defendant, are referred to hereinafter as "the
2 parties".

3 B. Plaintiff tribes are federally-recognized Indian tribes.
4 The plaintiff tribes, or other tribes or bands of which the
5 plaintiff tribes are successors-in-interest, are parties to
6 treaties with the plaintiff United States executed by their
7 representatives in the 1850's, each of which reserves to the
8 tribes, in substantially identical language, "the right of taking
9 fish, at all usual and accustomed grounds and stations, is further
10 secured to said Indians in common with all citizens of the
11 Territory, and of erecting temporary houses for the purpose of
12 curing.... Provided, however, That they shall not take shell-fish
13 from any beds staked or cultivated by citizens." [quoted from Art.
14 III, Treaty of Medicine Creek, 10 Stat. 1133] Tribes regulate the
15 shellfishing activities of their members to protect public health.

16 C. The United States Food and Drug Administration ("FDA") is
17 the agency of plaintiff United States having primary responsibility
18 for protecting the public from shellfish-borne illness. FDA
19 prepares and publishes the National Shellfish Sanitation Program
20 ("NSSP") Manual of Operations, which contains standards to be used
21 in regulating commerce in clams, oysters, mussels and scallops in
22 order to protect the public from shellfish-borne illness. FDA also
23 publishes the Interstate Certified Shellfish Shippers List, which
24 identifies all persons and entities who have been determined by FDA
25 or by an FDA-approved Shellfish Sanitation Control Agency to be in
26 compliance with the NSSP Manual and whose product may be shipped
27

28 CONSENT DECREE -- 2

1 interstate.

2 D. The state regulates shellfish harvest, processing and
3 sale in order to protect public health. The state is a member of
4 the Interstate Shellfish Sanitation Conference ("ISSC"), an
5 organization of states, the shellfish industry, and federal
6 agencies operating under a Memorandum of Understanding with FDA.
7 The ISSC provides a forum for its members to discuss shellfish
8 sanitation issues, and it suggests changes in the NSSP Manual to
9 the FDA.

10 II. RECITALS

11 A. As used in this Decree, "covered claims" means claims of
12 the plaintiffs, set forth in Part I of the Final Pretrial Order
13 approved by the Court in this subproceeding, that relate to the
14 application to or enforcement against the plaintiff tribes of state
15 laws, regulations, or policies which regulate the taking,
16 possession, or disposition of shellfish in order to protect the
17 public from shellfish-borne illness; and the claims of the State of
18 Washington set forth in Part II.B.1. of that Pretrial Order; and
19 any claim of any party related to the authority of the state to
20 regulate treaty shellfishing activities in order to protect the
21 public from shellfish-borne illness, which claim could have been
22 adjudicated in this subproceeding had it been prosecuted to final
23 judgment. For the purpose of determining whether claims could have
24 been adjudicated, reference shall be made to the facts and
25 allegations made in the documents filed with the Court in this
26 subproceeding prior to the date of entry of this Decree which

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CONSENT DECREE -- 3

1 relate to the protection of the public from shellfish-borne
2 illness, including facts and allegations made in the Requests for
3 Determination, the Amended Request for Determination, the Response
4 of the State to the Requests for Determination, and the Pretrial
5 Order approved by the Court pursuant to Local Civil Rules 16 and
6 16.1 of this Court.

7 B. This subproceeding was filed in 1989 seeking declaratory
8 and injunctive relief regarding the treaty right to take shellfish,
9 including a declaration and injunction regarding the authority of
10 the state to regulate treaty shellfishing activities for public
11 health purposes.

12 C. The United States and the tribes seeking relief in this
13 subproceeding have claimed that their treaties substantially
14 restrict state authority; these tribes, however, have acknowledged
15 a willingness to abide by state regulation of treaty shellfishing
16 activities to protect public health, so long as such regulation is
17 reasonable and necessary, non-discriminatory, and meets appropriate
18 standards. The United States and these tribes have further claimed
19 that some state shellfish sanitation laws, regulations and policies
20 do not meet this test and cannot be enforced against tribal treaty
21 shellfishing activities.

22 D. The state defendants claim that they may regulate Indian
23 treaty shellfishing activities of plaintiff tribes to protect human
24 health, safety and welfare, provided any such regulations are
25 reasonable and non-discriminatory. The state has denied
26 plaintiffs' claims regarding the restricted applicability of its
27

1 shellfish sanitation laws to Indian treaty shellfishing.

2 E. Without admission or adjudication of any covered claim,
3 and without waiving any objection, claim, or defense with regard to
4 claims other than the covered claims, in settlement of the covered
5 claims the parties have agreed, upon entry of this Consent Decree,
6 to participate in a cooperative investigatory and regulatory
7 program to protect the public from food-borne illness associated
8 with the consumption of contaminated shellfish. The tribes have
9 agreed that the performance criteria and other satisfactory
10 compliance provisions of the NSSP Manual will govern their treaty
11 shellfishing activities, with regard to species to which the Manual
12 applies. In addition, the parties have agreed to mechanisms
13 whereby any plaintiff tribe having treaty shellfishing rights may
14 implement certain shellfish sanitation measures independently of
15 the state.

16 F. The terms of this Decree are not intended, nor could they
17 be expected, to specify every detail of the operation of the
18 cooperative shellfish sanitation program. The parties have
19 attempted to specify, in the Appendix to the Settlement Agreement
20 which is part of this Decree, some of the details, particularly
21 technical ones, involved in the operation of their cooperative
22 program. Some such details must, of necessity, change as
23 scientific knowledge of shellfish and public health change.
24 Therefore, the parties have established mechanisms in the
25 Settlement Agreement and Appendix for the further refinement of
26 their cooperative program.

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CONSENT DECREE -- 5

1 G. The parties agree that the covered claims raise matters
2 of sovereign interest, and that their settlement of the covered
3 claims as set forth in this Decree is fair, adequate, reasonable,
4 equitable and in the public interest and is made in good faith
5 after arms-length negotiations, and that entry of this Consent
6 Decree is the most appropriate means to resolve the matters covered
7 herein.

8 NOW, THEREFORE, before the taking of any testimony, before the
9 adjudication of the covered claims, and without admission of any
10 issue of law, fact, or liability by the parties, IT IS HEREBY
11 ORDERED, ADJUDGED AND DECREED:

12 III. ORDER

13 A. The Court has jurisdiction over the subject matter of the
14 covered claims and over the parties pursuant to 28 U.S.C. §§ 1331,
15 1345, and 1362. Plaintiffs assert, but the state defendants
16 contest, that the Court also has jurisdiction pursuant to 28 U.S.C.
17 §1343(a)(3) and this Court's continuing jurisdiction as declared in
18 ¶ 24 of the Declaratory Judgment and Decree of February 12, 1974,
19 384 F.Supp. 312 at 408. All parties to this Decree, for purposes
20 of the entry and enforcement of this Decree, waive all objections
21 and defenses they may have to the jurisdiction of the Court, or to
22 venue in this District, or to service of process prior to the entry
23 of this Decree but not afterwards.

24 B. The provisions of this Decree shall apply to and be
25 binding on the parties, their agencies, subdivisions, boards, and
26 commissions, all agents and officers thereof, and all successors
27

1 and assigns of all such entities and individuals; and each of them
2 are hereby enjoined to comply with the provisions of this Decree.
3 Changes in the organizational structure of a party or any of its
4 agencies, subdivisions, boards and commissions shall have no effect
5 on its obligations under this Decree.

6 C. The attached Settlement Agreement, including the
7 Appendix, is hereby incorporated by reference in and made a part of
8 this Decree as if fully set forth herein.

9 D. Except as specifically provided for otherwise in the
10 Settlement Agreement, the plaintiffs covenant not to sue or to take
11 any other judicial or administrative action against any state
12 defendant, and the state defendants covenant not to sue or to take
13 any other judicial or administrative action against any plaintiff,
14 or against any member of a plaintiff tribe, for covered claims or
15 for any claims relating to or arising from the filing and
16 litigation of the covered claims and the negotiation, terms,
17 approval and implementation of this Decree.

18 E. If for any reason the Court should decline to approve
19 this Decree in the form presented, any statements made in
20 negotiation and the terms herein may not be used as evidence in any
21 litigation or administrative proceeding.

22 F. Each undersigned representative of the parties certifies
23 that he or she is fully authorized to enter into the terms and
24 conditions of the Decree and to legally execute, and bind such
25 party to, the Decree.

26 G. The terms of this Decree may be modified only by a
27

28 CONSENT DECREE -- 7

1 subsequent written agreement executed by all the parties and
2 approved by the Court. Notwithstanding the foregoing, the parties
3 by written agreement and without the need for Court approval may
4 modify or amend the Appendix to the Settlement Agreement, other than
5 Attachment A thereto, relating to procedures for the development of
6 implementation protocols and policies, which shall not be amended
7 without Court approval.

8 H. If for any reason the Court declines to approve this
9 Decree in the form presented, this Decree and the settlement
10 embodied herein shall be voidable at the sole discretion of any
11 party upon written notice to all parties and to the Court.

12 I. This Consent Decree shall be effective upon the date of
13 its entry by the Court.

14 J. The Court shall retain jurisdiction for purposes of
15 entering such further orders as may be appropriate for the
16 construction, implementation, or enforcement of the Decree. In the
17 event that the jurisdiction retained in this paragraph, or the
18 continuing jurisdiction of the Court over Civil No. 9213 or over
19 this subproceeding, is terminated, this Decree shall be enforceable
20 in the same manner as any final judgment and order of the Court.

21 K. The use of the terms "primary responsibility" and
22 "concurrent jurisdiction" in the Settlement Agreement shall not be
23 construed to confer or enlarge the jurisdiction of any plaintiff
24 tribe over non-Indians.

25 By signature below all parties consent to entry of this Decree
26

CONSENT DECREE -- 8

1 as an Order of the Court.

2 DATED AND SO ORDERED the _____ day of _____, 1994.

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Edward Rafeedie
Edward Rafeedie, Judge
United States District Court

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PRESENTED BY:

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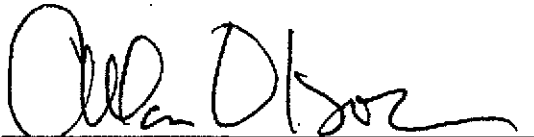
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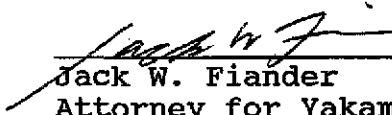
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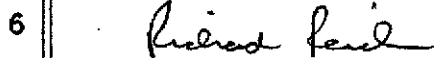
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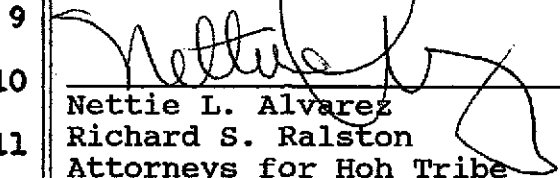
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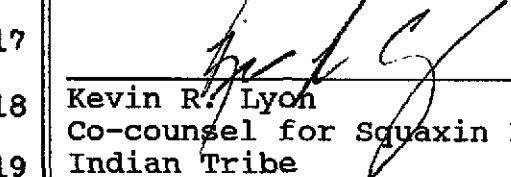
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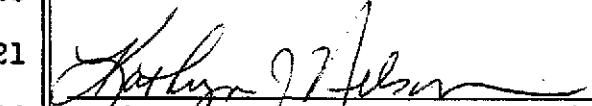
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35 and Lower Elwha S'Klallam
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UNITED STATES v. WASHINGTON
W.D. Wash. Civil No. 9213
Subproceeding 89-3

SETTLEMENT AGREEMENT

REGULATION OF TREATY SHELLFISHING FOR HEALTH PURPOSES

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1 REGULATION OF TREATY SHELLFISHING ACTIVITIES FOR HEALTH PURPOSES
2
3 SETTLEMENT AGREEMENT

4 The plaintiff tribes, United States, and State of
5 Washington, in settlement of the health protection issues raised
6 in United States v. Washington, W.D. Wash. Civil No. 9213,
7 Subproceeding 89-3, which involve the scope of state authority to
8 regulate treaty shellfishing activities for shellfish sanitation,
9 agree as follows.

10 I. ESTABLISHMENT OF COOPERATIVE, INTERGOVERNMENTAL SHELLFISH
11 SANITATION PROGRAMS

12 A. Objectives/Applicability of National Shellfish Sanitation
13 Program Manual

14 The tribal, United States, and state governments, which are
15 parties to this Agreement [hereafter "parties"], recognize that
16 they share a strong concern for shellfish sanitation and the
17 enforcement of effective measures to protect the public from
18 health hazards associated with shellfish contamination. The
19 parties agree that these mutual objectives can be effectively
20 addressed by cooperative, intergovernmental shellfish sanitation
21 programs in which the state and tribes accept varying degrees of
22 responsibility for shellfish sanitation matters related to treaty
23 shellfishing activities. The parties agree that these
24 intergovernmental programs are appropriate not only in protecting
25 public health but also in addressing the jurisdictional issues
26 surrounding treaty shellfishing rights, the special
27 federal/tribal relationship, and the State of Washington
28 Centennial Accord. In implementing all aspects of this
Agreement, the parties agree to be guided by the unique legal and

1 political status of the tribes, to the extent the level of health
2 protection provided by the programs would not be compromised.
3 The State of Washington agrees to support separate tribal
4 representation in the Interstate Shellfish Sanitation Conference
5 ("ISSC") and other intergovernmental organizations involved in
6 the development of shellfish sanitation standards, data, training
7 or information. The tribes agree that the performance criteria
8 and other satisfactory compliance provisions of the National
9 Shellfish Sanitation Program ("NSSP") Manual, currently in
10 effect, or as subsequently adopted, shall govern their treaty
11 shellfishing activities. The tribes retain the right to propose
12 and pursue changes in the NSSP Manual, in applicable federal law,
13 and in any state shellfish sanitation laws, regulations, or
14 policies. In proposing and pursuing such changes, the tribes
15 will not challenge the application of the terms of this Agreement
16 to them or their members as inconsistent with their treaty
17 rights, except that changes in the NSSP manual claimed to
18 discriminate against treaty shellfishing activities may be
19 challenged on that ground. Nothing in this Agreement shall
20 preclude a tribe from enacting ordinances or adopting regulations
21 more stringent than the NSSP standards.

22 **B. Independent Tribal Shellfish Sanitation Control Agencies**

23 A tribal government may undertake sole responsibility for
24 shellfish sanitation in its treaty shellfishing activities. A
25 tribe having sole responsibility for shellfish sanitation shall
26 be responsible for ensuring compliance in treaty fishing
27 activities with the NSSP Manual, both Parts I and II. The state
28 will have no responsibility for licensing, certifying or

1 inspecting such activities or any shellfish operation of such a
2 tribe, for the purposes of shellfish sanitation. The state also
3 will not conduct any shellfish sanitation enforcement as to such
4 treaty shellfishing. Such tribe could undertake independent
5 classification of growing areas within its usual and accustomed
6 areas, consistent with the concurrent jurisdiction provisions of
7 this Agreement, provided that such tribe may not undertake such
8 classification as to any bed staked or cultivated by citizens
9 unless afforded access to the bed by agreement of the owner or
10 lessee. A tribe in this category is not subject to Parts II,
11 III, §§B-F, V, VI and the Appendix to this Agreement, but may
12 choose to participate in any of the joint technical/protocol
13 development, enforcement, or other intergovernmental measures
14 provided for in those sections.

15 The tribes agree that before undertaking sole
16 responsibility, approval will be obtained from the appropriate
17 office of the United States Food and Drug Administration ("FDA")
18 for the tribe's independent shellfish sanitation program
19 ("SSCA"). FDA's approval will be based upon a tribe's ability to
20 meet the standards set forth in the NSSP Manual. In addition to
21 facilities, staff, and other resources of a tribal organization,
22 a contractor, or consultant may be relied upon to establish a
23 tribe's qualifications to act as an independent shellfish
24 sanitation control agency.

25 The parties recognize that a tribe's status as an
26 independent shellfish sanitation control agency may present
27 questions related to concurrent jurisdiction over growing areas
28 from which both tribal and non-tribal harvest is permitted.

1 Questions will relate, for example, to initial classification,
2 reclassification, and monitoring of growing areas and response to
3 actual or perceived emergencies. As part of any tribal request
4 for recognition as an independent shellfish sanitation control
5 agency, the state and tribe shall present either a joint proposal
6 to FDA for addressing these jurisdictional questions or a
7 statement of their respective positions on disputed
8 jurisdictional questions. Disputes over whether a particular
9 matter raises a meritorious claim of jurisdiction may be
10 submitted for federal court resolution. Where the state and
11 tribes agree or the court determines that concurrent jurisdiction
12 exists, disputes regarding the appropriate coordination or
13 exercise of such jurisdiction for public health protection shall
14 be resolved through the mechanism described in Part VIII, § A.3
15 of this Agreement. Any jurisdictional question identified after
16 the approval of a tribe as a SSCA, which for whatever reason, was
17 not addressed earlier shall be addressed and resolved by the
18 state and tribes and submitted to FDA using the same procedure
19 applicable to an initial request for recognition.

20 **C. Development And Expansion Of Intergovernmental Shellfish**
21 **Sanitation Programs/Technical Assistance**

22 The state shall seek funding for a well-qualified individual
23 who would be employed by the state for the purpose of assisting
24 the tribes in developing expertise in matters of public health
25 and shellfish sanitation. When funding for this position becomes
26 available or is reasonably anticipated, the state will provide
27 the tribes with a list of qualified individuals who have public
28 health expertise and, more specifically, expertise with respect

1 to shellfish sanitation. The state, in consultation with the
2 tribes, will select from this list one person whose
3 responsibility would be to advise the tribes with respect to
4 public health and shellfish sanitation. This individual will be
5 a state employee and the state will provide this individual's
6 salary and benefits for a period of five years. It is
7 contemplated that this individual would be officed in a tribal
8 facility such as the Northwest Indian Fisheries Commission
9 (NWIFC) office and will prioritize his or her activities as
10 determined by the tribes. During this time, those tribes
11 desiring to take responsibility for shellfish sanitation matters
12 will seek funding and/or other necessary support to hire and
13 integrate into their tribal shellfish programs persons with
14 experience in public health and shellfish sanitation matters.
15 The state may seek additional funding for the purpose of
16 assisting the tribes in developing expertise in matters of public
17 health and shellfish sanitation.

18 The state will provide additional technical assistance to
19 tribes wishing to increase their expertise in matters of public
20 health and shellfish sanitation subject to resource constraints.
21 Examples of technical assistance include training, agreements for
22 use of state laboratory facilities and access to state data, and
23 advice regarding program design and operation.

24 It is recognized by the parties that the personnel,
25 infrastructure necessary for a comprehensive shellfish sanitation
26 program, the wide array of technical expertise, and laboratory
27 support facilities would be more easily attained through
28 intertribal cooperation and sharing of resources. In

1 establishing the tribes' abilities to accept varying degrees of
2 responsibility leading to being recognized as independent tribal
3 SSCA's, the pooling of tribal resources and expertise shall be
4 considered consistent with the provisions of this Agreement and
5 is encouraged.

6 The tribes and state agree to establish regular meetings, at
7 least on a quarterly basis, to discuss shellfish sanitation
8 matters of concern, exchange information and knowledge, and
9 identify and implement mechanisms to further their cooperative,
10 intergovernmental approach, consistent with this Agreement.

11 Tribes shall be notified of and may participate in all
12 formal FDA and state shellfish sanitation training programs. The
13 Department of Health will use its best efforts to gain FDA
14 approval of a state laboratory certification officer. Upon
15 application, the state's lab certification officer will determine
16 whether the applicant's laboratory meets the requirements of Part
17 I of the NSSP Manual. This shall not preclude FDA certification
18 of a tribal laboratory.

19 **II. LICENSING, INSPECTION AND CERTIFICATION FOR INTERSTATE AND**
20 **INTRASTATE SHIPMENT**

21 Any state or tribal licensing or certification decision
22 regarding a tribal or individual tribal operation and relating to
23 shellfish sanitation shall be consistent with this Agreement.
24 The State agrees that, for the purpose of complying with this
25 Agreement, a tribe may license individual tribal members and
26 nonmember assistants to harvest, and to sell the shellfish they
27 have harvested, under the tribe's state license and certification
28 number, provided that the licensing of nonmember assistants

1 complies with the ruling of the court in United States v.
2 Washington, 384 F.Supp. 312, 412 (W.D. Wash. 1974) (Ruling on
3 Fisheries' Question No. 20).

4 **A. Tribes May Assume Primary Responsibility For Individual And**
5 **Tribal Shellfish Operations**

6 Although not approved as an independent shellfish sanitation
7 control agency, a tribe may assume primary responsibility for the
8 inspection and licensing of shellfish operations subject to its
9 jurisdiction by obtaining FDA recognition that a tribal employee,
10 consultant, or agent satisfies the qualifications for becoming a
11 "standard," in accordance with FDA procedures, and as provided in
12 the NSSP Manual. Such responsibility includes responsibility for
13 ensuring compliance of individual tribal harvesters and tribally
14 authorized shellfish dealers with Part II of the NSSP Manual.
15 This Agreement provides for the recognition of such tribal
16 standards. This provision, the parties agree, is a step toward
17 tribal autonomy with respect to the regulation of shellfish
18 sanitation. This provision also reduces burdens on the state
19 with respect to routine inspections. The standard shall have the
20 education and experience described in the Appendix, Attachment F.

21 The standardization requirement may be satisfied by the
22 standardization of a qualified employee, consultant, or agent of
23 a tribal organization or other entity from which it may obtain
24 the required evaluation services.

25 A "standard" who is to provide evaluation services to a
26 tribe must satisfy all requirements of the FDA or the NSSP which
27 apply to state standards, including but not limited to periodic
28 reevaluations, unless FDA determines that a particular

1 requirement, or requirements would impair a tribe's ability to
2 undertake primary shellfish sanitation responsibility and can be
3 waived without compromising public health protection. A standard
4 shall not have any inspection authority as to an operation in
5 which he or she has any proprietary or financial interest,
6 employment relationship or managerial responsibility.

7 Tribes under this Part II §A agree to obtain a state
8 shellstock shipper or shucker/packer license and certificate of
9 approval and state certification to the FDA for inclusion on the
10 Interstate Certified Shellfish Shippers List (ICSSL) provided
11 that such licensing and certification shall be deemed a voluntary
12 division of responsibility in furtherance of establishing
13 cooperative, intergovernmental shellfish sanitation programs.
14 Tribes and individual tribal operations obtaining a state license
15 and certification pursuant to either this Part II, §A or the
16 following Part II, §B shall not thereby become subject to any
17 state shellfish sanitation laws, regulation, or enforcement
18 authority, except as expressly provided in this Agreement.

19 The state will not license individual shellfish operations
20 within the jurisdiction of tribes under this Part II, §A. The
21 names of the individual shellfish operations will appear
22 separately on the ICSSL. Individual shellfish operations within
23 the jurisdiction of tribes, for purposes of this Agreement, means
24 any shellfish operation within the territorial jurisdiction of
25 the tribe, in which the tribe or any tribal member(s) own an
26 interest in excess of 50% and exercise actual management control.
27 The tribe shall notify the state of all such individual shellfish
28 operations. In licensing individual shellfish operations, the

1 tribe may retain direct responsibility for compliance with
2 specific components of Part II of the NSSP Manual.

3 The "standard" relied on by the tribe shall inspect,
4 evaluate and, as necessary, initiate sanctions against any
5 shellfish operation within the jurisdiction of the tribe. The
6 standard will perform these functions in accordance with Part II
7 of the NSSP Manual, as provided by tribal ordinance or
8 regulation. The standard will advise the state and FDA of his or
9 her inspection schedule and will provide copies of all inspection
10 reports, as well as prompt notice of any adverse action taken in
11 regard to a shellfish operation. A state and/or FDA standard
12 will be permitted to accompany the tribal standard on any
13 inspection. A state standard may independently conduct only such
14 inspections as are reasonably necessary to audit the tribal
15 program, pursuant to Part V of this Agreement. Any dispute over
16 whether state inspections are reasonably necessary to audit the
17 tribal program shall be subject to dispute resolution pursuant to
18 Part VIII, §A.3.

19 **B. State to Exercise Primary Responsibility**

20 The state will have primary responsibility for certain
21 shellfish sanitation matters as to treaty shellfishing activities
22 by any tribe not itself a shellfish sanitation control agency and
23 not having primary responsibility for inspection and licensing as
24 provided herein, unless the tribe notifies the state that the
25 tribe chooses not to permit shellfishing for commercial purposes,
26 does not itself engage in commercial shellfishing activities, and
27 identifies effective tribal controls to prohibit subsistence and
28 ceremonial harvests from being diverted to commercial use.

1 Effective controls are described in Part III, §C of this
2 Agreement. Primary responsibility means primary responsibility
3 for ensuring compliance with Part II of the NSSP Manual.
4 Accordingly, the state shall license, certify, and inspect
5 operations over which it retains primary responsibility. The
6 sanction, if any, against a tribe or individual tribal operation
7 shall be limited to license denial, suspension, modification or
8 revocation. Any action against a tribe shall be conducted as a
9 dispute resolution pursuant to Part VIII, §A.3 of this Agreement
10 with those responsible for dispute resolution having the power
11 to deny, suspend, modify or revoke the tribal license. License
12 actions against individual tribal operations shall be conducted
13 under the state administrative process.

14 **C. Tribal Certification -- Compliance with NSSP Manual Part II.**

15 If the state believes any tribe employing an FDA recognized
16 standard, or any shellfish operation subject to the jurisdiction
17 of such tribe, is out of compliance with Part II of the NSSP
18 Manual, the state shall so notify the tribe in writing, detailing
19 the deficiencies. A reasonable opportunity to take corrective
20 action shall be offered, consistent with Part II of the NSSP
21 Manual. Where consistent with the findings of a tribal standard
22 and with Part II of the NSSP Manual, the state may, for purposes
23 of the FDA's Interstate Certified Shellfish Shipper's List,
24 withhold or withdraw the certification of an individual shellfish
25 operation within the tribe's jurisdiction, if the deficiencies
26 are not corrected. The state may also initiate action under the
27 dispute resolution provisions, Part VIII, to suspend, modify or
28 revoke the license of any tribe employing an FDA recognized

1 standard which fails, under this subsection, to comply or insure
2 compliance with Part II of the NSSP Manual.

3 **D. License Fees**

4 The state shall not charge a fee for licensing any tribal
5 treaty or individual treaty shellfishing operation as provided
6 for in this Agreement.

7 **III. SHELLFISH SANITATION CRITERIA AND MEASURES APPLICABLE TO
8 TREATY SHELLFISHING ACTIVITIES**

9 **A. Compliance With NSSP Manual Sufficient**

10 The parties agree that compliance with the performance
11 criteria and other satisfactory compliance provisions set forth
12 in the NSSP Manual, with the terms of this Agreement, and with
13 all applicable federal laws or regulations governing shellfish
14 sanitation, is adequate to protect public health. The tribes
15 agree to regulate their treaty shellfishing activities, either
16 independently or in conjunction with the state as provided
17 herein, to maintain such compliance. Except as expressly
18 provided in this Agreement, the state will not apply its
19 shellfish sanitation laws, regulations, or policies to the tribes
20 or their members.

21 The Manual currently covers clams, mussels, oysters, and
22 scallops. The state and tribes agree to develop, as necessary, a
23 cooperative approach for health regulation of any shellfish
24 species subject to the tribes' treaty right which is not covered
25 by the NSSP Manual. This approach shall be consistent with and
26 modelled after the approach taken herein with respect to clams,
27 oysters, mussels and scallops. The approach shall provide for:

- 28 1) comparable opportunities for increasing, and ultimately

1 establishing exclusive tribal shellfish sanitation control;
2 this includes but is not limited to primary reliance on
3 tribal licensing, inspection, and other regulation;

4 2) an application of state sanitation laws to treaty
5 shellfishing which is limited to emergency situations and
6 those situations where a tribe has not yet developed an
7 effective program for protection of public health; such
8 application shall not discriminate against treaty
9 shellfishing activities;

10 3) joint development of regulatory protocols and decisions;

11 4) exclusive tribal enforcement over members where a tribe
12 has its own regulatory system in place; and

13 5) intergovernmental cooperation.

14 The state and tribes shall use the process outlined in the
15 Appendix, Attachment A to develop this approach, prioritized
16 according to the level of health concern. Any disputes as to the
17 state's legal authority in regard to species subject to the
18 tribes' treaty right and not presently covered by the NSSP
19 Manual, including questions involving the impairment of treaty
20 shellfishing rights, may be submitted to the federal court.

21 Other disputes shall be resolved pursuant to the dispute
22 resolution provisions of this Agreement. In the interim, if the
23 state seeks to apply a state shellfish sanitation law to a treaty
24 tribe, with respect to species subject to a tribe's treaty right
25 and not covered by the NSSP Manual, the state shall seek the
26 tribe's agreement including, where appropriate, voluntary
27 agreement to state licensure, inspection and compliance with
28 standards applied to non-treaty shellfishers. If the tribe

1 objects, the state may submit the matter to the federal court for
2 resolution, provided that Part III, §B. of this Agreement shall
3 apply in the case of a health emergency.

4 **B. Emergencies - Additional Measures, Including Closures, May Be**
5 **Applied To Treaty Shellfishing When Essential In Responding To A**
6 **Health Emergency**

6 1. Notwithstanding any other provision of this Agreement,
7 the state may take summary administrative action against the
8 tribal operation including license suspension, closing of growing
9 areas and seizure or recall of product, in the case of a health
10 emergency. A health emergency is a situation involving an
11 immediate danger to the public health requiring immediate action.
12 The state may take only such action as is necessary to prevent or
13 avoid the immediate danger to the public health and justifies use
14 of the emergency action.

15 2. The state agrees that in the case of a health emergency
16 it will notify affected tribes of the situation and will provide
17 available, relevant data as soon as possible. Consistent with
18 the gravity of the health threat and the need for immediate
19 response, the state will provide affected tribes an opportunity
20 for prior consultation and prior technical/policy review.

21 3. Health emergencies may occur, for example: where
22 established shellfish sanitation standards such as paralytic
23 shellfish poison levels are exceeded; where harvesting areas are
24 implicated in human illness; in the case of a catastrophic
25 polluting event of unknown impact such as floods and oil or
26 sewage spills; where contaminants present unknown health risks as
27 was the case with domoic acid; where commercial shellfish
28 operations engage in the sale of shellfish from closed areas

1 contrary to the provisions of this Agreement; or where a tribal
2 shellfish operation fails to meet a critical standard as defined
3 in Part II of the NSSP Manual.

4 4. The state shall defer to measures adopted by a tribe to
5 address a health emergency, where such measures would effectively
6 protect public health. Any tribe affected by the state's action
7 in the case of an alleged health emergency may invoke the dispute
8 resolution mechanism described in Part VIII, §3 of this Agreement
9 to challenge the appropriateness of the emergency measures,
10 either before or after they are implemented, but such measures
11 shall remain in effect until resolved otherwise through dispute
12 resolution.

13 **C. Commercial Harvests From Closed Areas Shall Be Prohibited**

14 1. A closed area is an area from which commercial shellfish
15 harvest is not permitted under the terms of this Agreement. Each
16 tribe will prohibit commercial harvest from closed areas and the
17 sale of shellfish from closed areas. Sanctions authorized by
18 tribal law for violation of such provisions shall be sufficient
19 to deter prohibited conduct. The state and tribes agree that any
20 harvest for human consumption from growing areas which are
21 closed, based on a sanitary survey or marine biotoxin report, is
22 undesirable. The state and tribes also agree that such harvest
23 should be discouraged through educational or other means.

24 2. Consistent with subsistence needs for all relevant
25 species, each tribe will impose restrictions or measures to
26 prevent the unlawful diversion to commercial use of shellfish
27 harvested for subsistence purposes. These could include
28 subsistence bag limits, restricting subsistence harvest in closed

1 areas to monitored conditions, or such other controls as are
2 effective. The tribe shall provide the state specific
3 descriptions of the tribe's restrictions and/or other measures
4 for review and comment. It is agreed that the current tribal
5 monitoring systems and controls described in the Appendix,
6 Attachment I, represent examples of effective restrictions or
7 measures. Sanctions authorized by tribal law for violation of
8 provisions established under this paragraph shall be sufficient
9 to deter prohibited conduct.

10 3. Tribes will notify the state shellfish sanitation
11 program in advance of any ceremonial harvest from closed areas
12 which does not comply in all respects with the limitations on
13 closed area subsistence shellfishing. The ceremonial harvests
14 will be subject to tribal controls similar to those enacted or
15 adopted to prevent the diversion of subsistence harvest into the
16 commercial market.

17 4. If after review and comment the state does not agree
18 that the tribe's controls for ceremonial or subsistence harvest
19 would be effective, the matter may be referred to dispute
20 resolution.

21 5. Consistent with the limitations on the release of
22 criminal record information and any other confidentiality
23 requirements imposed under state law, the state shall timely
24 notify the tribes of all citations and/or arrests for violation
25 of RCW 69.30.110, and any other state law imposed to prevent the
26 unlawful diversion to commercial use of shellfish harvested for
27 non-commercial purposes, issued or made by Washington Department
28 of Fish and Wildlife ("WDFW") officers and the disposition of

1 those cases. Each tribe shall timely notify the state of all
2 citations and/or arrests for violation of ordinances or
3 regulations enacted or adopted under paragraphs (1), (2), and (3)
4 of this section and the disposition of those cases, provided that
5 the tribes shall not be required to submit information different
6 in kind or with any greater degree of specificity or breadth of
7 disclosure than the state submits to the tribes.

8 6. After reasonable notice and an opportunity to correct
9 deficiencies, a state licensed tribe shall be subject to
10 suspension or revocation of its license and certification for
11 failure to reasonably prosecute tribal members for violation of
12 ordinances and/or regulations enacted or adopted under paragraphs
13 (1), (2), and (3) of this section or which fails to timely notify
14 the state of arrests, citations and the disposition of such
15 cases. Any such action to suspend or revoke a tribe's state
16 license shall be subject to dispute resolution as provided in
17 this Agreement.

18 7. The state will not enforce the state's presumptive
19 commercial limit as to the exercise of treaty shellfishing rights
20 by any member of a tribe which complies with the regulatory and
21 enforcement provisions set forth in paragraphs (1) through (5) of
22 this section.

23 **D. Commercial Harvests From Closed Areas Permissible If Not For**
24 **Human Consumption**

25 Notwithstanding Part II, §C, tribes may engage in or
26 authorize closed area shellfishing for bait, seed, or other use
27 which does not involve human consumption, consistent with the
28 protocols referenced in the Appendix, Attachment B. Consistent

1 with the protocols presently developed or developed in the
2 future, and referenced in the Appendix, Attachment A, a tribe,
3 prior to doing so, shall prepare and submit a plan to the state
4 for review and concurrence. The state shall complete its review
5 of the plan within 30 days after receipt.

6 **E. Joint Identification And Development Of Protocols, Standards
7 And Other Guidance For Implementation Of The NSSP Manual**

8 The state and tribes have identified certain elements of the
9 NSSP Manual which they believe require agreed approaches to
10 implementation. These include, among others, standards regarding
11 short-term relays, the placement of sanitary lines, bait and seed
12 harvest, and training requirements. Such shellfish sanitation
13 considerations are addressed in the Appendix to this Agreement,
14 which Appendix is incorporated herein by reference.

15 The Appendix contains protocols for certain matters and
16 procedures and timetables for completion of others. The state
17 and tribes, by agreement, may alter, expand, or limit the
18 measures, protocols, or other provisions set forth in the
19 Appendix, other than Attachment A.

20 **F. Growing Area Classification/Certification**

21 The state and tribes agree that growing areas shall be
22 classified and certified according to criteria set out in section
23 C and other applicable portions of Part I of the NSSP Manual.
24 Conditionally restricted and conditionally approved
25 classifications will be utilized according to protocols agreed to
26 by the state and tribes, which recognize budget limitations. The
27 adoption of additional or more specific criteria and measures to
28 implement the Manual shall be by joint agreement of the state and

1 tribes, pursuant to Part II, §E above.

2 The state will not, as a prerequisite to growing area
3 classification, require a tribe to demonstrate ownership,
4 leasehold interest, or permission from any owner, lessee, or land
5 manager, of a growing area within the tribe's usual and
6 accustomed areas and any portions thereof which are not "beds
7 staked or cultivated by citizens" as adjudicated or as agreed to
8 by the affected parties including any affected landowners. Nor
9 shall any review and concurrence as to a non-health related
10 matter, such as fish resource use priorities, be a condition of
11 such classification. The state may otherwise continue to request
12 a demonstration of ownership or landowner permission as a
13 prerequisite to growing area classification. It will be the
14 responsibility of the tribe to resolve any challenge to its
15 treaty right in a particular growing area. The state may
16 postpone action on a classification application until the dispute
17 is resolved.

18 Tribal applications for the classification of new growing
19 areas will be treated separately from nontribal applications for
20 purposes of prioritization. The state agrees to set aside at
21 least 50 % of funds and other resources available for the
22 classification of new growing areas for use in acting on tribal
23 applications for the classification or reclassification of
24 growing areas. This percentage shall be reevaluated by the state
25 and tribes at such time as any tribe is recognized by FDA as an
26 independent shellfish sanitation control agency. The state and
27 tribes agree to seek additional appropriations for classifying
28 and restoring areas identified by the tribes. For the tribes,

1 such funding efforts may focus on increasing the ability of the
2 tribes to gather the data and develop the evaluative expertise
3 for classification and restoration. By joint agreement among the
4 tribes, the tribes will develop criteria for prioritization of
5 tribal applications and identify a priority ranking, provided
6 that, if the tribes fail to reach agreement on such ranking at a
7 particular time, the state shall proceed to act on the
8 applications by random selection among such tribal applications
9 as have been filed with the department.

10 Before initially classifying a growing area or changing a
11 growing area classification, the state shellfish program will
12 notify affected tribes of facts indicating that a classification
13 may be appropriate or a classification change may be necessary.
14 The state and tribes will jointly determine a time period for
15 collection of pertinent information and analysis consistent with
16 the protocol for data collection and analysis developed as
17 indicated in the Appendix, Attachment A, Group 2 (d).

18 Following such analysis, the state shellfish program will draft a
19 proposed classification decision and submit the draft to all
20 affected tribes for review and comment. The tribes will provide
21 review and comment on a proposed classification decision, if any,
22 within thirty days.

23 Where an immediate downgrade in classification, or a
24 closure, is required by the NSSP Manual because of a failure to
25 meet the minimum classification criteria of the NSSP, and where
26 such failure does not constitute a health emergency as defined in
27 Part III, §B of this Agreement, then the action required by the
28 NSSP shall be taken. Prior to the action and at the earliest

1 possible time, the state will notify affected tribes of the
2 action and of facts the state believes demonstrate the need for
3 the action under the NSSP. Within ten days of the action and as
4 expeditiously as possible, the state and affected tribes will
5 consult regarding the action and shall jointly determine the need
6 and the time period for further investigations to confirm the
7 failure to meet NSSP criteria. The state and tribes may agree to
8 extend this period as appropriate. Thereafter, the downgrade or
9 closure decision shall be subject to dispute resolution as
10 provided in Part VIII of this Agreement. Any immediate downgrade
11 in classification, or closure, which is required by the NSSP
12 Manual because of a failure to meet the minimum classification
13 criteria of the NSSP and which also constitutes a health
14 emergency as defined in Part III, §B of this Agreement, shall be
15 handled as such an emergency under Part III, §B.

16 Any final decision regarding an initial classification or
17 reclassification shall reflect a thorough consideration of all
18 information and analysis supplied by a tribe and tribal comments,
19 which have been timely submitted.

20 Plans and procedures for water sampling, shoreline surveys,
21 monitoring, and other investigative work related to the
22 classification, reclassification, restoration, or monitoring of
23 growing areas subject to tribal harvest shall be jointly
24 developed and agreed upon by the state and tribes. Any tribe who
25 wishes to participate in such investigative work may do so in
26 accordance with the agreed plans and procedures. Such
27 participation will be encouraged and shall be a joint and
28 cooperative process between the tribe and state, conducted

1 through mutual consultation and sharing of expertise. Any tribe
2 who wishes to conduct any water quality studies or shoreline
3 surveys, other than shoreline survey on private land outside the
4 tribe's reservation boundaries, may do so in accordance with the
5 agreed plans and procedures and consistent with the expertise and
6 training requirements provided in the Appendix, Attachments G and
7 H. Tribes conducting shoreline surveys on private lands outside
8 their reservation boundaries will do so only in conjunction with
9 state or county health officials. Both the state and tribes may
10 audit the investigative work performed by the tribes for
11 compliance with the NSSP Manual.

12 The state or a tribe will notify affected parties to this
13 Agreement of its intent to conduct investigative work referenced
14 in this Agreement at least one week prior to conducting such
15 work. The state or a tribe planning to conduct such work will
16 notify affected parties to this Agreement of any change in
17 circumstance requiring deviation from the plan or schedule. A
18 telephone call shall be sufficient notice for purposes of this
19 paragraph. Tribes who do not wish to participate in routine
20 growing area monitoring shall advise the state that notice to
21 them of routine monitoring is not necessary.

22 IV. EXCHANGE OF REGULATIONS AND DATA/REPORTING ILLNESSES

23 Except as to the issuance of regulations for emergency
24 purposes as described in Part III §B of this Agreement, the state
25 and tribes shall distribute among themselves for review and
26 comment any proposed new or amended provisions of their shellfish
27 sanitation laws or guidance. At least thirty days will be
28 provided for review and comment of a draft. At least fifteen

1 days will be provided for review and comment of a final proposed
2 shellfish sanitation law or guidance. The state and tribes will
3 also distribute any shellfish sanitation data among themselves
4 upon request. FDA will provide the tribes copies of all NSSP
5 Manual interpretations and Manual updates.

6 Consistent with applicable confidentiality requirements, the
7 state and tribes will immediately report to all parties to this
8 Agreement information, within their possession, regarding any
9 shellfish-related, human illness.

10 V. STATE AUDIT OF TRIBAL PROGRAMS

11 The state may audit the shellfish sanitation activities of
12 tribes to evaluate compliance with this Agreement. Such audits
13 shall consist of periodic or occasional inspections of
14 facilities, places, or records, or interviews with persons
15 responsible for shellfish sanitation activities.

16 Where audit activities are conducted in person, the state
17 auditor shall, prior to or upon arrival, identify himself or
18 herself to the person in charge of the facility, place, or
19 records, and notify the tribal shellfish sanitation contact
20 identified pursuant to Part VII of this Agreement. The tribal
21 contact or his or her designee shall have the right to accompany
22 the auditor(s). The audit need not be delayed due to the
23 unavailability of the tribal contact or designee. Promptly upon
24 request, the tribe shall be provided a copy of all field notes,
25 reports, findings, conclusions, and written criteria produced
26 during an audit or used by the state to audit tribal compliance
27 with this Agreement.

1 VI. ENFORCEMENT

2 A. Nothing in this Agreement shall be construed to enlarge
3 the authority of state officers on reservations and any Indian
4 trust lands. Nothing in this Part VI shall be construed to
5 pertain to, restrict or alter the enforcement of laws other than
6 the shellfish sanitation laws of the parties.

7 B. Each tribe shall bear primary responsibility for
8 enforcement of shellfish sanitation laws against its members and
9 shellfishing permittees within its reservation, any tribal trust
10 lands, or within the tribe's usual and accustomed areas. To the
11 full extent permitted by applicable law, each tribe shall also
12 have primary responsibility against nonmember Indians within its
13 reservation or on any lands held in trust for the tribe or its
14 members. Any tribe may, at its discretion, refer to the state
15 for prosecution in state courts any violation of tribal law which
16 is also a violation of state law.

17 C. The state shall bear primary responsibility for the
18 enforcement of state shellfish sanitation laws against: 1) non-
19 Indians; 2) any Indian where the violation occurs outside of any
20 Indian reservation, Indian trust lands, and outside the usual and
21 accustomed fishing places of the tribe of which the violator is a
22 member; and 3) nonmember Indians within a tribe's reservation or
23 on any lands held in trust for the tribe or its members when,
24 under applicable law, such nonmembers are not subject to the
25 jurisdiction of the tribal court and jurisdiction lies with the
26 state.

27 D. It is the intent of the state and tribes that,
28 notwithstanding the existence of comparable laws of the State of

1 Washington, and unless provided to the contrary elsewhere in this
2 Agreement, violations of tribal shellfish sanitation laws by
3 members of tribes or by tribal licensees shall be prosecuted in
4 tribal courts.

5 E. If an enforcement officer of either the state or a tribe
6 finds a person subject to the primary enforcement responsibility
7 of the other entity, under Part VI, §B or §C, to be in violation
8 of the bag limits, growing area closures, or other shellfish
9 sanitation laws of the entity having primary responsibility, the
10 discovering officer shall contact a law enforcement officer of
11 the entity primarily responsible using common means of law
12 enforcement communication such as radio over common frequency,
13 telephone, or use of a dispatcher utilized by the party having
14 primary responsibility. The officer having primary
15 responsibility shall take such action regarding the offender and
16 any associated evidence or forfeitable property as he or she
17 deems appropriate, including arrest, citation, or requesting the
18 discovering officer if authorized under applicable law, to detain
19 or continue to detain the violator and to seize or retain
20 specified evidence or property pending the arrival of the officer
21 having primary responsibility. A state officer may hold or seize
22 any shellfish grown, harvested, transported, shipped, processed,
23 or sold by a treaty tribe member in violation of this Agreement.

24 F. If an officer having primary responsibility under this
25 Part VI cannot be contacted within a reasonable time (not less
26 than 30 minutes), the discovering officer will take the minimum
27 action within his or her authority which is needed to protect
28 officer safety and to prevent the loss or destruction of evidence

1 or of forfeitable property. Notwithstanding the previous
2 sentence, the discovering officer shall not detain an individual
3 longer than is allowed under the search and seizure law of the
4 jurisdiction having primary responsibility. The officer shall,
5 as soon as practicable, refer the matter to the enforcement
6 supervisor of the entity having primary responsibility for
7 prosecution under this section, together with a statement of
8 probable cause, any physical evidence or property held or seized
9 and not destroyed, and the custody of any persons held in
10 connection with the violation.

11 G. If a tribe does not have a regulatory prohibition
12 against an activity which is in violation of the Agreement and
13 led to a hold or seizure under §E. of this Part, the state
14 officer may take appropriate action with regard to the product as
15 provided by applicable state law.

16 H. The state and tribes shall maintain a proper chain of
17 custody of all evidence and proper receipts for any forfeitable
18 property.

19 I. The enforcement entity having primary jurisdiction shall
20 notify the enforcement supervisor of the discovering party, in a
21 timely manner, of any hearing or trial date which the discovering
22 officer must attend. The discovering entity shall make its
23 officers available for hearings and trial, and shall provide
24 reasonable cooperation in the prosecution.

25 J. Where any entity has commenced a civil, criminal, or
26 administrative enforcement action arising from a violation within
27 the primary jurisdiction of another entity, dismissal shall be
28 requested upon notice that the entity having primary jurisdiction

1 has commenced an action in its own jurisdiction against the same
2 offender and for the same incident.

3 K. Within a reasonable time after referral of a violation,
4 and at least semiannually, the entity having primary
5 responsibility shall, consistent with confidentiality
6 requirements, notify the referring entity of the status or
7 disposition of all referred cases, including whether and what
8 charges were filed, the amount of any fines, and the nature of
9 any other penalties, including permit suspension or revocation,
10 restrictions, or probation which were imposed.

11 L. If the entity with primary responsibility does not
12 initiate a prosecution within a reasonable time, not less than
13 ninety days, following referral, the referring entity, if
14 authorized by applicable law and with the agreement of the entity
15 having primary responsibility, may take such action under its
16 laws, consistent with this Agreement, as it deems proper.

17 M. All net proceeds from the sale of confiscated property
18 shall be delivered to the entity prosecuting the case, provided
19 that, if more than one entity initiates the prosecution, such
20 proceeds shall be delivered to the entity having primary
21 enforcement responsibility for the offense.

22 N. The enforcement supervisors of the state and tribes
23 shall meet as needed (at least annually for the first three years
24 following the effective date of this Agreement, and thereafter at
25 least every two years) to discuss matters related to
26 implementation of this Agreement, including the exchange of
27 information regarding violations, the training of officers, and
28 the planning of joint patrols or other joint operations.

1 O. In addition to the cooperative procedures set forth in
2 paragraphs (B) through (N) above, the state and tribes agree that
3 cross-deputization of their fisheries enforcement personnel is
4 desirable in order to augment their respective enforcement
5 capabilities. "Cross-deputization" means the issuance of special
6 commissions authorizing one entity's law enforcement officers to
7 issue citations, make custodial arrests, and otherwise act as
8 enforcement officers of the other entity, as specified in a
9 cross-deputization agreement. Each tribe agrees to deputize WDFW
10 enforcement officers to enforce tribal prohibitions on commercial
11 harvest from closed areas, tribal bag limits, and other tribal
12 shellfish sanitation laws adopted pursuant to Part II, §C above,
13 provided the following conditions are met:

14 1. The WDFW officer satisfies the minimum criteria (other
15 than tribal membership criteria, if any) required to be
16 commissioned as a fisheries enforcement officer of that
17 tribe; and

18 2. WDFW agrees to deputize fisheries enforcement officers
19 of that tribe to enforce state shellfish sanitation statutes
20 and regulations.

21 WDFW shall not require, as a condition precedent to
22 deputizing tribal officers, that those officers meet any more
23 stringent criteria than are required to be a commissioned WDFW
24 enforcement officer.

25 The state and tribes agree to use their best efforts to
26 develop, within eighteen months after the effective date of this
27 Agreement, a form of cross-deputization agreement that will
28 specify procedures and requirements for cross-deputization,
consistent with the terms of this Agreement, provided that tribal
officers, under such agreement, are required to meet the minimum

1 criteria required of commissioned WDFW officers and further
2 provided that such agreement addresses the liability concerns of
3 the state and tribes to their mutual satisfaction.

4 VII. NOTIFICATION

5 To comply with the various notice provisions of this
6 Agreement, each tribe that is a party to this Agreement shall
7 designate an individual and an alternate who shall serve as the
8 state's contact for purposes of notification. The state and FLDA
9 likewise shall each designate an individual and alternate who
10 shall serve as the tribes' contact for notification purposes.
11 Written notice to one or the other of the identified individuals
12 shall be construed as sufficient notice under this Agreement.
13 Facsimile transmission may be used, so long as it is followed by
14 delivery or mail of the original.

15 VIII. DISPUTE RESOLUTION

16 A. Matters reviewable

17 Except where an alternative dispute resolution mechanism is
18 expressly provided for in other sections of this Agreement,
19 including the Appendix attached hereto, this section shall govern
20 the resolution of all disputes arising from the implementation of
21 this Agreement. Any reference to dispute resolution in a
22 particular section of this Agreement shall not be construed to
23 limit the availability of dispute resolution as to other matters.

24 The parties recognize three kinds of disputes potentially
25 arising from the implementation of this Agreement: first, those
26 involving legal issues such as determinations of jurisdiction or
27 interpretation of state or tribal law or of this Agreement;
28 second, those involving the interpretation of NSSP Manual

1 compliance standards; third, those involving the administration
2 of shellfish sanitation programs and of this Agreement, both
3 through the development of policies and through the application
4 of regulatory standards in case specific situations. The parties
5 recognize that it may, in some cases, be difficult to
6 characterize such disputes as arise. The parties therefore
7 acknowledge and agree that, whenever a party initiates one of the
8 three dispute resolution mechanisms described hereunder, it shall
9 be the right of the responding party, at the threshold, to
10 contest the characterization of a dispute and to seek its
11 transfer to what the responding party considers the most
12 appropriate forum.

13 1. Any party to this Agreement may invoke the jurisdiction
14 of the federal court to resolve legal issues related to the
15 implementation of this Agreement, provided that the tribes will
16 not challenge in court the application of the terms of this
17 Agreement to them or their members as inconsistent with their
18 treaty rights.

19 2. The FDA and the ISSC have established a mechanism for
20 resolving ambiguities in the compliance standards set out in the
21 NSSP Manual of Operations, using the Interpretations process.
22 The state and tribes shall utilize this process to resolve any
23 disputes involving ambiguities in the compliance standards set
24 out in the NSSP Manual of Operations and the decision of the FDA
25 shall be binding on the parties.

26 3. The parties recognize a difference between preliminary
27 decisions involving the day-to-day administration of shellfish
28 sanitation programs by the state or the tribes and which

1 generally involve data collection and preliminary analysis, and
2 final decisions such as growing area classifications, which are
3 based on such data and preliminary analysis. Unless provided
4 otherwise in this or a subsequent agreement of the state and
5 tribes, the dispute resolution process described hereunder shall
6 be available with respect to decisions of the latter sort but not
7 of the former. The dispute resolution process described
8 hereunder shall also be available to review the propriety of
9 generally applicable policies or procedures employed or proposed
10 to be employed by the state or a tribe in the implementation of
11 this Agreement; the failure of the state or a tribe to provide
12 required notice to or to consult with another party; the failure
13 of the state to follow tribally-determined growing area
14 classification priority list; any decision of a tribe or the
15 state, clearly made in violation of a specific prohibition or
16 requirement of this Agreement; and any decision of a tribe or the
17 state that would result in irreparable harm to the party seeking
18 review. The dispute resolution process described hereunder shall
19 also be available to resolve license actions taken by the state,
20 as provided in this Agreement, and the decision maker shall have
21 the authority, in such actions, to deny, suspend, modify, or
22 revoke a license. A preliminary action not directly subject to
23 dispute resolution shall be reviewable as part of a decision,
24 based on such preliminary action, which is subject to dispute
25 resolution.

26 4. The FDA and an independent tribal SSCA having a dispute
27 involving satisfactory compliance with the NSSP Manual which has
28 a direct public health significance may submit the dispute for

1 resolution through the ISSC Unresolved Issue process, provided
2 that, after completion of that process or in lieu thereof, a
3 tribe may, at its option, request an informal hearing, under 21
4 CFR Part 16, subject to judicial review in accordance with the
5 federal Administrative Procedures Act.

6 **B. Dispute Resolution Committee**

7 The state and tribes shall each appoint one individual
8 having experience in public health and shellfish sanitation, to
9 form the Dispute Resolution Committee. At the time of submission
10 of a matter to dispute resolution, the state and the tribes shall
11 each identify a qualified member. Upon agreement of the state
12 and the tribes, either may appoint additional qualified members
13 of the Committee to serve in a particular case.

14 The decisions of the Committee shall be by consensus and
15 binding upon the state and tribes. The state or affected tribe
16 may seek federal court review of any legal issues that remain
17 unresolved.

18 In the event consensus is not reached, the state and/or
19 affected tribe(s) may request FDA, within fifteen days after
20 conclusion of the committee process, to provide technical
21 assistance to resolve the matter. In disputes regarding
22 satisfactory compliance with the NSSP Manual which have direct
23 public health significance, FDA will provide such technical
24 assistance to the Dispute Resolution Committee. The technical
25 assistance shall consist of expertise in public health and
26 shellfish sanitation and the application and implementation of
27 the requirements of either Part I or Part II of the NSSP Manual,
28 or both Parts, depending on which Part or Parts is at issue. The

1 technical assistance will be made available as soon as possible.
2 If within ten days after FDA receives the request, FDA has not
3 provided such technical assistance, any party to the dispute
4 resolution proceeding may invoke the master expert procedure in
5 §C. below. Any party to the dispute may also invoke the master
6 expert procedure when consensus has not been reached either prior
7 to or following the provision of technical assistance by FDA.

8 **C. Appointment of Master Expert**

9 If the members of the Dispute Resolution Committee are
10 unable to resolve a dispute by consensus, or if the state or any
11 affected tribe is dissatisfied with the decision of the
12 Committee, then such entity may, within fifteen days after the
13 conclusion of the Committee process, give notice to FDA of its
14 intent to utilize a master expert. FDA shall maintain a list of
15 persons eligible to serve as a master expert, which persons shall
16 be considered by FDA to have expertise in public health and
17 shellfish sanitation and the application and implementation of
18 the requirements of either Part I or Part II of the NSSP Manual,
19 or of both Parts, depending on which Part or Parts are at issue
20 in the dispute. In compiling the list, FDA shall seek
21 suggestions from the tribes and the state, which may include FDA
22 employees.

23 The state and affected tribe(s) shall select by agreement a
24 person from the list to act as master expert in the dispute. An
25 FDA employee will not be used as a master expert without
26 agreement of FDA. FDA will select a person from the list, to act
27 as a master expert if the parties cannot agree. A non-FDA master
28 expert shall be reasonably compensated by the non-prevailing

1 party, provided that if the master expert's decision is reverse
2 the party prevailing on appeal shall be reimbursed by the
3 opposing party for compensation paid the master expert. The
4 master expert shall be authorized to make a decision binding on
5 the state and affected tribes. FDA will receive notice of the
6 decision. FDA will have thirty days to review the decision
7 before it becomes final and shall make, in writing within the
8 thirty-day period, any objection it has to the decision. The
9 master expert will be responsible for keeping minutes of any
10 dispute resolution proceeding in which he or she is involved.

11 Any party aggrieved by the master expert's decision or
12 aggrieved by FDA's objection to the master expert's decision,
13 shall have the right to appeal, within thirty days, either
14 determination to the federal court, or as otherwise provided by
15 law.

16 D. Review Procedure

17 Disputes shall be submitted for review by a brief, written
18 statement setting out the points of disagreement and the
19 submitting party's position and reasons. Within seven week days
20 of delivering the statement to the decision maker(s) and to other
21 involved parties, any other involved party may submit a written
22 response, briefly stating its position and the reasons. The
23 parties shall be provided an opportunity for an oral or
24 telephonic presentation and submission of supporting documents.
25 A written decision shall be issued within 30 days after the
26 submission was received, provided that a decision may be
27 postponed for a reasonable period of time to obtain additional
28 information that is likely to aid in resolving the dispute. In

1 an emergency, the decision may be delivered orally, with a
2 written memorandum of decision issued shortly thereafter. In the
3 event a matter involving an emergency has been submitted, the
4 matter shall be determined as expeditiously as possible but no
5 later than 3 business days after receipt by the body issuing the
6 decision.

7 The Committee or the master expert may adopt such additional
8 review procedures as they deem appropriate, so long as adopted in
9 consultation with the state and tribes and so long as consistent
10 with the provisions of this Agreement. Within 180 days following
11 Court approval of this Agreement, the Dispute Resolution
12 Committee shall prepare and disseminate to the state and tribes
13 for their comment a document setting forth the review procedures
14 contained in this Agreement and any additional, generally
15 applicable procedures adopted.

16 In the alternative to any other means of dispute resolution
17 authorized by this Agreement, and absent objection by any
18 interested party, a party may invoke the processes of the ISSC to
19 resolve the issue.

20 **IX. CONSISTENCY OF AGREEMENT WITH NATIONAL SHELLFISH SANITATION**
21 **PROGRAM/ANTI-DISCRIMINATION PROVISION**

22 In agreeing to this settlement, the United States, through
23 the Federal Food and Drug Administration, confirms that the
24 cooperative, intergovernmental shellfish sanitation programs
25 provided for, and the other divisions of responsibility and
26 authority contained herein, do not conflict with the National
27 Shellfish Sanitation Program or current provisions of federal law
28 applicable to shellfish sanitation. Compliance with this

1 | Agreement will not jeopardize FDA certification of the state or
2 | tribal programs or be the cause for any federal punitive action.
3 | The FDA specifically agrees not to sanction the state for any
4 | difference in the way the state treats tribal and nontribal
5 | shellfish operations, so long as such treatment is consistent
6 | with this Agreement. The FDA further agrees to counsel member
7 | states of the Interstate Shellfish Sanitation Conference (ISSC)
8 | against imposing any barrier to interstate commerce of shellfish
9 | harvested in Washington State, whether by tribes or others,
10 | because of this Agreement.

11 | **X. AMENDMENTS**

12 | The parties recognize that individual tribes, groups of
13 | affiliated tribes, the tribes collectively, the state or the FDA
14 | may wish to amend this Agreement or to reach new agreements
15 | governing shellfish sanitation and, to that end, any of these
16 | entities or groups may propose an amendment for consideration by
17 | the parties. Unless the parties agree otherwise, or a compelling
18 | reason exists for more frequent amendment, proposed amendments
19 | shall be considered at an annual meeting to review the parties'
20 | progress in implementation.

21 | Until an amendment or a new agreement is adopted by the
22 | parties, and court approval is obtained where required, this
23 | Agreement shall be binding.
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28 |

1 XI. INTENT TO BIND POLITICAL SUBDIVISIONS, ETC.

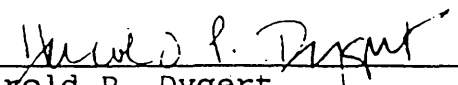
2 It is the desire of the parties to this Agreement that it
3 shall bind all agencies, officers, boards, commissions, and
4 political subdivisions of the parties to the greatest extent
5 allowed by law. It is the position of the state, however, that
6 it may lack authority to bind all its political subdivisions and,
7 in particular, local law enforcement and prosecutors. The state
8 shall provide a summary and a copy of this Agreement to county
9 prosecutors, county sheriffs, and local health jurisdictions in
10 waterfront counties and make every reasonable effort to ensure
11 that they will conform their actions to the agreed upon scope of
12 state authority. Nothing in this Agreement shall be deemed to
13 bar a tribe or its members from challenging local enforcement
14 based on treaty right violations as well as other grounds, if it
15 exceeds the state's authority under this Agreement.

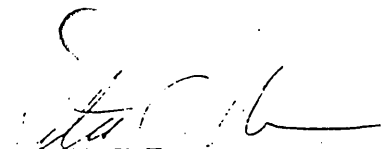
16 XII. JUDICIAL APPROVAL

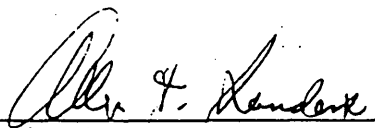
17 This Agreement shall become effective upon signature of the
18 authorized representatives of the parties and approval of the
19 Court in United States v. Washington, Subproceeding 89-3. This
20 Agreement is not intended and shall not be construed as the
21 admission of any party, as findings of fact, conclusions of law,
22 or the interpretation or construction of the law applicable to
23 this case. No party shall be considered to have prevailed with
24 respect to resolution of this issue or shall be entitled to its
25 costs or fees.


26
27 DATED this _____ day of April, 1994.
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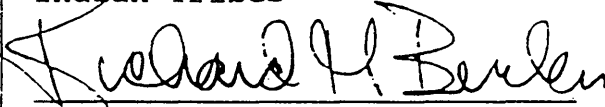
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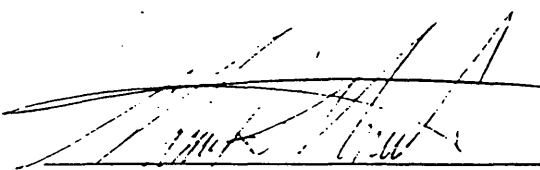

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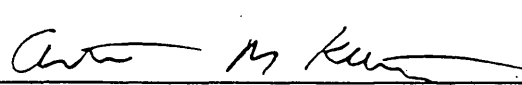

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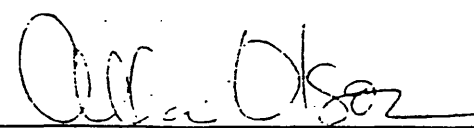

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APPENDIX

Group I

With regard to each of the following activities, the state and tribes will adhere to the protocols set forth in the designated attachments to this Appendix, as agreed mechanisms for implementing the Agreement and the NSSP Manual:

- a). Harvest from closed areas for bait or other use which does not involve human consumption, Attachment B, (Bait and non-consumptive use Protocol);
- b) Short-term relay, that is, relay in which shellfish are held in approved waters for a period of 60 days or less, Attachment C, (Short-term Relay Protocol);
- c) Location of sanitary lines at the boundaries of areas having different growing area classifications pursuant to Part I of the NSSP Manual, Attachment D, (Sanitary Line Protocol);
- d) Establishment of prohibited areas surrounding marinas and point source discharges of sewage or other contaminants, Attachment E, (Point Source and Marina Closure Protocol);
- e) Procedures and requirements for approval of state or tribal agents as "standards" for the implementation of Part II of the NSSP Manual, Attachment F; and
- f) Minimum qualifications for personnel conducting shoreline surveys and water quality studies, Attachment G.

Group 2

For the following activities, there is a need to jointly develop protocols which will insure compliance with the NSSP:

- a) Long-term relay, that is, relay in which shellfish are held in approved waters for a period of more than 60 days (Long-Term Relay Protocol);
- b) Harvest from closed areas for seed, (Seed Harvest Protocol);
- c) Depuration; and
- d) Data collection and analysis for purposes of growing area classification.

The state and tribes, through the Technical Team established below, will make their best efforts to develop the protocols in this category within two years following their execution of this Agreement and its approval by the Court. The Technical Team shall meet at least once each quarter following approval of this Agreement, according to a schedule to be developed by the Team. If the Team fails to agree on a draft protocol within two years, any party who has participated in the Team may invoke the dispute resolution procedures of this Agreement.

Group 3

In addition to those matters identified in groups 1 and 2 above, additional matters may come to the attention of the parties, as to which there may be a need to develop policies or protocols, in order to implement and comply with the NSSP Manual, consistent with the principles of this Agreement. The parties also recognize that retail food service regulation for public health protection is another matter which may need to be addressed as to off reservation treaty shellfish activities. If in the future, the NSSP Manual is amended to provide for additional standardized processes other than growing area classification, the parties will develop protocols to provide the tribes an opportunity to obtain standardization with respect to those processes. At such time as the parties may agree, but at least every two years, policy representatives designated by each party shall meet and identify any such matters, which shall be referred to the Technical Team for action. The first such policy meeting shall occur no later than eighteen months after the effective date of this Agreement. Additional such matters may be referred to the Technical Team at any time by agreement of the state and one or more tribes.

Technical Team

Each tribe or group of tribes will identify a technical representative, and the state will identify one or more technical representatives, who shall constitute the Technical team. The purpose of the team is to cooperatively assemble and evaluate information regarding shellfish sanitation, and to develop proposed policies and protocols, based on sound scientific and statistical methods, to be presented to policy representatives of the parties for approval.

The Team may in its discretion appoint working groups, coordinators, or other officers, and may adopt a work plan and any procedures it deems useful. Decisions of the Team shall, where possible, be made by consensus and within 30 days after a matter is presented for consideration. Where consensus cannot be achieved, the Team shall present majority and minority reports to the parties' policy representatives for consideration. Issues

which cannot be resolved by agreement of the parties' policy representatives shall be referred to dispute resolution under this Agreement.

Draft protocols and guidance based on scientific method, developed by the Team, shall become effective as to any tribe upon approval by such representatives of that tribe and of the Washington State Department of Health.

SHELLSTOCK HARVEST FOR BAIT

PROPOSED REQUIREMENTS

- Any person desiring to harvest molluscan shellfish for use as bait must first obtain a permit from the state or tribal regulatory authority.
- Bait harvest shall only be allowed in designated areas at specified times.
- Bait shellstock shall be dyed with an approved dye, such as FD&C #1 Blue, before being transferred from the harvest area, unless the shellstock remains under direct regulatory supervision until dyed. Such shellstock shall be labeled "NOT FOR HUMAN CONSUMPTION-BAIT USE ONLY." Bait shellstock shall be stored in a location physically separated from product intended for human consumption.
- Bait shellstock must be completely immersed in dye to impart a visible color to the shellstock.
- All bait harvesting activities and dying of shellstock shall be done under immediate regulatory supervision.
- Complete records of all bait harvesting activities shall be kept, including harvest location, date, quantity, species, and distribution of product.
- Bait shellstock found in violation of these requirements shall be subject to immediate seizure and destruction.

SHORT-TERM RELAYING PROTOCOL
AND GENERAL REQUIREMENTS

The practice of relaying involves the harvest of shellfish from polluted waters and, therefore, strict controls over the harvest, transport, laying down, surveillance, and reharvest are necessary to prevent contaminated shellfish from entering commercial channels and posing the threat of shellfish-related disease outbreaks. In addition, significant resources are required to adequately monitor relay activities.

Definitions

Approved Area: The classification of a shellfish growing area which has been approved by the state shellfish control agency (SSCA) for growing or harvesting shellfish for direct marketing. The classification of an approved area is determined through a sanitary survey conducted by the SSCA in accordance with Section C of Part 1 of the National Shellfish Sanitation Program Manual of Operations. An approved shellfish growing area may be temporarily made a closed area when a public health emergency resulting from, for instance, a hurricane or flooding, is declared.

Commingling: The act of combining different lots of shellfish.

Container: A container such as a bag, tray or float used to hold shellfish during the purification process.

Container Relaying: The transfer of shellfish from restricted areas to approved or conditionally approved areas for natural biological cleansing in a container using the ambient environment as a treatment system.

Department: The Washington Department of Health, Office of Shellfish Programs.

Harvester: A person who takes shellfish by any means from a growing area. A harvester may be a person, firm or corporation ultimately responsible for harvest operations.

Long-term Relay: A relay operation that utilizes purification times of more than 60 days.

Lot of Shellfish: A collection of bulk shellstock or containers of shellstock of no more than one day's harvest from a single defined growing area harvested by one or more harvesters.

Attachment C

National Shellfish Sanitation Program (NSSP): The cooperative program for the certification of interstate shellfish shippers as described in the National Shellfish Sanitation Program Manual of Operations, Parts I and II. Foreign countries may participate by having an effective agreement with the FDA.

Prohibited Area: State waters that have been classified by the state shellfish control agency as prohibited for the harvesting of shellfish for any purpose except depletion. A prohibited shellfish growing area is a closed area for the harvesting of shellfish at all times.

Reharvester: A person, firm or corporation who reharvests the purified shellfish after relaying. The Harvester/Reharvester may be the same or different entities.

Relaying: The transfer of shellfish from restricted areas to approved areas for natural biological cleansing using the ambient environment as a treatment system.

Restricted Area: State waters that have been classified by the state shellfish control agency as an area from which shellfish may be harvested only if permitted and subjected to a suitable and effective purification process.

Short-term Relay: A relay operation that utilizes purification times of 60 days or less.

State Shellfish Control Agency: The state agency or agencies having legal authority to classify shellfish growing areas and issue permits for the interstate shipment of shellfish in accordance with the provisions of the NSSP Manual of Operations, Parts I and II.

Responsibilities of Parties		
Dept. of Health *	Harvester	Reharvester
Classification of the growing area.	Complete and submit application.	Complete and submit application.
Review and approve the application by the harvester.	Submit Harvest Schedules.	Identify Relay Site.
Review and approve the application by the reharvester.	Identify harvest sites.	Maintain shellfish identification during relay.
Review and approve harvest and relay sites.	Properly label harvested shellfish.	Maintain records of placement and reharvest.
Coordinate harvest surveillance.	Maintain harvest records.	Record environmental measurements such as water temperature as required by DOH.
Assist in and approve verification studies, including design.	Submit samples as required.	Sample collection as required by DOH.
Collect and analyze samples.	Conduct harvest surveillance.	Relay site surveillance and security.
Interpret data.		
Conduct water quality monitoring.		
Review Records.		
Facilitate regulation enforcement.		

* A treaty tribe may perform certain of these functions as provided in this agreement.

REQUIREMENTS FOR RELAYING SHELLFISH
Administration and Permits

The harvester/reharvester must complete an application for a Shellfish Operation License and Certificate of Approval.

The harvester/reharvester must complete an Application for Relaying Shellfish. The application must be approved by the Department of Health. The relay permit shall run concurrently with the certification period (certificates expire on September 30). Copies of the relay application will be forwarded to other state agencies having an interest, such as the Departments of Fisheries, Natural Resources and Parks.

The Department shall respond to relay applications within 30 days of receipt.

A harvest schedule, which includes specific dates and times of harvest, shall be submitted with the application. The Department must be notified of any changes to the schedule.

The method of deposition of laying down of shellfish at the relay site must be outlined and approved by the Department.

It should be recognized that conditions in the marine environment during certain times of the year may render the natural purification process and subsequent bacterial reductions ineffective. Low water temperature and salinities are the primary factors contributing to this effect. Therefore, the Department reserves the right to approve or deny relay permits on a seasonal basis.

Approval of the relay operation may be subject to cancellation due to failure to comply with these requirements or as a result of adverse conditions at either the initial harvest site or the relay area.

Monitoring and Standards

The initial harvest site must be classified as Restricted or Conditionally Restricted. The relay site must be classified as Approved or Conditionally Approved.

A verification study shall be performed to show that the relay is effective in reducing bacteriological contamination (see Verification Study Procedures and Monitoring Requirements for Commercial Relay Operations).

The relay area must be at least 25 feet from adjacent, approved shellfish and may require greater separation as determined by the Department.

Shellfish samples from both the initial harvest site and the

relay area shall be maintained and furnished to the Department as required.

Surveillance: Short Term

A detailed surveillance plan must be submitted by the harvester/reharvester. It must specify surveillance activities to be performed by the harvester/reharvester to insure the security of relayed product for the duration of the relay. The surveillance plan will be evaluated and a determination will be made as to what Departmental resources will be expended on surveillance activities. The surveillance plan must be approved by the Department.

The initial harvest site must be well defined. It shall be the responsibility of the harvester to identify the site with appropriate markers as required by the Department.

The relay area must be well defined. It shall be the responsibility of the reharvester to identify the relay area with appropriate markers as required by the Department.

Site visits may be made by Department staff to both the initial harvest site and relay area.

The relay area must lend itself to effective surveillance.

The harvester shall be responsible for effective supervision and management of the harvest. Supervision shall include methods to insure:

1. Product is removed only from the designated harvest site.
2. Product is transferred exclusively to the approved relay site.
3. Records of harvesters and quantities harvested are maintained.

The reharvester shall be responsible for the effective supervision and management of the transport, laying down of the contaminated shellfish, relay site surveillance and security, and the reharvest of the purified shellfish.

The method and route from the initial harvest site to the relay site must be outlined and approved by the Department.

For container relay, harvest tags stating "For Relay Only" in indelible ink must be attached to each container of shellfish to be relayed.

Records

All lots of relayed shellfish shall be identified by waterproof tags or labels throughout the relay process, including a specific number for each lot. However, bulk or ground relay can be marked with poles, pipes, or other suitable means.

Accurate, written records shall be maintained and submitted on a monthly basis or more frequently as determined by the Department. Such records must be available for inspection by the Department at any time.

Relaying records shall consist of initial harvest area location, initial harvest dates and quantities harvested, dates of placement in the relay area and quantities placed, relay area location, and dates of removal from the relay area and quantities removed.

VERIFICATION STUDY PROCEDURES
AND MONITORING REQUIREMENTS
FOR SHORT TERM COMMERCIAL RELAY OPERATIONS

A verification study is required prior to approval of relay to determine if the process is effective in reducing bacteriological contaminants. This document sets forth the procedures to be used to establish relay effectiveness, as well as the monitoring requirements necessary for approved relays. Prior to initiating a verification study, the proponent must submit a completed relay application for review by the affected tribe and the Department of Health. Approval by the Department of Health of that application is required before the study is initiated.

1. Verification study procedures.

To determine relay effectiveness, at least two verification studies shall be conducted. Verification studies shall not run concurrently, but may be initiated one week apart. A decision as to the maximum length of time the study will be run must be made prior to initiating the test relay. Shellfish test lots that do not meet the required bacteriological endpoint will be destroyed or returned to the original harvest area at the conclusion of the verification study.

Verification studies shall be conducted as follows:

- a. Sufficient shellfish shall be harvested from the restricted area to approximate commercial relay conditions. The same relay process (bags, trays, floats, etc.) shall be used in the study as is intended for the commercial operation.
- b. Department or tribal staff will collect at least five representative 0-day samples from the restricted area for bacteriological analysis.
- c. Department or tribal staff will collect at least five samples from the relayed product after seven days and five samples after fourteen days. An additional five samples will be collected at the endpoint of the relay if a prior decision has been made to proceed with a relay longer than fourteen days. Succeeding samples may be taken at a frequency determined by the Department and the tribes.

2. Evaluation of relay effectiveness. The endpoint relay samples shall be used to establish a geometric mean for each verification study. The fecal coliform geometric mean of the endpoint relay samples shall not exceed 75/100 grams and no values shall be greater than 230 fecal coliforms/100 grams.

Both verification study lots must meet the required endpoint criteria for the relay to be approved. A decision as to whether to proceed with further verification studies in the event that the initial test relays do not sufficiently reduce contaminants shall require a comprehensive review of the proposed relay by the proponent, the Department and the tribes. All commercial relays will be required to run at least fourteen days unless sufficient data has been collected to show that a shorter time period will consistently reduce bacteriological contaminants to the required level. In no case will the required time period be reduced below fourteen days until the relay has successfully operated for at least six months.

3. Monitoring of approved commercial relays. In addition to sampling of relayed shellfish, additional water quality monitoring must be conducted at the relay site. Monthly water samples shall be collected in the relay area (at least three stations) to assure that approved area criteria are being met.

The first four lots of relayed shellfish shall be sampled at the relay endpoint (at least five samples per lot). Further monitoring will be conducted as determined by the Department and the tribes. If relay times of less than fourteen days are approved, each lot shall be sampled before relay and at the endpoint, until sufficient data has been collected to justify decreasing sampling frequency.

The permit to relay may be subject to cancellation if any test lot of relayed shellfish fails to meet the established endpoint criteria. A retest shall be conducted immediately if product exceeds endpoint standards. If the endpoint is exceeded in lot follow-up, an investigation will be conducted, after which a determination will be made if the relay should continue.

PROCEDURES FOR ESTABLISHING SANITARY LINES
IN SHELLFISH GROWING AREAS

Sanitary Lines are established in shellfish growing areas to define the location of the various harvest classifications recognized under the NSSP Manual. Factors considered in establishing such lines include the following:

- Prohibited areas around point source outfalls are established in accordance with criteria set forth in Part I of the NSSP Manual (see Attachment E.1-3 for details).
- Prohibited areas around marinas are established in accordance with criteria set forth in Part I of the NSSP Manual (see Attachment E.4-5 for details).
- All sampling stations within areas classified as approved must meet the coliform standard based on an annual review of data. Location of the sanitary line defining approved areas is also based on sanitary survey information which describes the location of actual and potential pollution sources and their impact on the growing area.
- Sanitary lines are located such that they are easily identifiable (easily visible land marks, etc.)
- The location of shellfish resources is always taken into account when establishing sanitary lines and sampling stations to maximize resource availability.
- Sanitary lines defining conditionally approved areas are based on detailed studies showing the extent of potential impact of a particular point or nonpoint source(s) on the growing area. The sanitary line is placed such that all sampling stations that meet the coliform standard when the area is open to harvest are included in the conditionally approved area.
- In addition to microbiological data from marine sampling stations, consideration is given to hydrographic characteristics of the area in establishing sanitary lines.

PROCEDURES FOR ESTABLISHING SANITARY

LINES AROUND WASTEWATER OUTFALLS

The Shellfish Program of the Department of Health establishes Prohibited Areas around wastewater outfalls in accordance with the policy outlined in the NSSP Manual. The sections of the NSSP Manual of Operations Part I which describe the factors to be taken into consideration in the establishment of sanitary lines which define the appropriate Prohibited Area include Sections: C.2 (Classification of Growing Areas); C.3 (Approved Areas); C.4 (Conditionally Approved Areas); and C.7 (Prohibited Areas). It should be emphasized that a Prohibited Area is required adjacent to any wastewater outfall of public health significance.

As stated in recent revisions of the Manual, the effectiveness of wastewater treatment processes must be considered in establishing the appropriate classification of nearby shellfish production areas. In particular, the wastewater treatment must be evaluated in terms of the minimum treatment which can be expected with the possibility of malfunctioning, overloading, or poor operations. These evaluations are conducted by the DOH Shellfish Program on a site-specific basis, through technical "reliability" evaluations of the wastewater treatment facilities.

Several factors are taken into consideration by the DOH Shellfish Program in establishing the location of the appropriate sanitary lines for the Prohibited Area (and Conditionally Approved Area if applicable). The principle factors which involve operations in the treatment plant include:

- effluent volume at high and/or low hydraulic loading;
- bacteriological and physical quality of the effluent, and
- identification of factors which can cause plant failure.

In addition, the major hydrographic factors in the receiving waters which need to be taken into consideration include:

- current velocity;
- receiving area geometry;
- direction of travel and stratification;
- location of discharge;
- tidal characteristics;
- orientation and configuration of the outfall pipe and diffuser, and
- physical characteristics of the receiving water.

These factors which are listed above are usually used as input parameters in the CORMIX (Cornell Mixing Zone) modelling program, an Expert System approved by EPA for far-field modelling of

effluent dispersion from outfalls. More infrequently, field studies using dye and/or drogues are utilized by DOH in the establishment of sanitary lines for wastewater treatment plants. The selection of the most appropriate approach to be used is often a site-specific consideration, based on Best Professional Judgment. As stated in the NSSP Manual, the SSCA shall choose the most appropriate method in which to apply the factors previously described. These methods can include hydrographic field and/or computer models pertinent to the discharge and receiving water application. In addition, a reliability evaluation of the wastewater treatment plant should be conducted to ascertain the principle factors which involve operations at the plant and which affect the quality and quantity of its effluent.

Generally, the DOH Shellfish Program assumes that the bacteriological quality of the effluent is approximated under theoretical upset conditions at the wastewater treatment plant by that of the treated-but-not-disinfected effluent. This is a conservative assumption applicable to most plants evaluated by DOH, and has been previously suggested by FDA in outfall studies. It should be emphasized that the DOH Shellfish Program generally assumes adverse conditions at the plant and in the receiving waters, rather than worst-case conditions, in assuming a theoretical condition of malfunction or poor operation at the treatment plant. This approach is similar to that used by DOE in establishing dilution zones protective of aquatic life.

Hydrographic and receiving water information is usually obtained by DOH from a variety of sources. These sources include DOE-mandated mixing studies; ambient monitoring water quality data; as-built plans and field studies from the files of DOE, universities, the permittee, or consultants, and information collected by DOH and FDA. Adverse receiving water conditions are assumed in the CORMIX model iterations.

The sanitary line for a wastewater discharge is established at the location where the water quality is projected to meet the shellfish water quality standard of 14 fecal coliforms/100 ml. In certain situations, depending upon the location of the nearest shellfish resource, no Conditionally Approved Area may be needed to meet this criteria. In such situations, the water quality standard is required to be met at the edge of the Prohibited Area.

In other situations, a Conditionally Approved Area is required adjacent to the Prohibited Area. In these situations, the Prohibited Area serves to provide a transport or transit time, for notification of any plant upset to DOH. DOH is then responsible for notifying any commercial shellfish producers in

the affected Conditionally Approved Area, and to temporarily close down harvesting of shellfish in the Conditionally Approved Area. The cooperation of the treatment plant operators and all certified growers in the Conditionally Approved area with DOH is required for this classification.

PROCEDURES FOR ESTABLISHING SANITARY

LINES AROUND MARINAS

The shellfish closure zones around marinas will be established in accordance with the policy outlined in the current NSSP Manual. As currently stated in the Manual of Operations Part 1, Section C.9:

Determining the impact to adjacent waters will be based upon a dilution analysis for the marina which incorporates the following assumptions:

- i. an occupancy rate of the marina;
- ii. an assumed rate of boats which will discharge untreated water;
- iii. an occupancy rate of two (2) persons per boat;
- iv. a rate of discharge of 2×10^9 fecal coliforms per person per day;
- v. wastes are completely mixed in and around the marina;
- vi. closure is based upon a theoretical calculated fecal coliform of 14 MPN per 100 ml; and
- vii. closure is based on the volume of water in the marina.

These assumptions are incorporated into the shellfish closure zone analyses conducted for marinas by the DOH Shellfish Program. To facilitate and promote the application of these assumptions for specific marina evaluations, the DOH Shellfish Program uses the Virginia Institute of Marine Sciences (VIMS) computer model, which was obtained from FDA staff. The VIMS model incorporates the specific assumptions listed in the NSSP Manual in Section C.9.

The occupancy rate of a marina is deemed to be the actual (rather than potential) occupancy of the marina during high usage periods, unless a boat count is unavailable. The assumed rate of boat discharge generally applied in marina evaluations is: 50% for recreational craft in marinas without boat waste pumpouts; 30% for recreational craft in marinas that have boat waste pumpouts, and 10% for commercial boats or boats that have long-term moorage but are infrequently used or occupied. However, as noted in the NSSP Manual, site-specific considerations using Best Professional Judgement can and should be used by the SSCA with respect to sanitary significance relative to actual or potential contamination.

The shellfish closure zone for a marina may be seasonal in nature, based upon the high-use season evidenced at the marina.

For example, the high use season may be during fair-weather months of the year for recreational boats, or during commercial seasons for commercial craft. The sanitary line for the shellfish closure zone is established at the location where the model indicates that the water quality meets the standard of 14 fecal coliforms/100 ml.

MINIMUM QUALIFICATIONS
FOR
STANDARDIZED SHELLFISH INSPECTORS

STANDARDIZED INSPECTORS MUST HAVE A BACKGROUND IN PUBLIC HEALTH THAT INCLUDES EXPERIENCE IN INSPECTION ACTIVITIES AND A GENERAL KNOWLEDGE OF MICROBIOLOGY AS IT RELATES TO FOOD SERVICE SANITATION.

GENERAL REQUIREMENTS:

A Bachelor's degree in public health, environmental health or closely allied field and 2 years experience in a public health or environmental health position, including at least one year experience in food service inspection.

Specific training by the Food and Drug Administration and certification as a Standardized Shellfish Inspector is also required. This process includes classroom type instruction for a 4 to 5 day period and joint field inspection activities that may require several months to complete. Field verification inspections and other FDA required training is periodically necessary in order to maintain "standard" status.

TYPICAL DUTIES:

Plans, organizes, and directs the shellfish dealer inspection program. Conducts inspections and determines compliance with national standards and state or tribal regulations as appropriate. Initiates enforcement action as needed. Provides technical review of plans for new construction or remodeling of facilities. Serves as a consultant to shellfish dealers on matters relating to plant sanitation and handling of shellfish. Provides liaison and coordination with FDA, tribal, state and local agencies.

MINIMUM QUALIFICATIONS FOR CONDUCTING
WATER QUALITY STUDIES

WATER QUALITY STUDIES ARE A KEY COMPONENT OF GROWING AREA CLASSIFICATION THAT REQUIRE AN UNDERSTANDING OF INDICATOR ORGANISM BEHAVIOR IN THE MARINE ENVIRONMENT. PERSONS INVOLVED IN STUDIES MUST HAVE A WORKING KNOWLEDGE OF SAMPLING PROGRAM DESIGN, HYDROGRAPHICS, MARINE MICROBIOLOGY, AND THE FATE OF POLLUTANTS IN THE MARINE ENVIRONMENT.

PERSONNEL REQUIREMENTS FOR WATER QUALITY STUDIES:

WATER QUALITY LEAD WORKER: A Bachelor's degree in environmental or physical science, natural science, environmental planning, or other closely allied field and 2 year's experience in environmental monitoring, environmental health or environmental planning. Specific training in water quality monitoring design, sampling procedures, and operation of watercraft is also required.

TYPICAL DUTIES: Plans, organizes and conducts water quality studies in shellfish growing areas. Establishes sampling stations, identifies growing area boundaries, and collects water samples and other environmental data. Organizes data and prepares reports of findings. Trains lower level staff in proper sampling technique, equipment operation, and boating safety procedures.

WATER QUALITY ASSISTANT: Previous experience as an environmental technician or field work related to one of the natural sciences and specific training in water sampling techniques and watercraft operation.

TYPICAL DUTIES: Assists the lead worker in conducting water quality studies in shellfish growing areas. Collects samples and environmental data and records information. Operates watercraft and other sampling equipment.

MINIMUM QUALIFICATIONS FOR CONDUCTING
SHORELINE SURVEYS

SHORELINE SURVEYS ARE A KEY COMPONENT OF GROWING AREA CLASSIFICATION THAT REQUIRE A THOROUGH KNOWLEDGE OF NONPOINT POLLUTION AND ITS IMPACT ON MARINE WATERS. PERSONS INVOLVED IN CONDUCTING THESE SURVEYS MUST HAVE A PUBLIC HEALTH BACKGROUND INCLUDING EXPERIENCE IN ENVIRONMENTAL HEALTH OR ASSESSMENT, AND A GOOD UNDERSTANDING OF ON-SITE WASTE DISPOSAL, POLLUTION TRANSPORT MECHANISMS, AND BASIC MICROBIOLOGY.

PERSONNEL REQUIREMENTS FOR SHORELINE SURVEYS:

SHORELINE SURVEY LEAD WORKER: A Bachelor's degree in public health, environmental health or allied science and 4 years experience in a public health or environmental health position, including at least 2 years of field experience evaluating nonpoint water pollution sources and 1 year evaluating or designing on-site sewage systems.

TYPICAL DUTIES: Plans, organizes and conducts the shoreline survey component of sanitary surveys in shellfish growing areas. Trains and directs lower level staff in conducting surveys. Evaluates completed survey documents and develops final report recommendations. Coordinates program activities with state, federal, tribal and local agencies. Provides technical support and consultation on nonpoint pollution and shellfish sanitation.

SHORELINE SURVEY ASSISTANT: A Bachelor's degree in environmental or physical science, natural science, environmental planning, or other closely allied field and one year of experience in environmental analysis, environmental health, or environmental planning. Specific training or experience in evaluating nonpoint water pollution sources and on-site systems is also required.

TYPICAL DUTIES: Assists the lead worker in conducting shoreline surveys of shellfish growing areas. Assesses sources of point and nonpoint pollution, prepares reports and maps of findings and assists in conducting special studies as required. Collects environmental samples as needed.

**EXAMPLES OF EFFECTIVE TRIBAL PROGRAMS TO PREVENT
SALE OF CEREMONIAL AND SUBSISTENCE HARVEST**

The following procedures are agreed to be effective tribal means of preventing the sale of clams, oysters, mussels and scallops (hereinafter "shellfish") taken in tribal ceremonial and subsistence (C&S) fisheries.

I. EXAMPLE ONE

1. All areas fished by the tribe shall be closed to all harvest of shellfish, unless opened by tribal regulation.

2. Each regulation opening an area of tideland shall state the dates and times of both opening and closure, and the species to be available for harvest. Each such regulation shall also identify the harvest area as precisely as practicable, for example, by use of a unique six digit Beach Identification Number (BIDN) assigned by agreement of the tribe and the State of Washington. The BIDN or other harvest area identification shall identify a relatively small area sharing a common growing area classification and common water quality conditions.

3. The tribe shall maintain a toll-free phone number with a recorded message regarding current and upcoming openings and closures, or shall maintain another effective method of providing up to date opening and closure information to harvesters.

4. One or more tribal personnel ("monitor(s)") shall be present at the growing area throughout every commercial opening, but shall not engage in harvesting. No product shall be allowed to leave the growing area during a commercial opening without inspection by a tribal harvest monitor, who shall prepare a contemporaneous record showing the name of the tribe and a unique identifier of the tribal harvester; the BIDN or other unique growing area identification; the species and estimated quantity of harvest; and the date of harvest. The tribe shall maintain all such records in its custody.

5. To facilitate the detection of sale of shellfish taken in a C & S fishery, the tribe shall require that, upon sale of any shellfish, a record of the transaction shall be completed which includes the shellstock shipper license number of the tribe, tribal organization, or tribal member engaging in the harvest; the BIDN or other unique growing area identification number; the species and quantity sold; and the dates of harvest and sale. Where harvest is by a person who does not personally have a shellstock shippers license, the record shall also show the unique identifier of the harvester. A copy of the transaction record shall be distributed to the tribe as soon as possible.

6. Tribal fisheries enforcement officers patrol growing areas subject to tribal jurisdiction, conduct routine, scheduled patrols of areas that are open for any type of shellfish harvest, and investigate reported or suspected violations.

7. Tribal law specifies that no more than the following quantities of shellfish may be taken by a tribally-licensed harvester in one day for ceremonial or subsistence purposes without a special permit:

a) Native littleneck clams, butter clams, cockles, and manilla clams in any combination: fifty pounds in shell;

b) Horse clams: fifty clams;

c) Oysters: twenty count;

d) Geoducks: six geoducks;

e) Mussels: ten pounds in shell.

8. The above bag limits may be exceeded by special ceremonial or subsistence permit, issued to the harvester by the tribe prior to harvest, which state the place and time at which harvest will be permitted, the species and quantity that can be taken, and the name of the harvester.

II. EXAMPLE TWO

1. Tribal regulations that govern tribal ceremonial, subsistence, and commercial fisheries are enforced by tribal enforcement staff conducting routine scheduled patrols of growing areas subject to tribal jurisdiction and investigating reported or suspected violations.

2. Tribal ceremonial shellfisheries are discrete in time and place and are opened by tribal regulation as provided for in the individual tribe's fisheries ordinance. Tribal regulations opening a ceremonial shellfishery designate the catch area and specific beach opened for harvest, the species to be harvested, the gear restrictions, date and times of opening and closure, a limited number of tribal members authorized to participate in the ceremonial fishery, the target harvest quantity and the reporting requirements. The designated tribal members participating in the fishery are required by regulation to report the harvest quantity to the tribal fisheries office within 24 hours of the close of the fishery. Records of time, place, and quantity of harvest are maintained by the tribal fisheries office.

3. Tribal subsistence shellfisheries are controlled by tribal annual and emergency regulations. Any beaches in the treaty area and subject to tribal harvest may be opened for tribal subsistence harvest, except those beaches closed for human health protection or for resource protection needs. Subsistence fishery daily bag limits per fisher are as follows:

- a) Littleneck, manilla, butter, soft-shell:
50 pounds combined, of which there can be no more than 25 pounds combined total of littleneck and manilla clams
- b) Horse: 50 clams
- c) Geoduck: 6 clams
- d) Cockle: 50 clams
- e) Mussel: 40 pounds
- f) Oyster: 100 oysters

4. Management provisions that govern the commercial fisheries can prevent the sale of non-commercial harvest. Commercial clam and oyster harvests are managed by specific beach openings and closures using emergency tribal regulations. Catch is accounted for primarily by an on-the-beach monitor who records information contained on the attached harvest monitor form. The tribe maintains all such records of commercial catch. At the time of sale, all tribal commercial catches are recorded on fish receiving tickets which are compiled, summarized and entered into a data base which is maintained at the tribal fisheries office.