

January 2012

## I. EXECUTIVE SUMMARY

This management plan for commercial shellfishing in Drakes Estero, Marin County, California, was developed pursuant to the National Shellfish Sanitation Program (NSSP) Model Ordinance, Chapter IV (2009). The Management Plan has been prepared for adoption in accordance with the procedures set forth in Division 104, Part 6, Chapter 5 of the California Health and Safety Code Section 112150 et seq. Any temporary closures to shellfish harvesting that may be declared pursuant to this Management Plan after its adoption shall be deemed to meet the requirements of Section 112160, Health and Safety Code, pertaining to notice and opportunity to submit data, views, or arguments. This Management Plan establishes the standards and procedures used to regulate commercial shellfish harvesting in Drakes Estero.

The primary purpose of the Management Plan is to define the criteria and procedures used by the State shellfish authority for determining when bivalve shellfish can be harvested for marketing from a shellfish growing area classified as *Conditionally Approved*. Harvest activities may only occur during times when the respective growing area is open to shellfish harvesting as described in this document.

The California Department of Public Health is the lead agency in the State Shellfish Program, which certifies and regulates sanitary procedures followed in the harvesting, handling, processing, storage, and distribution of bivalve molluscan shellfish intended for sale for human consumption. Within CDPH, the Environmental Management Branch in the Division of Drinking Water and Environmental Management regulates water quality and shellfish sanitation in the growing waters, while the Food and Drug Branch in the Division of Food, Drug, and Radiation Safety regulates shellfish sanitation after harvest. This Management Plan was prepared and is administered by the Environmental Management Branch's Environmental Health Services Section, State Shellfish Program, in cooperation with the shellfish grower, public agencies, and other involved parties. The NSSP requires that the shellfish growers, the wastewater treatment plants involved, and the applicable local and State agencies agree with the Management Plan. The "Failure of any one party to agree shall constitute justification to deny the application of the conditional classification to the growing area." (Model Ordinance, 2009).

One commercial shellfish harvester, Drakes Bay Oyster Company (DBOC) operates in Drakes Estero in lease areas M-438-01 and M-438-02, issued by the California Department of Fish and Game. These state water bottom leases, covering approximately 1600 acres, cover almost all of Drakes Estero, including Barries Bay, Creamery Bay, Home Bay, and all but the central channel of Schooner Bay. Oysters and clams are grown and harvested by DBOC. Oyster production by DBOC is entirely Pacific oysters (*Crassostrea gigas*) and is sold both in the shell and as shucked product. With the exception of a small *Approved* area in the outer portion of Drakes Estero, the growing areas in Drakes Estero are classified as *Conditionally Approved*. The purpose of the *Conditionally Approved* classification is to provide a mechanism for the declaration of harvest closures during predictable periods when the shellfish growing area may not meet NSSP standards for harvesting shellfish for

direct marketing for human consumption. The *Conditionally Approved* classification is based on rainfall, which has the potential to affect the water quality in this area. The removal of shellstock from the growing waters constitutes harvesting, which is prohibited during any closure. Shellstock should not be removed from the growing area during any closure except with written permission from the Department of Public Health.

This Management Plan establishes procedures for the temporary harvest closures of the *Conditionally Approved* areas based on rainfall measurements recorded by a Department of Public Health designated rain gauge, a National Weather Service rain gauge or other approved rain gauge designated by the California Department of Public Health. It also provides procedures for emergency notification and harvest closures in case of accidental sewage or hazardous substance spills. Water quality monitoring is conducted at least monthly during open periods and the growing area classifications and closure rules are reevaluated annually.

The Management Plan also stipulates that shellstock should not be removed from the growing areas during any closure except with written permission from the California Department of Public Health. Each Shellfish grower is responsible for water quality monitoring monthly during open harvest periods. The water quality monitoring data collected by the commercial shellfish growers are analyzed at least annually to determine the appropriate growing area classifications.

II. TABLE OF CONTENTS

I. EXECUTIVE SUMMARY .....2

II. TABLE OF CONTENTS .....4

III. ABBREVIATIONS AND DEFINITIONS .....7

V. ORGANIZATION AND RESPONSIBILITIES .....10

    A. CALIFORNIA DEPARTMENT OF PUBLIC HEALTH .....10

        1. Environmental Management Branch.....10

        2. Food and Drug Branch.....10

    B. U.S. FOOD AND DRUG ADMINISTRATION .....10

    C. CALIFORNIA DEPARTMENT OF FISH AND GAME .....10

    D. SAN FRANCISCO BAY REGIONAL WATER QUALITY CONTROL BOARD..11

    E. MARIN COUNTY COMMUNITY DEVELOPMENT AGENCY .....11

    F. POINT REYES NATIONAL SEASHORE.....11

    G. DRAKES BAY OYSTER COMPANY .....11

VI. GROWING AREA CLASSIFICATION.....11

    A. CONDITIONALLY APPROVED AREAS .....11

    B. APPROVED AREA.....12

    C. CLASSIFICATION MAINTENANCE.....12

VII. PERFORMANCE STANDARDS .....13

    A. POTENTIAL NON-POINT SOURCES OF POLLUTION .....13

    B. POTENTIAL POINT SOURCES OF POLLUTION .....13

    C. PROHIBITED AREAS ESTABLISHED .....13

        1. Wastewater Treatment Plants.....13

        2. Marinas .....13

        3. Residential Facilities .....14

        4. Unclassified Areas .....14

        5. Violation of State Laws and Regulations.....14

VIII. HARVEST CLOSURE AND NOTIFICATION PROCEDURES.....14

    A. RAINFALL CLOSURES .....14

        1. Closure Zones.....15

        2. Closure Rules .....15

        3. Extreme Environmental Conditions.....16

    B. EMERGENCY CLOSURES: SEWAGE COLLECTION SYSTEM UPSETS .....18

    C. EMERGENCY CLOSURES: HAZARDOUS SUBSTANCE SPILLS.....18

    D. OTHER EMERGENCY CLOSURES.....19

    E. NOTIFICATION PROCEDURES.....19

        1. California Department of Public Health .....19

        2. San Francisco Bay Regional Water Quality Control Board .....21

        3. Marin County Environmental Health Services Division .....21

        4. Wastewater Treatment Plants.....22

        5. Impact Assessment.....22

IX. CERTIFIED SHELLFISH HARVESTER RESPONSIBILITIES .....22

    A. SEED .....22

    B. HARVEST CLOSURE .....22

        1. Business Hours.....23

        2. Non-Business Hours .....23

C. RECEIVING AND ACKNOWLEDGING NOTIFICATIONS .....	23
D. REPORTS OF SEWAGE OR HAZARDOUS SUBSTANCE SPILLS .....	23
1. Business Hours .....	23
2. Non-Business Hours .....	23
E. RECORD KEEPING .....	24
F. WILDLIFE .....	24
X. REOPENING PROCEDURES .....	25
A. RAINFALL CLOSURES .....	25
B. SEASONAL CLOSURES .....	25
C. SEWAGE OR HAZARDOUS SUBSTANCE SPILLS.....	25
1. Investigation.....	25
2. Harvest Reopening .....	25
3. Notification .....	25
XI. PREVENTION OF ILLEGAL HARVESTING (PATROL) .....	25
A. ILLEGAL HARVESTING OF SHELLFISH.....	25
B. DEPARTMENT OF FISH AND GAME, WILDLIFE PROTECTION DIVISION..	26
C. ILLEGAL MARKETING .....	26
XII. WATER AND SHELLFISH QUALITY MONITORING .....	27
A. WATER SAMPLING REQUIREMENTS .....	27
B. TRANSPORTATION .....	27
C. LABORATORY .....	28
D. WATER SAMPLES EXCEEDING NSSP CRITERIA.....	28
XIII. MARINE BIOTOXIN MONITORING.....	29
A. CONDITIONS AND PROCEDURES .....	29
1. Phytoplankton Observations. ....	29
2. Domoic Acid Analysis. ....	30
4. Field Sampling Protocol .....	30
5. Additional Sampling .....	30
B. CLOSURE CRITERIA .....	31
1. Domoic Acid Alert Level.....	31
2. Paralytic Shellfish Poisoning Alert Level .....	31
3. Samples Exceeding the Alert Level .....	31
4. Failure to Submit Required Samples .....	31
C. SIZE OF CLOSED AREA.....	32
D. SPECIES RESTRICTIONS.....	32
E. SAMPLING DURING A MARINE BIOTOXIN CLOSURE .....	32
F. REOPENING CRITERIA .....	32
XIV. GROWING AREA REEVALUATION .....	33
XV. AGREEMENT OF INVOLVED PARTIES .....	33
A. PUBLIC AGENCIES.....	33
B. COMMERCIAL SHELLFISH GROWER .....	34
C. FORWARDING OF SIGNED STATEMENTS .....	34
XVI. SUMMARY OF AGREEMENTS .....	34
A. CALIFORNIA DEPARTMENT OF FISH AND GAME .....	34
B. SAN FRANCISCO BAY REGIONAL WATER QUALITY CONTROL BOARD..	34
C. MARIN COUNTY COMMUNITY DEVELOPMENT AGENCY, DIVISION OF ENVIRONMENTAL HEALTH SERVICES.....	34
Table 1. Drakes Estero primary sampling stations.....	36

MANAGEMENT PLAN FOR DRAKES ESTERO, JANUARY 2012

Table 2. Drakes Estero secondary sampling stations.....36  
Table 3. Rainfall closure criteria for Drakes Estero by growing area. .... 37  
Table 4. Management decision criteria for domoic acid toxicity in bivalve shellfish.... 38  
Figure 1. Drakes Estero, California..... 40  
Figure 2. Drakes Estero leases and growing beds..... 41  
Appendix A. Contact List For Commercial Shellfishing at Drakes Estero ..... 44  
Appendix B. Notification of Shellstock Movement During a Growing Area Closure.... 46  
Appendix C. Wastewater Upset Response Procedures..... 47  
Appendix D. Harvester’s Monthly Report of Rainfall and Harvest Operations ..... 51  
Appendix E. Standard Operating Procedure for Responding to Elevated Levels of  
Paralytic Shellfish Poisoning Toxin in Shellfish from Drakes Estero ..... 52  
Appendix F. Marine Biotoxin Monitoring Procedures ..... 56  
Appendix G. Statements of Agreement ..... 61  
Appendix H. Summary of Changes.....62

III. ABBREVIATIONS AND DEFINITIONS

This document contains many acronyms and abbreviations. In general, an abbreviation will be given in parentheses ( ) following the first time a title or term is used, and the abbreviation will be used in almost all cases in place of that term later. The following alphabetical list of abbreviations used in this document is provided to assist the reader:

<b>ABBREVIATION</b>	<b>DESCRIPTION</b>
DBOC	Drakes Bay Oyster Company
DFG	California Department of Fish and Game
CDPH	California Department of Public Health
CDPH/DDWEM	Division of Drinking Water and Environmental Management
CDPH/EHSS	Environmental Health Services Section (within CDPH/EMB)
CDPH/EMB	Environmental Management Branch (within CDPH/DDWEM)
CDPH/FDB	Food and Drug Branch (within CDPH)
CDPH/PSU	California Department of Public Health, Preharvest Shellfish Unit
ELAP	Environmental Laboratory Accreditation Program
FC	Fecal Coliform
FDA	U.S. Food and Drug Administration
GIL	Grower Information Line, (510) 412-4644
gm	Gram
H & S	California Health and Safety Code
MCDEHS	Marin County Community Development Agency, Division of Environmental Health Services
mL	Milliliters
MOU	Memorandum of Understanding
MPN	Most Probable Number
NPS	National Park Service
NSSP	National Shellfish Sanitation Program
PRNS	Point Reyes National Seashore
PSP	Paralytic Shellfish Poisoning
RDO	Rainfall Duty Officer (a designated staff person in CDPH/PSU)
SFBRWQCB	San Francisco Bay Regional Water Quality Control Board
SOP	Standard Operating Procedure
SRS	Systematic Random Sampling
SSP	Shellfish Sanitation Program
WDRs	Waste Discharge Requirements
WWTP	Waste Water Treatment Plant

The following definitions shall apply to this document:

**Harvest.** The act of removing shellstock from growing areas and its placement on or in a manmade conveyance or other means of transport.

**Shall.** The term "shall" is used in this plan in its legal or regulatory sense to denote a mandatory requirement.

**Shellfish grower or harvester.** For the purposes of this plan, the terms "grower" and "harvester" refer to the same persons or firms and may be used interchangeably. Because the plan relates primarily to the management of shellfish harvesting, the term "harvester" will be found most frequently.

**Direct marketing.** Direct marketing means the sale of shellfish harvested without undergoing purification (relaying or depuration).

#### IV. INTRODUCTION

Drakes Estero, Marin County (Figure 1), is one of the largest commercial shellfish producing areas in California. With 1,600 acres in two aquaculture leases, it ranks second only to Humboldt Bay. Only one company operates in the Estero, the Drakes Bay Oyster Company (DBOC). Production is entirely Pacific oysters (*Crassostrea gigas*). The state water bottom leases issued by the California Department of Fish and Game (CDFG) to DBOC cover almost all of Drakes Estero, including Barries Bay, Creamery Bay, Home Bay, and all but the central channel of Schooner Bay (Figure 2). Non-point sources of contamination from the watershed for this area have the potential for impacting the growing area, mainly during rainfall related runoff.

With the exception of a small *Approved* area in the outer portion of Drakes Estero, most areas in Drakes Estero are subject to intermittent microbiological pollution from non-point sources. As a result, those areas are classified as *Conditionally Approved*. The National Shellfish Sanitation Program (NSSP) Model Ordinance (2009), Chapter IV, requires development of a Management Plan for any *Conditionally Approved* growing area. This Management Plan sets forth the standards and criteria necessary to manage the harvesting of bivalve molluscan shellfish intended for human consumption from the *Conditionally Approved* areas.

This Management Plan establishes the standards and procedures used to regulate commercial shellfish harvesting in Drakes Estero, and has been prepared for adoption in accordance with the procedures set forth in Sanitary Control of Shellfish, (Division 104, Part 6, Chapter 5 of the California Health and Safety Code Section (H&S §) 112150 et. seq.) and will constitute an order of the Director of the California Department of Public Health (CDPH) as described in H&S § 112160(c).

A key part of this Management Plan is the establishment of standards, conditions, and procedures for closure of the growing area at times of predictable elevated pollution following periods of significant rainfall, as well as for emergency closures established for unpredictable events such as sewage spills or oil spills. They have been set forth in this plan such that when the specified events occur, then predetermined actions are implemented. Any temporary closure to shellfish harvesting resulting from these pollution events that may be declared pursuant to this Management Plan shall be deemed to meet the requirements of H&S § 112160(d) pertaining to notice and opportunity to submit data, views, or arguments. Rainfall closures declared under this Management Plan are not considered “emergency actions” referred to in the California Health and Safety Code (H & S) § 112160(e), but instead are dealt with as part of the Director’s order establishing this plan. Compliance by the certified shellfish grower/harvester with the conditions and procedures set forth in this Management Plan is mandatory as a condition of the Shellfish Growing Area Certificate.

## V. ORGANIZATION AND RESPONSIBILITIES

Numerous agencies and individuals are involved in the management of Drakes Estero. A detailed contact list is provided in Appendix A.

### A. CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

California Department of Public Health (CDPH) is the lead agency for the State Shellfish Program (SSP) and is the agency responsible for growing area classification, issuing growing area certificates and for decision making regarding harvest closures and reopening of commercial shellfish growing areas. Within CDPH, the Deputy Director for Prevention Services has overall responsibility for the California SSP. Two major program segments are housed in the following branches:

#### 1. Environmental Management Branch

The Chief of the CDPH, Environmental Management Branch (CDPH/EMB), through the Chief of the CDPH, Environmental Health Services Section (CDPH/EHSS), is responsible for the CDPH Shellfish Program. The Chief of the CDPH Preharvest Shellfish Unit (PSU) heads a staff of several Environmental Scientists and coordinates activities as it relates to the evaluation, classification, and certification of commercial shellfish growing areas as well as routine monitoring for marine biotoxins.

#### 2. Food and Drug Branch

The Chief of the California Department of Public Health, Food and Drug Branch (CDPH/FDB) is responsible for the post harvest SSP as it relates to the regulation of shellfish handling, processing, storage, and distribution after harvest, including the labeling and identification of shellfish moving in commerce. FDB provides assistance in the area of patrol, prevention of illegal shellfish harvesting and illness investigations.

### B. U.S. FOOD AND DRUG ADMINISTRATION

A primary responsibility of the U.S. Food and Drug Administration (FDA) is to ensure conformity of state shellfish sanitation programs with the guidelines and procedures for the classification and management of shellfish growing areas as outlined in the NSSP Model Ordinance (2009). Conformity with the Model Ordinance ensures national uniformity of state programs, and the health and safety of shellfish products in intra- and interstate commerce. FDA conducts annual reviews and evaluations of state shellfish sanitation programs, and provides recommendations, technical assistance, and training designed to improve the effectiveness of those programs.

### C. CALIFORNIA DEPARTMENT OF FISH AND GAME

The California Department of Fish and Game (DFG) participates in the SSP through the terms of the "Memorandum of Understanding between DFG and CDPH

regarding the California Shellfish Sanitation and Paralytic Shellfish Poisoning Prevention Program." Within DFG, the Wildlife Protection Division, with its game wardens, provides assistance to CDPH in the area of patrol and prevention of illegal shellfish harvesting by both sport and commercial harvesters. In addition, CDFG's Marine Resources Division issues and administers State aquaculture leases for the California Fish and Game Commission.

#### D. SAN FRANCISCO BAY REGIONAL WATER QUALITY CONTROL BOARD

The San Francisco Bay Regional Water Quality Control Board (SFBRWQCB) is responsible for regulating dischargers of wastes to any body of water within its region. SFBRWQCB sets standards for waste dischargers, issues permits to the dischargers in the form of Waste Discharge Requirements (WDRs) and Monitoring and Reporting Program (MRP), and monitors their performance.

#### E. MARIN COUNTY COMMUNITY DEVELOPMENT AGENCY

The County Health Officer is responsible for all matters pertaining to public health within Marin County, including the County's incorporated cities. Within this Agency, the Director of the Division of Environmental Health Services (MCDEHS) is responsible for enforcing the laws and regulations pertaining to environmental health, including the proper handling and disposal of sewage from private premises and notifying the public, by posting and other media, for sewage spills.

#### F. POINT REYES NATIONAL SEASHORE

All of the lands surrounding Drakes Estero, including its entire watershed, lie within the boundaries of Point Reyes National Seashore (PRNS), a part of the National Park Service (NPS) system. Tidal and submerged lands were ceded to the United States with the exception of fishing and mineral rights.

#### G. DRAKES BAY OYSTER COMPANY

The only commercial shellfish grower located in Drakes Estero is DBOC. Historically Johnson's Oyster Company, Inc. (JOC) operated the leases in the Drakes Estero and was certified by CDPH for commercial shellfish growing and harvesting of oysters and clams from this location. In January 2005, Mr. Kevin Lunny began operating (JOC) and initiated the process to purchase it and the growing area leases in Drakes Estero. In December 2005 the sale of JOC to Mr. Lunny was completed and the name of the business changed to DBOC.

### VI. GROWING AREA CLASSIFICATION

#### A. CONDITIONALLY APPROVED AREAS

The majority of Drakes Estero, including most of Schooner Bay and the areas of Creamery, Barries, and Home Bay, is classified as *Conditionally Approved* (see Figure 2). A small area of Schooner Bay near the on-shore facilities of DBOC is

classified as *Prohibited*. The inner reaches of Creamery, Barries and Home Bays are currently unclassified and therefore *Prohibited*. These unclassified areas were previously classified as *Conditionally Approved*, but were removed from this classification because of elevated fecal coliform (FC) concentrations. It was found that the inner reaches of these bays did not meet the *Conditionally Approved* classification under the existing rainfall closure rules. It is possible that these areas could be managed in such a way (e.g., with a longer rainfall closure period) that they could be returned to the *Conditionally Approved* classification. A *Conditionally Approved* area is one that meets the National Shellfish Sanitation Program (NSSP) water quality standards for an approved area (an area from which shellfish may be harvested for direct marketing for human consumption), except during relatively short periods of time when it does not meet the standards and must be closed. Direct marketing means the sale of shellfish harvested without undergoing purification (relaying or depuration). The factors determining closed periods must be known, predictable, and not excessively complex. The purpose of the *Conditionally Approved* classification is to provide a mechanism, through this Management Plan, for the declaration of harvest closures when pollution impacts to the growing area would cause water and shellfish quality to potentially exceed the standards for an *Approved* area.

## B. APPROVED AREA

A small area of the outer Estero is classified as *Approved* (Figure 2). The *Approved* area of Drakes Estero consists of an approximately 25-acre parcel located in the outer Estero, along the southernmost boundary of Lease M-438-01, Parcel 2. The grower is responsible to mark the boundaries of the *Approved* area, so that it is clearly visible. The grower shall ensure adequate separation of all aquaculture shellstock located in the *Approved* area from those located in the adjacent *Conditionally Approved* areas. The grower shall maintain a record keeping system that provides appropriate inventory control for all shellstock in the *Approved* area, which includes tracking of shellstock moved into the *Approved* area for wet storage.

## C. CLASSIFICATION MAINTENANCE

### 1. Water Quality Sampling

To maintain the *Conditionally Approved* classification, DBOC shall take a minimum of one water sample per month when in an open status at each primary sample site (Table 1). Sampling shall be accomplished using the systematic random sampling protocol in accordance with the current Sampling Plan for Water Quality Monitoring. (See Section XII, A, for additional information on water quality sampling requirements)

### 2. Grower Classification

Growers will be evaluated on an annual basis to ensure that they are performing all tasks associated with water quality sampling properly. During these annual field audits new employees can also be trained to perform water quality sampling

## VII. PERFORMANCE STANDARDS

### A. POTENTIAL NON-POINT SOURCES OF POLLUTION

Non-point sources of pollution are those sources that cannot be attributed to a specific discharge location. The sources of pollution most likely to adversely affect water quality in Drakes Estero are the non-point sources. The Estero is unique in that it lies completely within the Point Reyes National Seashore, an area that lacks any urban or industrial development. Potential pollution sources are limited to cattle pastureland, deer and other terrestrial wildlife, birds, harbor seals, sea lions, and, to a minor degree, human activity. The common problems with live-aboard boats and failing septic systems (with the possible exception of the DBOC facility) are absent from Drakes Estero. Rainfall-related closures of the commercial shellfishing areas are established, as set forth in the next section, to help mitigate the impact from these pollution sources. These rainfall closure rules were based on the results of a sanitary survey of Drakes Estero, which is updated annually and includes a reevaluation of these rainfall closure rules. The closure period takes into account (1) the time required for the Estero water quality to return to acceptable levels following cessation of rain, and (2) the time required for the shellfish to cleanse themselves sufficiently so as to meet the fecal coliform market standard for shellfish meats.

### B. POTENTIAL POINT SOURCES OF POLLUTION

Sources of pollution that can be attributed to a specific site or location are known as “point sources”. As noted above, there are no Wastewater Treatment Plants (WWTP) on the Drakes Estero watershed, nor are there any other point sources of pollution affecting the Estero.

### C. PROHIBITED AREAS ESTABLISHED

#### 1. Wastewater Treatment Plants

No WWTPs discharge effluent to Drakes Estero, nor to any tributaries to the Estero. Therefore, no prohibited areas are established as safety zones around WWTP point source discharges.

#### 2. Marinas

Drakes Estero contains no marinas. Other than the working boats and barges used by DBOC, there is only very occasional use by small craft (e.g., kayaks and canoes). There are no public boat launching ramps in the Estero; the public uses the shoreline area in inner Schooner Bay to launch kayaks and canoes. In addition to being inaccessible to boats from land, the entrance to the ocean is not navigable due to the presence of a shallow sand bar at the mouth of the Estero. Because of the lack of marinas, no prohibited areas of this type are necessary.

### 3. Residential Facilities

Drakes Estero is unique among all other bays and estuaries used for shellfish aquaculture in California in that there is no urban development on the watershed. There are no shoreline residences, except in the immediate area of the DBOC facility at the upper end of Schooner Bay (Figure 2). In addition to the business facility itself, there are several residential trailers occupied by the employees of DBOC and some of their families. Because of the residential units, company buildings, and the on-site septic system, a small *Prohibited* area has been established at the upper end of Schooner Bay. This area extends approximately 50 feet outward in all directions from the shellfish plant. The prohibited zone is meant to prevent the use of these near-shore waters for wet storage or relaying due to the possibility of accidental contamination from the on-shore facilities. Sampling station 8 (Figure 3) is inside this prohibited area at the intake of the water for the shucking plant.

### 4. Unclassified Areas

All parts of Drakes Estero not specifically designated as a certified aquaculture lease are unclassified and therefore considered *Prohibited* areas. The inner reaches of Creamery, Barries and Home Bays are currently unclassified and therefore *Prohibited*.

### 5. Violation of State Laws and Regulations

It is a violation of State laws and regulations to culture, harvest, or hold shellfish intended for sale for human food except in or from areas that have been specifically identified in a valid Shellfish Growing Area Certificate issued by CDPH/PSU. The holding of shellfish in any other waters prior to on-shore processing, storage, and marketing is a prohibited activity. Any shellfish held in uncertified waters, or in water-filled tanks or containers that have not been specifically approved by CDPH/PSU for that purpose, are subject to embargo and/or destruction by CDPH/PSU.

## VIII. HARVEST CLOSURE AND NOTIFICATION PROCEDURES

This section describes the procedures to be followed by certified commercial shellfish harvesters and by State and local agencies, to ensure prompt notification and subsequent closure of Drakes Estero to shellfish harvesting. These procedures shall be followed whenever any pollution event or condition occurs as described below, that is likely to degrade the water quality in any *Conditionally Approved* shellfish growing area of the bay to the degree that it does not meet the NSSP minimum standards for an *Approved* area.

### A. RAINFALL CLOSURES

Since rainfall closures are an important management tool for the growing area, the grower should call the Grower Information Line (GIL) prior to harvesting during any period of rainfall. If the grower is still unsure as to the status of the growing area, he

should contact the rainfall duty officer (RDO) at (510) 412-4633 to determine if the GIL is in the process of being updated (on weekends and off-hours, leave a message on the GIL). CDPH/PSU staff will make all reasonable efforts to ensure that the GIL is current and accurate. However, the GIL is not updated on a continuous basis, and changes that occur in the growing area status due to overnight rainfall will not be updated on the GIL until business hours the following day. If there has been rainfall in the past 24 hours, the grower shall not harvest unless there is an updated message on the GIL, CDPH/PSU staff states that the growing area is open, or the grower is able to obtain reliable information that the growing area is open. If the grower harvests before obtaining current information on the growing area status, and the growing area is closed, the grower shall be responsible to return all harvested shellfish to the same location it was harvested from.

### 1. Closure Zones

All certified growing areas in Drakes Estero are divided into two rainfall closures zones as follows (Figure 2):

- a. Inner Schooner Bay, defined as the area from Water Quality Station #8 to the *Prohibited* area.
- b. All other *Conditionally Approved* areas.

### 2. Closure Rules

All shellfish growing areas in the *Conditionally Approved* areas in Drakes Estero adhere to the established rules summarized in Table 3. The closure shall start immediately when the 24-hour cumulative rainfall at DBOC exceeds the thresholds listed below. CDPH/PSU will notify the commercial shellfish grower whenever the rainfall threshold is exceeded and the growing area is closed. The commercial shellfish grower shall acknowledge receipt of this notification within 24-hours. When determined, an estimated reopening time will be provided. The status of the growing area can be obtained by calling the 24-hour GIL at (510) 412-4644. See Section X for the requirements for reopening.

The shellfish growing areas located in Drakes Estero shall be closed when the 24-hour rainfall, as recorded at the automated remote weather station located at DBOC (Peet Brothers Gauge) operated by the CDPH or any other rain gauge designated and approved by CDPH/PSU, which exceeds the following thresholds:

- a. Inner Schooner Bay shall be closed for a minimum of 7 days when rainfall exceeds 0.70 inch during any 24-hour period.
- b. All *Conditionally Approved* areas except Inner Schooner Bay shall be closed for a minimum of 3 days when rainfall exceeds 0.75 inch during any 24-hour period.

c. All *Conditionally Approved* areas shall be closed for one additional day if 7-day cumulative rainfall exceeds 2.00 inches.

DBOC will maintain a rain gauge on their premises as a backup to the automated remote weather station. 24-hour cumulative readings shall be recorded daily and submitted to CDPH/PSSU monthly. DBOC will be notified whenever their local gauge is being used as the primary gauge and will provide readings as requested.

### 3. Extreme Environmental Conditions

In the case of unusually heavy or prolonged rainfall, exceeding the conditions documented in the Sanitary Survey upon which this Management Plan is based, the closure rules set forth above no longer apply. Cumulative 7-day rainfall in excess of 2.50 inches shall result in immediate closure of all growing areas, *including the Approved area in the outer Estero*. CDPH will determine the reopening criteria and develop a data collection strategy, based on the nature and severity of the event, and in consultation with the affected grower(s). Section X.C.2 of this Management Plan outlines reopening procedures for such events. The cumulative 7-day rainfall threshold of 2.50 inches is subject to change as additional data on the impacts of extreme rainfall events on Estero water quality become available. The grower is therefore encouraged to collect samples following extreme rainfall events. CDPH will provide guidance on extreme event sampling.

### 4. Movement of Shellstock

The harvest of shellstock during a closure is prohibited. Harvesting is defined as the act of removing shellstock from growing waters and placing it on or in a manmade conveyance or other means of transport. There are three conditions outlined in this section when shellfish may be “harvested” during a shellfish closure solely for the purposes of sorting and culling prior to returning to the growing area, and not for market.

Rainfall closures are necessary for shellstock to depurate to acceptable levels after rainfall events. Closure times are based on depuration studies performed in the growing area and the time required for adequate depuration of contaminants. Depuration does not occur when shellstock is out of the water. Shellstock removed from growing waters during closure periods shall have the number of hours and minutes that the shellstock is out of the water added onto its respective closure time before it can be harvested for market. All shellfish must be in water for the entire length of time that it would otherwise have been had it not been removed from the growing waters before the end of the rainfall closure. If shellstock is removed from the growing waters during closed periods, it must be tagged to ensure that the shellstock is not harvested for market prior to the required depuration time.

In an effort to protect public health, CDPH has established procedures to prevent illegal harvesting of shellfish from closed growing areas. To verify compliance with the rainfall closure rules, CDPH conducts or arranges for patrols of closed growing areas, and audits the shellfish growers’ harvest records. Growers shall maintain

additional documentation for shellstock that is taken out of the water during a closure to ensure that the shellstock is traceable if an illness event occurs.

There are three identified conditions in which shellstock may be removed from the growing waters during a closure: 1) the shellstock is harvested and worked on (e.g., sorted, culled) on-site without leaving the specific lease/parcel; 2) the shellstock is harvested from the lease/parcel, transported to another area where it is worked on, then transported back to the same lease/parcel; and 3) the shellstock is harvested from the lease/parcel, worked on, then placed in a different lease/parcel.

The following actions are required by the grower when harvesting shellstock during a rainfall closure.

Condition 1:

Shellstock is harvested but is worked on on-site, and is NOT removed from the area of the grower's lease/parcel.

Required Action:

Notification by the grower to CDPH is not required. The grower must label the bag in such a manner to ensure that it will not be harvested until the number of hours it was out of the water has been added onto the reopening time for the growing area. Shellstock that has been moved shall be tagged to differentiate it from shellstock that has not been moved. The amount of time that shellstock is out of the water shall be recorded to ensure that the correct depuration time has occurred. Records of all these operations shall be maintained by the shellfish grower and made available to CDPH upon request.

Condition 2:

Shellstock is harvested from the grower's lease/parcel during a closure, transported off the lease/parcel to be worked on, and then returned to the original lease/parcel. NOTE: Shellstock shall not be placed in, or come in contact with, uncertified growing waters.

Required Action:

The grower shall contact the CDPH/PSU Richmond office in writing, using the attached form in Appendix B a minimum of two working days prior to the start of work if possible, or as soon as possible, and must obtain written permission prior to start of work. This written permission must be on site while working with shellstock that has been temporarily removed from the growing water. Removed shellstock shall have the number of hours that shellstock was out of the water added onto the reopening times for harvest purposes in the same manner as described in Condition 1 above. Shellstock that has been moved shall be tagged to differentiate it from shellstock that has not been moved. Records of all these operations shall be maintained by the shellfish grower and made available to CDPH upon request.

Condition 3:

Shellstock is harvested from one *Conditionally Approved* grower's lease/parcel and placed into another *Conditionally Approved* lease/parcel, owned by the same

grower, during a closure. This activity is prohibited unless the grower receives approval by CDPH for this activity. Both parcels must be under the control and authority of the named grower (i.e., product cannot be moved onto another shellfish grower's lease). NOTE: Shellstock shall not be placed in, or come in contact with, uncertified growing waters.

**Required Action:**

The grower shall obtain prior authorization by CDPH and approval of a standard operating procedure (SOP) to ensure safety of the product.

Only under extreme circumstances will CDPH pre-approve this activity during closed harvest periods. Commercial shellfish growers must submit a plan to conduct this activity to CDPH. This plan must include procedures to prevent shellfish from Prohibited or closed water from commingling with shellfish from another lease/parcel. The plan shall be submitted in writing and will be the basis of a standard operating procedure (SOP) for such activity. CDPH reserves the right to reject any plan if it does not conform to specific NSSP guidance such as allowing shellstock to properly depurate during a closure. Shellstock that has been moved shall be tagged to differentiate it from shellstock that has not been moved. The amount of time that shellstock is out of the water shall be recorded to ensure that the correct depuration time has occurred. Records of all these operations shall be maintained by the shellfish grower and made available to CDPH upon request.

**B. EMERGENCY CLOSURES: SEWAGE COLLECTION SYSTEM UPSETS**

Accidental sewage releases from wastewater collection systems servicing the Drakes Estero watershed may adversely affect the water quality in shellfish growing areas. The potential for sewage "upsets" to adversely impact shellfish-growing waters is related to the estimated volume of the discharge, the location of the discharge with respect to the growing areas, tides, and the timing of the discharge with respect to rainfall closures of the growing areas. Faulty on-site waste disposal systems located in the Drakes Estero watershed could potentially contaminate the shellfish growing areas in the Estero. On-site waste disposal systems located near the shorelines of Home and Schooner Bays pose a greater risk of contaminating Drakes Estero than others that are scattered throughout the watershed. Raw sewage from these systems could enter directly into nearby tributaries that discharge into the Estero, or could enter the Estero via runoff from the nearby hillside (See Table C-1 of Appendix C for threshold values for accidental releases of sewage). Criteria for determining whether an emergency closure will be implemented as a result of a sewage spill, and criteria for reopening growing areas are presented in Appendix C.

**C. EMERGENCY CLOSURES: HAZARDOUS SUBSTANCE SPILLS**

In the event of a reported hazardous substance spill that could impact a shellfish growing area, the Office of Emergency Services (OES) is notified, who in turn will contact the CDPH Duty Officer (on call 24 hours a day). The CDPH Duty Officer will

notify the CDPH/PSU supervisor or the next manager in the chain of command. Additional involved agencies will have their own reporting requirements.

Upon notification of a hazardous substance spill CDPH/PSU will determine the status of the growing area and will notify the growers if a closure is warranted. A harvest closure resulting from a hazardous substance spill shall remain in effect while CDPH/PSU evaluates the event and determines the required actions. See Section X for reopening requirements.

#### D. OTHER EMERGENCY CLOSURES

Other emergency situations in which the discharge of a toxic or deleterious substance to shellfish growing waters is presumed to be likely, but during which communications with CDPH/PSU may be compromised, such as after a natural or man-made disaster, will be evaluated by CDPH/PSU for possible closure of the growing areas.

#### E. NOTIFICATION PROCEDURES

##### 1. California Department of Public Health

a. CDPH is the agency responsible for decision making regarding harvest closures and reopening of shellfish growing areas.

b. CDPH/PSU will maintain a telephone message recorder (the GIL) at the Richmond office, (510) 412-4644, to provide information about closures to commercial shellfish harvesters during non-business hours. CDPH/PSU will update the recorded message as needed and will monitor the line at least twice each day for recorded messages from the harvesters.

c. If CDPH/PSU decides to close a shellfish growing area to commercial shellfish harvesting, CDPH/PSU will notify each affected certified harvester by telephone of that decision. When CDPH/PSU decides to reopen a shellfish growing area to commercial shellfish harvesting, CDPH/PSU will notify each affected certified harvester by telephone of that decision. In the case of rainfall closures there are times when storm activities can interfere with the ability of CDPH/PSU to obtain current rainfall information. Beyond normal business hours and weekends CDPH/PSU may not be able to update the closure or reopening information immediately. If a harvester has any question or uncertainty regarding a closure or a reopening, they shall contact the GIL ((510) 412-4644) for guidance prior to resuming any harvest activities. If additional rainfall has occurred since the last GIL update, or if the grower is unsure about the harvest status of the growing area, they shall consider the area closed to harvest and contact the RDO at (510) 412-4633 for more information (on weekends and off-hours, leave a message on the GIL). The grower should also contact their shellfish growing area specialist during normal business hours for more information. If the grower harvests before obtaining current information on the growing area status, and the growing area is closed, the grower

shall be responsible to return all harvested shellfish to the same location it was harvested from.

d. CDPH/PSU will maintain a current contact listing of CDPH/PSU personnel and certified commercial growers and provide this listing to the WWTPs, the RWQCB, and other applicable parties.

e. Procedures for seasonal/rainfall closures.

(1) CDPH/PSU will establish a duty roster of staff specialists designated to monitor rainfall at all *Conditionally Approved* growing areas, including Drakes Estero. A staff specialist will be designated to be on call for duty as RDO for every day of the year, including weekends and holidays.

(2) The RDO will monitor weather forecasts and reports to determine whether significant rainfall is predicted or has occurred at the *Conditionally Approved* growing areas. If so, the RDO will contact designated rain gauge stations as needed to obtain current rainfall measurements to determine when the conditions requiring a rainfall closure are met. The designated rain gauge station for rainfall closures for Drakes Estero's *Conditionally Approved* growing areas is Davis Instrument gauge located at the PRNS North District Ranger Station on the Pierce Point Road.

(3) When the RDO determines that conditions have occurred which require a shellfish harvest closure, he/she will notify the commercial harvester immediately by telephone that the area is closed to harvesting and will inform them, if known, when it will reopen.

(4) The RDO will maintain records of rainfall measurements and harvest closure notifications.

g. Procedures for emergency closures:

(1) Upon notification of any pollution event that might be cause for an emergency closure of the Drakes Estero growing area, CDPH/PSU will consult with the responsible agency to consider the extent and severity of the pollution. If an emergency closure is needed to protect sport shellfish harvesters, CDPH/PSU will consult with the MCDEHS to determine the location and scope of sport shellfish closures.

(2) CDPH/PSU will notify the harvesters by telephone when it declares an emergency closure. When required under H & S § 112160, written confirmation will be sent to the commercial harvesters and copies will be sent to FDB, DFG, RWQCB, the FDA Regional Shellfish Specialist, and any other interested persons. Emergency closure letters shall contain the information required in H & S § 112160(d), so as to afford the recipients reasonable opportunity to submit data, views, or arguments.

(3) As soon as reasonably possible after declaring an emergency closure, CDPH/PSU will initiate an investigation of the effects of the pollution event on water quality, including such factors as the volume, nature, and location of the discharge, hydrographic factors, and sampling data.

(4) CDPH/PSU will reopen the Drakes Estero shellfish growing areas as soon as it determines that shellfish harvested from the area do not exceed NSSP standards or otherwise pose a public health risk.

(5) CDPH/PSU will notify the commercial harvesters when it decides to reopen the growing area after a closure. When required under H & S § 112160, written confirmation will be mailed to the harvester within five (5) working days after the telephone notification, and copies will be sent to FDB, DFG, RWCQB, the FDA Regional Shellfish Specialist, and other interested parties.

(6) CDPH/PSU will provide to the WWTP, the RWQCB, and to the County Environmental Health Services, a contact list of the certified shellfish growers and CDPH/PSU personnel to be called as required in this document. This listing will be updated as needed.

## 2. San Francisco Bay Regional Water Quality Control Board

a. The San Francisco Bay Regional Water Quality Control Board (SFBRWQCB), as an involved party in this Management Plan, agrees to notify the CDPH/PSU immediately of any pollution event, such as a sewage spill or any discharge of a hazardous chemical, pesticide, or petroleum product, which may adversely affect water and shellfish quality in Drakes Estero. Such events include, but are not limited to:

(1) Any discharge of effluent to Drakes Estero or a tributary due to an accidental or illegal discharge from a septic tank;

(2) Any discharge of hazardous chemicals, pesticides, petroleum or petroleum products that could adversely affect water and shellfish quality in Drakes Estero.

## 3. Marin County Environmental Health Services Division

a. The Marin County EHS will notify CDPH/PSU as soon as possible of any pollution event, such as a discharge of a hazardous chemical, pesticide, or petroleum product, which may pose a threat to water and shellfish quality in Drakes Estero. If any areas are closed to sport shellfish harvesting, it is the responsibility of the County EHS to post the areas and to inform the public of such closures through news media releases.

b. In cases when CDPH/PSU receives notification of a pollution event from information sources other than MCDEHS, CDPH/PSU will notify Marin County EHS of the pollution event and the resulting decision regarding harvest closures and reopening of shellfish growing areas.

#### 4. Wastewater Treatment Plants

The absence of WWTPs that discharge effluent to Drakes Estero or its tributaries makes it unnecessary to develop formal notification procedures between WWTPs and the CDPH/PSU. However, current law requires wastewater treatment facilities to report sewage releases to the Governor's Office of Emergency Services. This reporting requirement is described in the OES Fact Sheet on winter storm preparedness and reporting sewage releases.

#### 5. Impact Assessment

The responsible party shall provide sufficient information to CDPH/PSU such that the magnitude of the impact to the growing area can be assessed. This information should include, but not be limited to, the location of the discharge, a detailed characterization of the discharge when petrochemicals or other hazardous materials are involved, the rate and volume of the discharge, the point of discharge into Drakes Estero and the identification and flow rate of any receiving waters, when appropriate. It is recommended that water samples be collected for the appropriate analysis from the area of impact, as well as from nearby sites outside the zone of impact. Under some circumstances it may also be necessary to analyze shellfish tissue samples to assess the impact to the product in the growing areas.

### IX. CERTIFIED SHELLFISH HARVESTER RESPONSIBILITIES

This section contains the major responsibilities of the certified shellfish harvester; additional responsibilities are included elsewhere in the Management Plan.

#### A. SEED

The certified shellfish harvester shall obtain approval from CDPH/PSU of all sources of seed shellstock, in accordance with the NSSP, prior to placing the seed in the certified growing area.

#### B. HARVEST CLOSURE

DBOC shall cease harvesting operations when notified by CDPH/PSU of a harvest closure or when otherwise required by the closure rules and procedures set forth in this Management Plan. Compliance with this Management Plan is mandatory as a condition of the Shellfish Growing Area Certificate issued by CDPH/PSU. Any violation of a harvest closure declared pursuant to this Management Plan may be cause for suspension or revocation of a certificate or for other disciplinary actions as provided by law. If the harvester has any questions or uncertainties regarding a rainfall closure, he should contact CDPH/PSU for guidance or clarification prior to commencing harvesting or marketing operations.

### 1. Business Hours

During normal State business hours, the harvester should call the CDPH/PSU field staff at (510) 412-4631. If a shellfish specialist cannot be reached the harvester should try alternate contacts on the most current CDPH staff call down list (Appendix A).

### 2. Non-Business Hours

During non-business hours, the harvester should call the CDPH/PSU commercial shellfish GIL. After listening to the recorded message, if more information is needed, the harvester should leave a message identifying the caller and providing the telephone number for a return call.

## C. RECEIVING AND ACKNOWLEDGING NOTIFICATIONS

DBOC shall maintain a 24-hour telephone line with an answering service or recorder and provide the telephone number to CDPH/PSU. If notified of a closure by CDPH/PSU via the telephone message recorder, the harvester shall acknowledge receipt of that message within 24 hours by return call to the CDPH/PSU shellfish specialist at (510) 412-4631 or the CDPH/PSU shellfish GIL at (510) 412-4644. If a recorder answers these lines, after the recorded message the commercial harvester shall leave a message acknowledging receipt of the closure notification.

## D. REPORTS OF SEWAGE OR HAZARDOUS SUBSTANCE SPILLS

If DBOC has knowledge of any potential sewage or hazardous substance spill which may adversely affect water and shellfish quality in Drakes Estero, or of any suspected illness resulting from the consumption of shellfish harvested from any San Francisco Bay area, the commercial harvester shall close the growing area to harvesting and shall notify CDPH/PSU immediately by telephone.

### 1. Business Hours

During normal business hours the commercial grower shall contact CDPH/PSU staff using the call-down list provided in Appendix A.

### 2. Non-Business Hours

During non-business hours, or if CDPH/PSU staff cannot be reached, the grower shall call the State Office of Emergency Services in Sacramento at (800) 852-7550 or (916) 262-1621. Provide your name, firm, and telephone number, the reason for the call, and ask to be contacted by a staff person from the CDPH/PSU. The grower should also leave a message on the GIL at (510) 412-4644 regarding the details of the reported spill.

## E. RECORD KEEPING

DBOC shall keep records showing the dates and times of all harvest closures, reopenings, and harvest operations. These records shall be kept on a form similar to that shown in Appendix D. Completed forms shall be maintained in a file at the harvester's place of business for no less than two years. One copy of the completed form shall be submitted to the CDPH/PSU Richmond office upon request. Since rainfall closures are an important management tool for the growing area, the grower should call the GIL (510) 412-4644 prior to harvesting during any rainfall activity. Storm activities can interfere with CDPH/PSU's ability to obtain current rainfall information. If the grower is still unsure as to the status of the growing area, he should contact the RDO at (510) 412-4633 to determine if the GIL is current, or, during off-hours or on weekends, leave a message on the GIL.

## F. AUDITS

The grower shall comply with all field audits and harvest log reviews. The grower will accommodate CDPH in all aspects of the field audits including but not limited to: scheduling the audit, providing safe boat support to the growing area, and collecting samples at primary sites. Failure to comply with the audits could result in suspension or revocation of the shellfish Growing Area Certificate issued by CDPH/PSU.

## G. WILDLIFE

It is the growers' responsibility to take measures to prevent wildlife (including birds and marine mammals) from defecating on floating shellfish culture bags, barges, floats, or floating wet storage structures from which shellfish are suspended from, or which are within 50 feet of any cultured shellfish. All growers shall consult with the appropriate agencies to determine which measures are acceptable and legal in preventing wildlife from contaminating shellfish. All growers are responsible for any state or federal permits that may be required to prevent wildlife from contaminating shellfish.

Contamination from wildlife can be erratic and therefore unpredictable. The commercial shellfish growers must have on file with CDPH/PSU either a *Wildlife Management Plan* to prevent product contamination or an approved Standard Operating Procedure (SOP) detailing methods used to mitigate fecal contamination of the product caused by this wildlife. The SOP shall include product descriptions, areas designated for product grow-out, transfer, and harvest, and specific procedures and time frames for purposes of mitigating wildlife impact on marketable product. The SOP must have approval by CDPH/PSU prior to implementation and shall be revised yearly or as procedures change. This SOP and *Wildlife Management Plan* are part of a pilot program intended to mitigate the impact of marine mammals and birds to shellfish and growing waters while preventative measures are being implemented, or when measures have been proven ineffective.

## X. REOPENING PROCEDURES

### A. RAINFALL CLOSURES

The *Conditionally Approved* areas will be reopened after a rainfall closure period described in section VIII, unless additional rainfall necessitates extending the rainfall closure. As soon as possible after a rain event has passed CDPH/PSU staff will post a tentative reopening time on the GIL. Prior to reopening following a closure due to rainfall, the grower shall contact the GIL (510 412-4644) to determine if any change has occurred in the reopening sample time for the growing area. If there is any uncertainty about the message or if no message is found on the GIL the grower shall contact the RDO at (510) 412-4633.

### B. SEASONAL CLOSURES

There are no seasonal closures presently identified for these growing areas.

### C. SEWAGE OR HAZARDOUS SUBSTANCE SPILLS

#### 1. Investigation

As soon as reasonably possible after declaring an emergency closure, CDPH/PSU will initiate an investigation of the effects of the pollution event on water quality, including such factors as the volume, nature, and location of the discharge, hydrographic factors, and sampling data. Criteria for determining whether an emergency closure will be implemented as a result of a sewage spill are described in Appendix C.

#### 2. Harvest Reopening

Criteria for reopening growing areas after a sewage spill are described in Appendix C. Due to the variable and unpredictable nature of hazardous material spills, reopening criteria for these events will be determined on a case by case basis.

#### 3. Notification

CDPH/PSU will notify the commercial harvesters when it decides to reopen the growing area after an emergency closure. When required under H & S § 112160, written confirmation will be mailed to the harvester within five (5) working days after the telephone notification, and copies will be sent to FDB, DFG, RWCQB, the FDA Regional Shellfish Specialist, and other interested parties.

## XI. PREVENTION OF ILLEGAL HARVESTING (PATROL)

### A. ILLEGAL HARVESTING OF SHELLFISH

During harvest closures implemented by CDPH, CDPH/PSU staff coordinates regular patrols of shellfish growing areas to prevent illegal harvesting activity on the

part of growers or unauthorized individuals. In addition to this Management Plan, three other documents describe the activities of CDPH/PSU (including that part of the program administered by FDB) and DFG in preventing illegal harvesting of shellfish, preventing the movement of contaminated and/or toxic shellfish into avenues of commerce, and for ensuring the proper handling and identification of shellfish after harvest. These documents are: (1) the Memorandum of Understanding (MOU) between DFG and CDPH, signed August 1991; (2) the CDPH Patrol Policy Document; and (3) the CDPH "Contingency Plan for Marine Biotxin in California Shellfish".

#### B. DEPARTMENT OF FISH AND GAME, WILDLIFE PROTECTION DIVISION

Areas that contain significant naturally occurring shellfish resources are patrolled by California Department of Fish and Game; they also patrol commercial shellfish areas to determine whether illegal shellfish harvesting is occurring at any time. DFG officers have a broad range of enforcement duties, shellfish being only one part of their responsibilities.

The provisions of this Management Plan as it applies to the obligations of the commercial shellfish harvester are enforced by CDPH/PSU, not DFG. DFG agrees to assist CDPH/PSU, when specifically requested by CDPH/PSU, by redirecting some of its patrol effort to monitor commercial harvesters for compliance with harvest closures. If DFG patrol personnel find or suspect any commercial shellfish harvesting in violation of a harvest closure established pursuant to this plan, DFG will report their finding to CDPH/PSU.

#### C. ILLEGAL MARKETING

DFG also makes periodic checks for the illegal marketing of uncertified shellfish by means of market and restaurant inspections. This activity also is carried out by local environmental health agencies. Shellfish in the marketplace are inspected for proper identification and records of purchase. The Marin County EHS or the State CDPH/FDB can confiscate and destroy any shellfish that lack proper identification or have been subject to improper handling or storage. DFG can take action on shellfish that lack proper identification.

#### D. HARVESTER COMPLIANCE WITH CLOSURES

(1) CDPH/PSU (or DFG patrol personnel, or FDB inspectors, upon request from CDPH/PSU) will field check the harvest area to look for harvesting activity during closure periods.

(2) CDPH/PSU will review harvester records of closure and harvesting dates.

(3) CDPH/PSU will spot check by telephone to ascertain whether harvester is conducting operations during closed periods.

(4) CDPH/PSU will maintain records of all compliance monitoring activities and findings.

## XII. WATER AND SHELLFISH QUALITY MONITORING

DBOC is responsible for providing water quality monitoring data from its growing area, as required by the NSSP Model Ordinance, Chapter IV (2009), with coordination and oversight from the CDPH/PSU. The grower submits samples according to a sampling plan approved by CDPH/PSU. Failure to maintain the required sampling schedule is a violation of the NSSP requirements and may result in reclassification of the growing area to *Prohibited* as well as disciplinary actions including, but not limited to, the revocation and or suspension of the growing area certificate as provided for by law. The following is a summary of the requirements associated with routine monitoring of shellfish growing waters and shellfish.

### A. WATER SAMPLING REQUIREMENTS

Water samples are collected at least monthly during periods when the growing area is open for harvesting. Sampling shall be accomplished using the Systematic Random Sampling (SRS) protocol in accordance with the current Sampling Plan for Water Quality Monitoring. The certified shellfish grower submits samples according to a sampling plan approved by CDPH/PSU (see Table 1 for the exact location of monthly primary water quality stations). *The samples shall be collected during any adverse condition(s) identified in Section VII (e.g., ebb tide when potential pollution sources are upstream of the sampling location).* If a sampling date occurs during a rainfall closure, the sampling of *Conditionally Approved* areas shall be conducted on the first open day (i.e., the day of reopening). **The sampling of the *Approved* area shall be conducted on the regularly scheduled sample date.** In order to obtain data of rainfall-related impacts to water quality, additional samples should be collected whenever possible during periods of adverse pollution conditions, such as immediately following rainstorms or on the first days of reopening following a closure. In addition, a number of secondary sampling sites have been identified (Table 2). These secondary stations are sampled less frequently.

The grower shall notify CDPH/PSU in writing prior to the scheduled sampling date when sampling will not occur on the scheduled date (and the area is in the open status) and shall request an alternative date. A reason for the deviation from the Sampling Plan schedule must be provided. If CDPH/PSU approves the request, a new date will be assigned. If CDPH/PSU does not approve the request, the grower will be required to sample on the original date specified in the schedule. Samples collected on incorrect dates will not be identified as a compliance samples, and will not be used in the calculations for verifying classification of the area.

### B. TRANSPORTATION

The grower provides his own boat and all necessary sampling equipment for routine water quality monitoring. Boat trips for CDPH/PSU staff may be scheduled with the grower for special sampling and survey trips, and to monitor sampling by the grower.

Growers shall be responsible for transporting samples to the certified laboratory and meeting proper holding times and temperature limitations as detailed in the sampling plans.

### C. LABORATORY

The County of Sonoma Public Health Laboratory in Santa Rosa, a State-certified laboratory in accordance with the Environmental Laboratory Accreditation Program (ELAP), or any other certified shellfish laboratory, shall analyze samples taken by the grower. Analytical results are to be transmitted directly from the laboratory to CDPH/PSU. The CDPH Microbial Diseases Laboratory in Richmond may analyze supplemental samples submitted under the direction and coordination of CDPH/PSU.

### D. WATER SAMPLES EXCEEDING NSSP CRITERIA

Water sample results that exceed NSSP criteria may indicate a public health threat, and must be responded to immediately. A two-tiered response protocol is described in the following paragraphs. *In any case when a sample exceeding NSSP criteria results in a growing area closure, the closure shall be effective at the date and time the sample was collected. Reopening following satisfactory sample results shall be effective at the date and time that sample results are received from the laboratory.*

Any sample collected from an open area that contains fecal coliform concentrations *greater than or equal to 43 MPN/100 mL but less than or equal to 107 MPN/100 mL*<sup>1</sup> must be re-sampled immediately at the certified grower's expense. Re-sampling must be conducted within 24-hours of notification of initial sample results. If re-sampling is not conducted within the specified time frame, the portion of the lease or growing area represented by the sampling station in question shall be closed for harvest until re-sampling is conducted and results demonstrate that fecal coliform concentrations have returned to acceptable levels. The commercial shellfish grower should refrain from harvesting from the area represented by the sampling station until re-sample results are received and are acceptable relative to commercial growing areas standards.

If re-sampling results are greater than or equal to 43 MPN/100 mL fecal coliform, the represented portion of the lease or growing area shall immediately be closed to harvest. The area will be considered for reopening when further re-sampling produces a result below 14 MPN/100 mL fecal coliform. In certain cases, CDPH staff may consider reopening based on a re-sample result below 43 MPN/100 mL combined with a declining trend in fecal coliform levels at the compliance sampling station and surrounding areas. In order to establish fecal coliform trends in surrounding areas it is recommended that re-sampling be conducted both at the primary compliance station(s) and other surrounding water quality stations. CDPH will advise the grower as to which water quality stations should be sampled.

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<sup>1</sup> The 99<sup>th</sup> percentile of a population with a geometric mean of 14 MPN/100 mL and a 90<sup>th</sup> percentile of 43 MPN/100 mL.

A sample collected from an open area that contains *greater than or equal to 107 MPN/100 mL* fecal coliform shall result in immediate closure of the portion of the growing area represented by the sampling station from which the elevated sample was collected. The area will be considered for reopening when re-sampling produces a result below 14 MPN/100 mL fecal coliform or a result below 43 MPN/100 mL combined with a declining trend in fecal coliform levels at the compliance sampling station and surrounding areas. Reopening criteria are as described above.

If re-sampling continues to yield elevated fecal coliform levels CDPH/PSU will conduct an investigation, which may include additional sampling, to confirm the elevated indicator levels and determine the source, and will notify all relevant regulatory agencies. If a source is identified, CDPH/PSU will refer the matter to the appropriate regulatory agency for corrective action. The commercial shellfish growing area will remain closed until the pollution problem is identified and remediated, and the commercial shellfish growing area is determined to be free of pathogens and to meet NSSP standards, or until the area is correctly reclassified by CDPH/PSU. CDPH will analyze the most recent water quality data and determine if the current shellfish growing area classification is correct or if the commercial growing area needs to be closed or reclassified.

### XIII. MARINE BIOTOXIN MONITORING

#### A. CONDITIONS AND PROCEDURES

DBOC is responsible for monitoring domoic acid and paralytic shellfish poisoning (PSP) biotoxins in the shellfish growing areas. All samples submitted to the CDPH laboratory should be accompanied by a CDPH sample submission sheet. Biotoxin sampling described below shall be conducted during, and for at least two weeks prior to any harvest activities. Long-term phytoplankton monitoring has demonstrated that *Pseudo-nitzschia spp.*—the organism that produces domoic acid—is uncommon in the Estero, and rarely occurs in significant numbers in this waterbody. The Estero is considered to be at greater risk for the occurrence of PSP biotoxins than for domoic acid. DBOC shall comply with the procedures stated in the “Standard Operating Procedures (SOP) for Responding to Elevated Levels of Paralytic Shellfish Poisoning Toxin in Shellfish from Drakes Estero” (Appendix E).

Due to the uncertainty involved with domoic acid and PSP toxicity, special management protocols were developed (Table 4 and Appendix E) that detail response activities for different concentrations of each biotoxin. The protocols detail the specific requirements for maximum time between sampling and harvest. This protocol may be modified as experience with domoic acid and PSP toxicity is gained.

##### 1. Phytoplankton Observations.

DBOC shall collect at least weekly samples of phytoplankton for the early detection of toxic blooms. CDPH will provide training in the sampling of phytoplankton.

## 2. Domoic Acid Analysis.

a. If phytoplankton sampling identifies significant numbers of *Pseudo-nitzschia* spp. in the Estero, CDPH may require DBOC to collect weekly samples of all harvested species for domoic acid analysis. Samples shall be submitted to a lab certified for domoic acid analysis by the CDPH Environmental Laboratory Accreditation Program (ELAP). It is the responsibility of the grower to identify an appropriate ELAP-certified lab. Samples shall be collected as closely as possible to the time of harvest. Specific requirements for maximum time between sampling and harvest are described in Table 4. If the CDPH laboratory is available, all samples shall arrive at the laboratory by Tuesday or Wednesday morning but no later than Thursday morning. More frequent sampling may be required by CDPH to adequately track an impending or existing bloom. Sampling shall continue until domoic acid and *Pseudo-nitzschia* levels fall to acceptable levels as determined by CDPH/PSU, and declining trends are observed in the Estero and surrounding waters.

b. If significant numbers of *Pseudo-nitzschia* are identified in the Estero, CDPH/PSU may require DBOC to collect a sample of each harvest lot and immediately test it for the presence of domoic acid using a commercially-available diagnostic kit. DBOC shall follow the protocol provided by CDPH (Appendix F). Assay results and other required information shall be recorded on page 2 of the sample submission form provided. The test strip shall be labeled as described in the assay protocol (Appendix F). A digital photograph of the developed test strip or a brief report of the assay result shall be emailed to [glangloi@cdph.ca.gov](mailto:glangloi@cdph.ca.gov) and [vanessa.zubkousky@cdph.ca.gov](mailto:vanessa.zubkousky@cdph.ca.gov) on the day of the test. Test strips shall be shipped to CDPH with the remaining shellfish sample to the address provided on the sample submission form.

## 3. Paralytic Shellfish Poisoning Analysis.

DBOC shall comply with procedures described in the “Standard Operating Procedures for Responding to Elevated Levels of Paralytic Shellfish Poisoning Toxin in Shellfish from Drakes Estero” (Appendix E).

## 4. Field Sampling Protocol

DBOC shall follow the field sampling protocol for marine biotoxins provided by CDPH for sample collection, preparation, and submission (Appendix F).

## 5. Additional Sampling

DBOC shall increase the sampling frequency, expand sampling to include any other commercial shellfish species designated in the Shellfish Growing Area Certificate, and/or cease harvesting as directed by CDPH.

## B. CLOSURE CRITERIA

When a sample exceeds the biotoxin alert level, the growing area shall be closed immediately, effective on the date and time the sample was collected. FDB will be notified and will be responsible for decisions regarding product recall or destruction.

### 1. Domoic Acid Alert Level

In compliance with the NSSP Model Ordinance, the alert level for domoic acid is reached when the concentration of the toxin in shellfish meat equals or exceeds 20 micrograms per gram of tissue (i.e., 20 parts per million [ppm]).

### 2. Paralytic Shellfish Poisoning Alert Level

The “Standard Operating Procedures (SOP) for Responding to Elevated Levels of Paralytic Shellfish Poisoning Toxin in Shellfish from Drakes Estero” (Appendix E) describes the alert levels that shall be used in managing shellfish growing areas in Drakes Estero.

### 3. Samples Exceeding the Alert Level

The Drakes Bay Oyster Company shall immediately implement a harvest closure when a domoic concentration is detected at or above the respective alert level in one or more samples of commercial product in the growing area prior to harvest, or in commercial channels after harvest. DBOC shall contact FDB to discuss issues pertaining to harvested product. Closures due to elevations in PSP concentrations shall follow the guidelines established in the “Standard Operating Procedures (SOP) for Responding to Elevated Levels of Paralytic Shellfish Poisoning Toxin in Shellfish from Drakes Estero” (Appendix E).

A biotoxin concentration at or above the respective alert level in one or more samples of commercial product in the growing area prior to harvest, or in commercial channels after harvest, will trigger an immediate closure of the growing area until follow-up sampling confirms that the toxin has returned to safe levels as described in section E, Table 4 and Appendix E. If notified of a biotoxin-related closure or harvest restriction by CDPH/PSU via telephone message recorder, the harvester shall acknowledge receipt of the message within 24-hours by return call to the CDPH/PSU shellfish specialist at (510) 412-4631, the unit supervisor at (510) 412-4635, or the CDPH/PSU shellfish growers information line (GIL) at (510) 412-4644.

### 4. Failure to Submit Required Samples

It is the responsibility of DBOC to collect and ship the required samples to a certified laboratory for biotoxin analysis. Failure to submit the required samples or inability of the analytical laboratory to provide results in a timely manner may result in an immediate harvest closure. CDPH/PSU will notify FDB, who will determine if a product recall is warranted.

### C. RESTRICTED HARVEST CRITERIA

The special management protocols in Table 4 and Appendix E outline multiple alert stages for concentrations of biotoxins below the closure alert level. The tables identify restricted harvest criteria and sampling actions for each stage of toxin concentration. When there is an increase in alert stage, the increase will be effective on the date and time that samples are collected. Alert stages below the closure alert level will be decreased effective on the sampling date and time after the sample results are received from the laboratory. To be considered for a decrease in alert stage, successive samples collected at least three (3) days apart (i.e., 72 hours) must meet the toxin level requirements for that stage.

### D. SIZE OF CLOSED AREA

Harvest closure or implementation of harvest restrictions for DBOC is detailed in Table 4 and Appendix E. In reopening any commercial area, or any part of that area located within two miles by water of any site where toxin in a shellfish sample was detected above the alert level, the criteria in section G apply.

### E. SPECIES RESTRICTIONS

A closure or harvest restriction of a commercial growing area may be limited to the shellfish species determined to have reached the alert level, or it may include all species in the growing area.

### F. SAMPLING DURING A MARINE BIOTOXIN CLOSURE OR HARVEST RESTRICTION

Follow-up sampling will be continued throughout a closure or harvest restriction. All commercially harvestable shellfish species in the growing area will be sampled unless otherwise specified by CDPH. In cases of elevations in PSP concentrations, DBOC shall sample according to the guidelines established in the "Standard Operating Procedures (SOP) for Responding to Elevated Levels of Paralytic Shellfish Poisoning Toxin in Shellfish from Drakes Estero" (Appendix E). In cases of elevations in domoic acid concentrations, CDPH will determine sampling sites and times. Sites will be selected so that no part of any certified growing area is more than two miles by water from a sampling site for the species of shellfish harvested in that growing area.

### G. REOPENING CRITERIA

Prior to being considered for reopening from a biotoxin closure, The Drakes Bay Oyster Company shall collect successive samples at least three (3) days apart (i.e., 72 hours) that are found to be below the federal alert level for the toxin of concern. Reopening shall be contingent upon these sampling results and downward trends in biotoxin levels in the surrounding area. A reopened area is still subject to the harvest restrictions set forth in Tables 3 and Appendix E. Reopening shall be effective on the date and time that sample results are received from the laboratory.

Harvesting during a growing area closure by a certified commercial grower is a serious violation and may result in suspension or revocation of their growing area certificate.

#### XIV. GROWING AREA REEVALUATION

CDPH/PSU will review and reevaluate water quality and other sanitary survey data at least annually, in accordance with procedures set forth in the Model Ordinance, Chapter IV (2009), to confirm the classification of the growing area and to determine if changes are needed in the closure rules. At least once a year, CDPH/PSU will conduct an on-site audit to determine grower compliance with the water quality sampling plan. The findings will be presented in an annual growing area sanitary survey update report.

When a growing area fails to meet the water quality standards for its classification, the NSSP requires that if the annual reevaluation determined that conditions have changed based on the information and data collected during the annual review and that the growing area classification is incorrect, immediate action shall be initiated to reclassify the area. If determined that an emergency condition or situation exists, then the growing area will be immediately (within 24 hours) placed in the closed status.

#### XV. AGREEMENT OF INVOLVED PARTIES

The NSSP Model Ordinance, Chapter IV (2009) section @.03 C.4(a), requires that "The Management Plan shall be developed by the authority, in coordination with: the local shellfish industry, the individuals responsible for the operation of any wastewater treatment plants involved and any local or State agencies." In addition, NSSP Model Ordinance, Chapter IV (2009) section @.03 C.4(b) states "Failure of any one party to agree shall constitute sufficient justification to deny creation of a Conditionally Approved area." This Management Plan is in effect as long as the area remains certified and may be modified when conditions warrant it, with the concurrence of the involved parties. (The Sanitary Survey Report is updated annually; any significant changes in this report will necessitate a revision to the Management Plan).

##### A. PUBLIC AGENCIES

Authorized persons from the following public agencies are required to review this Management Plan and to sign and return the statement of agreement provided in Appendix G, which states that "The undersigned has read and understands the purpose of the '*Conditionally Approved*' classification of the commercial shellfish growing area in Drakes Estero and the conditions of its Management Plan, dated \_\_\_\_\_, and agrees to comply with the conditions and procedures set forth in the Management Plan."

1. California Department of Fish and Game, Wildlife Protection Division

2. San Francisco Bay Regional Water Quality Control Board
3. Marin County Community Development Agency, Division of Environmental Health Services

## B. COMMERCIAL SHELLFISH GROWER

Compliance with this Management Plan is mandatory for the commercial shellfish grower as a condition of their Shellfish Growing Area Certificate issued by CDPH/PSU. Noncompliance may result in suspension or revocation of the certificate. DBOC is requested to review this document and to sign and return the statement provided in Appendix G, which states that "The undersigned has read and understands the purpose of the '*Conditionally Approved*' classification of the commercial shellfish growing area in Drakes Estero and the conditions of its Management Plan, dated \_\_\_\_\_, and understands that compliance with the conditions and procedures set forth in the Management Plan is mandatory as a condition of Shellfish Growing Area Certificate issued by the California Department of Public Health."

## C. FORWARDING OF SIGNED STATEMENTS

Signed statements shall be mailed to:

California Department of Public Health, EMB  
850 Marina Bay Parkway, # G165  
Richmond, CA 94804

## XVI. SUMMARY OF AGREEMENTS

### A. CALIFORNIA DEPARTMENT OF FISH AND GAME

Upon request from CDPH/PSU, to field check commercial shellfish growing areas during closed periods to monitor for illegal harvesting activity, and to report compliance monitoring activities and findings to CDPH/PSU.

### B. SAN FRANCISCO BAY REGIONAL WATER QUALITY CONTROL BOARD

To notify, or to require designated persons or agencies to notify, CDPH/PSU of any pollution events, as soon as they become aware of discharges which may pose a threat or adversely affect water quality in Drakes Estero.

### C. MARIN COUNTY COMMUNITY DEVELOPMENT AGENCY, DIVISION OF ENVIRONMENTAL HEALTH SERVICES.

To notify CDPH/PSU as soon as possible of any pollution events, such as discharges of hazardous chemicals, pesticides, or petroleum products, which may adversely affect water and shellfish quality in Drakes Estero.

# TABLES

Table 1. Drakes Estero primary sampling stations.

<b>Sampling Site</b>	<b>Location</b>
WQ Station #4	Outer Barries Bay
WQ Station #7	Outer Home Bay
WQ Station #8	Inner Schooner Bay, water intake
WQ Station #9	Inner Schooner Bay
WQ Station #13	Drakes Estero, North Central Area
WQ Station #15	Inner reach of Creamery Bay
WQ Station #17	Outer Barries Bay, Approved Area

Table 2. Drakes Estero secondary sampling stations.

<b>Sampling Site</b>	<b>Location</b>
WQ Station #1	Inner Schooner Bay
WQ Station #2	Outer Schooner Bay
WQ Station #3	Outer Creamery Bay
WQ Station #6	Drakes Estero, East Shore
WQ Station #10	Inner Home Bay
WQ Station #11	Inner Creamery Bay
WQ Station #12	Inner Barries Bay
WQ Station #14	Drakes Estero, South Central Area
WQ Station #16	Drakes Estero, West Shore
WQ Station #18	Drakes Estero, South Central Area
WQ Station #19	Drakes Estero, South Central Area
WQ Station #20	Outer Home Bay
WQ Station #21	Outer Schooner Bay, East Shore

Table 3. Rainfall closure criteria for Drakes Estero by growing area.

<b>Growing Area</b>	<b>24-Hour Cumulative Rainfall Total Threshold&gt;</b>	<b>Start Closure</b>	<b>Closure Length</b>	<b>Prior 7 day Cumulative Rainfall &gt;2.0 inches</b>
Inner Schooner Bay	0.70 Inches	When the approved rain gauge is exceeded	End of storm + 168 hrs (7 days)	24 hrs (1 day)
<i>All Conditionally Approved areas except Inner Schooner Bay</i>	0.75 Inches	When the approved rain gauge is exceeded	End of storm + 72 hrs (3 days)	24 hrs (1 day)
<i>Approved area</i>		Only under extreme environmental conditions <sup>1</sup>		

<sup>1</sup> Extreme environmental conditions occur when the cumulative seven day rainfall exceeds 2.50 inches. All of the growing areas are immediately closed.

Table 4. Management decision criteria for domoic acid toxicity in bivalve shellfish.

<b>ALERT STAGE</b>	<b>DOMOIC ACID CONCENTRATION<sup>1</sup></b>	<b>ACTION<sup>2,3</sup></b>
<b><i>Jellett Result Negative<sup>4</sup> (optional):</i></b>		
<b>No Alert</b>	<b>Nondetectable: &lt; 2.5 ppm</b>	- Routine Sampling; - Harvest date must be < 96 hours from sampling date.
<b>1<sup>st</sup> Stage</b>	<b>2.5 – 4.9 ppm</b>	- Harvest date must be < 48 hours from sampling date; - Immediate resample <sup>5</sup> ; - Additional sampling as directed.
<b>2<sup>nd</sup> Stage</b>	<b>5 – 9.9 ppm</b>	- Harvest date must be < 24 hours from sampling date; - Immediate resample; - Immediate harvest closure if harvest lot laboratory results have not been obtained; - Twice-weekly sampling at minimum <sup>5</sup> ; - Expand sampling to adjacent growing areas.
<b><i>Jellett Result Positive<sup>4</sup> (optional):</i></b>		
<b>3rd Stage</b>	<b>10 – 19.9 ppm</b>	- Batch release <sup>3,5,6</sup> ; - Immediate harvest closure if harvest lot laboratory results have not been obtained; - Immediate resample; - Twice-weekly sampling at minimum <sup>5</sup> ; - Expand sampling to adjacent growing areas.
<b>4th Stage</b>	<b>≥ 20 ppm</b>	- Closure of growing area; - Batch release <sup>3,5,6</sup> of shellstock from adjacent harvest areas that remain open; - Twice-weekly sampling <sup>5</sup> ; - Expand sampling to adjacent growing areas.

<sup>1</sup> As determined by NSSP-approved analytical method. Specified concentrations are subject to change based on acquisition of new data.

<sup>2</sup> No harvesting can be conducted without quantitative PSP and Domoic Acid results from samples collected within 96 hours prior to harvest.

<sup>3</sup> For each alert stage, the alert shall be continued until either (a) a higher stage alert is declared, or (b) two successive samples taken over a minimum period of three days have domoic acid levels consistent with a lower alert stage and downward trends in biotoxin levels in the surrounding area.

<sup>4</sup> Applies to both the rapid extraction and methanol extraction methods.

<sup>5</sup> Contingent upon arrangement with certified laboratory.

<sup>6</sup> Batch release means that the grower must submit samples from each harvested lot of shellfish and shall not release that lot to market until CDPH has verified its safety based on satisfactory analytical results. Product must be held under appropriate temperature control while awaiting analytical results. Growers should consult the CDPH Food and Drug Branch for guidance on proper handling and storage of the batch-harvested shellstock.

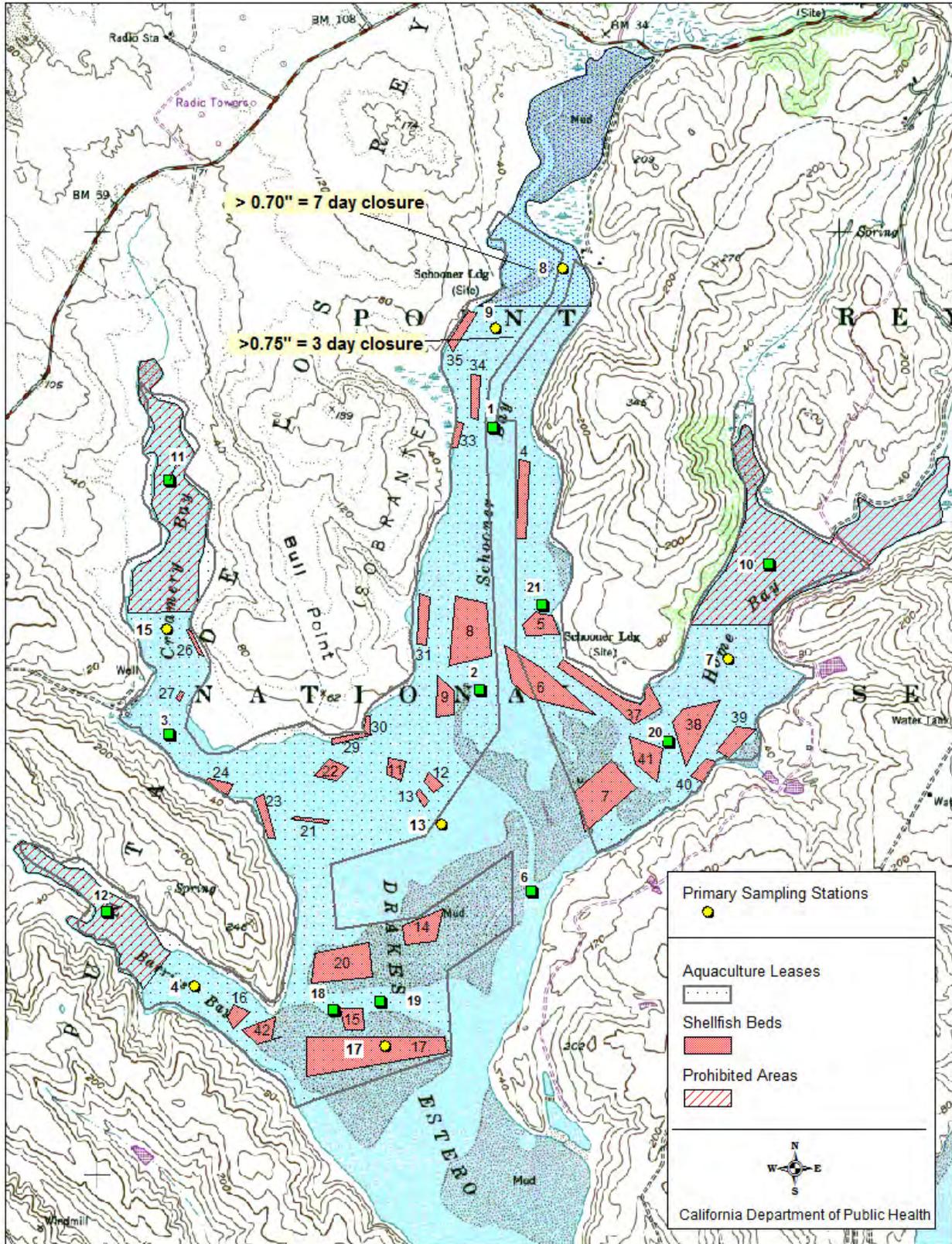
# FIGURES

Figure 1. Drakes Estero, California.



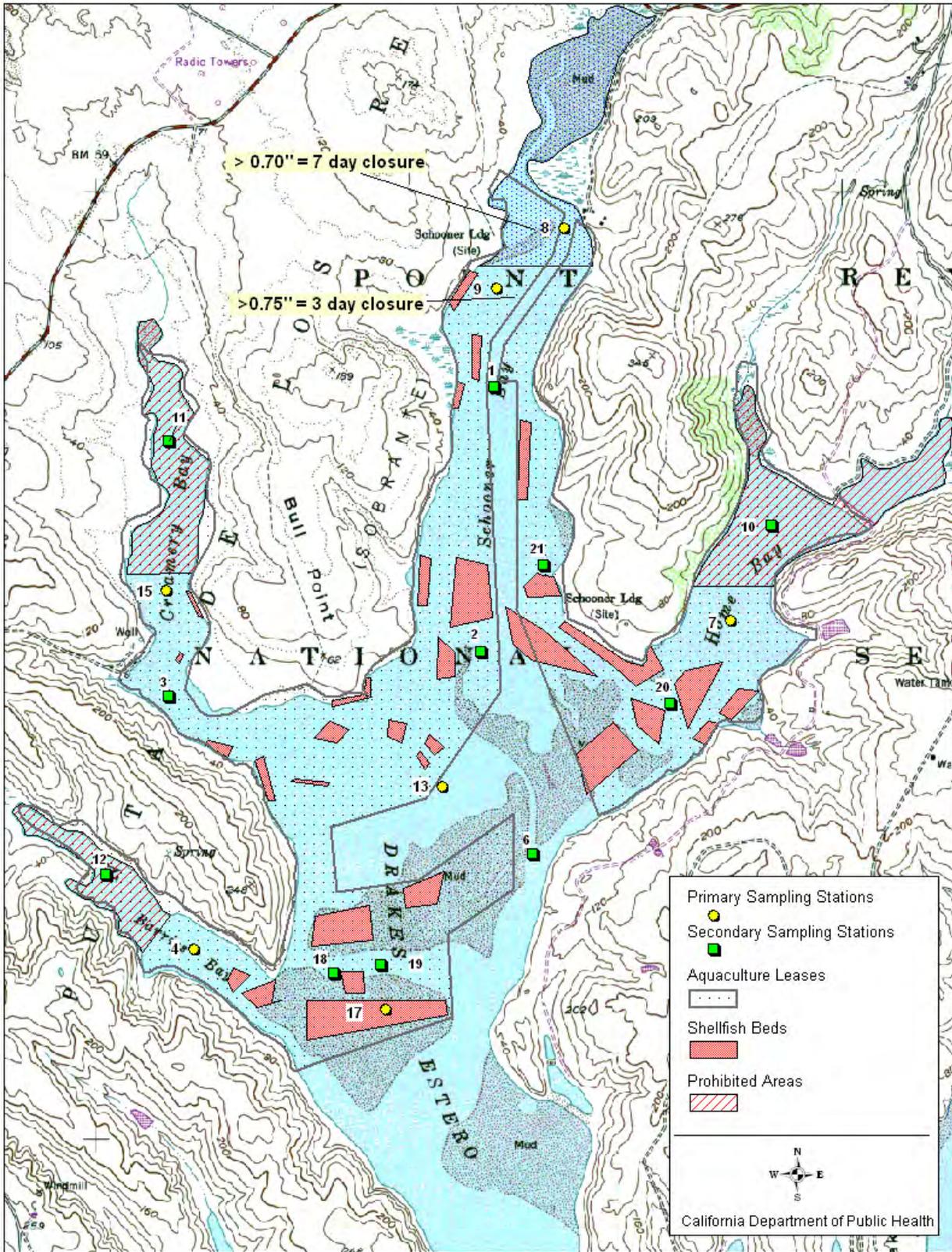
Figure 1. Location of Drakes Estero, California.

Figure 2. Drakes Estero leases and growing beds<sup>2</sup>.



<sup>2</sup> This is not a legal representation of the exact lease locations or bed locations. The beds indicated may not include all of the beds located in the Estero.

Figure 3. Drakes Estero primary and secondary sampling locations<sup>3</sup>.



<sup>3</sup> This is not a legal representation of the exact lease locations or bed locations. The beds indicated may not include all of the beds located in the Estero.

# APPENDICES

Appendix A. Contact List for Commercial Shellfishing at Drakes Estero

**CALL-DOWN CONTACT LIST**

Vanessa Zubkousky  
Preharvest Shellfish Unit  
Environmental Management Branch  
California Department of Public Health  
510-412-4631

Gregg Langlois  
Chief, Preharvest Shellfish Unit  
Environmental Management Branch  
California Department of Public Health  
510-412-4635

Jill Baltan  
Preharvest Shellfish Unit  
Environmental Management Branch  
California Department of Public Health  
510-412-4633

Eric Trevena  
Preharvest Shellfish Unit  
Environmental Management Branch  
California Department of Public Health  
916-449-5695

**AFTER HOURS SHELLFISH NOTIFICATION:**

Office of Emergency Services  
800-852-7550 or 916-262-1621

**OTHER CONTACTS**

Glenn Takeoka, Chief  
Environmental Health Services Section  
California Department of Public Health  
916-449-5693

Tony Falzone  
Food and Drug Branch  
California Department of Public Health  
916-650-6600

Kirsten Ramey  
California Department of Fish and Game  
Marine Aquaculture Coordinator  
707-445-5365

Cicely Muldoon, Superintendent:  
Point Reyes National Seashore  
415-663-8525  
William Shook, Resource Management Spec.:  
415-663-8525

Kristine Barsky  
Associate Marine Biologist  
California Department of Fish and Game  
Marine Resources Division  
805-568-1220

Rebecca Ng, Director  
Marin County Community Development Agency,  
Div. of Environmental Health Serv  
3501 Civic Center Dr.  
San Rafael, CA 94903  
415-499-6919

California Department of Fish and Game  
Warden: Matt Parlato  
707-568-7782

Dominic Gregorio  
State Water Resources Control Board  
Ocean Standards Unit, Division of Water Quality  
1001 I. St.  
Sacramento, CA 95814

Tim Sample  
Regional Shellfish Specialist  
U.S. Food and Drug Administration  
206-553-7001, ext 45

Michael Antee  
Regional Shellfish Specialist  
U.S. Food and Drug Administration  
206-553-7001, ext 13

Jessie DeLoach  
Regional Shellfish Specialist  
U.S. Food and Drug Administration  
253-383-5252 x115

Kevin Lunny  
Drakes Bay Oyster Company  
17171 Sir Francis Drake Blvd.  
Inverness, CA 94937  
415-669-1149 or 415-669-1209

Janet Hashimoto, Chief  
Marine Protection  
U.S. Environmental Protection Agency  
415-947-8021

Dale Hopkins, Water Quality Planning Unit  
Regional Water Quality Control Board  
San Francisco Bay Region  
1515 Clay St., Suite 1400  
Oakland, CA 94612  
510-286-4398

Coast Guard, In cases of emergency  
Officer of the day:  
415-331-8247

Appendix B. Notification of Shellstock Movement During a Growing Area Closure

Shellstock removed from growing waters during closure periods shall have the number of hours that the shellstock was out of the water added onto its respective closure time before it can be harvested. All shellfish must be in water for the entire length of time that it would otherwise have been had it not been harvested before the end of the rainfall closure. If shellstock is removed from growing waters during closed periods, it must be tagged to ensure that the shellstock is not harvested for direct marketing prior to the required depuration time.

Email or fax this form to CDPH/PSU at:  
Email: [vanessa.zubkousky@cdph.ca.gov](mailto:vanessa.zubkousky@cdph.ca.gov)  
Fax: (510) 412-4637

Company Name: \_\_\_\_\_

Date of Movement: From \_\_\_\_\_ To: \_\_\_\_\_

Location of Product: \_\_\_\_\_

Species of Product Moved: \_\_\_\_\_

Reason for Movement: \_\_\_\_\_

Estimated date(s) product will be returned: \_\_\_\_\_ Location: \_\_\_\_\_  
\_\_\_\_\_ Location: \_\_\_\_\_  
\_\_\_\_\_ Location: \_\_\_\_\_  
\_\_\_\_\_ Location: \_\_\_\_\_

Comments (Including method used to ensure shellstock requiring added holding time before harvesting is adequately identified (required for approval)) \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

Preharvest Shellfish Unit acknowledgement of shellstock movement.

Signature \_\_\_\_\_ Date \_\_\_\_\_

## Appendix C. Wastewater Upset Response Procedures.

The following procedures shall be followed in the event of a failure in the wastewater collection system resulting in a “wastewater upset”. A wastewater upset occurs whenever inadequately treated wastewater has exited the confines of the wastewater treatment or collection system and has the potential to enter Drakes Estero or one of its tributaries.

In the event of a wastewater upset that results in a potential or actual discharge of inadequately treated effluent into Drakes Estero and its tributaries, the responsible agency will notify CDPH and the grower of the location and estimated volume of wastewater released to the waterbody. Upon notification of a sewage spill the shellfish grower shall consider their growing areas closed to harvesting. CDPH/PSU will contact the shellfish grower to confirm that notification of the wastewater upset event has been received, and that grower has ceased harvest operations prior to the start of the upset (See figures C-1 and C-2). Harvesting shall not occur until after CDHS/PSU has evaluated the event and determined the required actions. If harvesting has occurred after the start of the spill, the grower should consult CDPH Food and Drug Branch to determine the disposition of harvested shellstock.

### Spill Volume Thresholds:

CDPH/PSU will establish that the spill has been abated and determine if the spill volume and location warrant closure of the growing area. Minimum spill volume thresholds that will result in closure are presented in Table C-1. For spill locations not specified in Table C-1, thresholds will be determined by interpolation or extrapolation from a nearby location in Table C-1. If this is not possible, threshold spill volume for the new location will be calculated in the manner described in the Drakes Estero Sanitary Survey.

CDPH/PSU may modify the above procedure based on the specific conditions of the reported spill. After the determination has been made, CDPH/PSU will notify the grower of the status of the growing area(s).

### Spill Attenuation:

CDPH/PSU will conduct analyses to estimate when fecal coliform concentrations resulting from an upset will be attenuated to acceptable levels (14 MPN/100 mL) through tidal flushing. Attenuation analysis will be conducted as described in the Drakes Estero Sanitary Survey. The analysis only accounts for tidal flushing, and ignores bacterial die-off. This conservative approach is appropriate because die-off rates of many of the pathogenic viruses associated with sewage, and for which fecal coliforms serve as imperfect indicators, are unknown.

CDPH/PSU will instruct the grower to begin collecting samples when the attenuation analysis indicates acceptable water quality. If this date falls within a rainfall closure, sampling will not be conducted until the rainfall closure ends. The grower should not sample until instructed to do so by CDPH.

Sampling and Reopening Criteria:

When instructed by CDPH, the grower will collect one water quality sample at each site specified in Table 1 and deliver samples to an ELAP-certified laboratory for fecal coliform analysis. Fecal coliform results must be equal to or lower than 14 MPN/100mL for the growing area to be considered for reopening. In addition, consistent, acceptable levels of fecal coliforms must be obtained from all sites in the surrounding area, and the source of contamination must have been abated. If results for any sampling stations are above the acceptable level, growers will be instructed to resample. Sampling will continue until all sampling stations meet the above target. Results from all sampling stations must meet the target before the growing area can be reopened.

Table C-1. Sewage upset threshold volumes to close shellfish growing waters<sup>4</sup> to harvest activities.

<b>Receiving water</b>	<b>Threshold Volume (Gallons)</b>	<b>Affected oyster beds</b>
Home Bay	28	Home bay
Schooner Bay	76	Schooner bay
Home Bay plus body of estero	222	Home Bay plus body
Schooner Bay plus body of estero	269	Schooner bay plus body

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<sup>4</sup> Volumes are based on the distance to the nearest growing waters.

MANAGEMENT PLAN FOR DRAKES ESTERO, JANUARY 2012

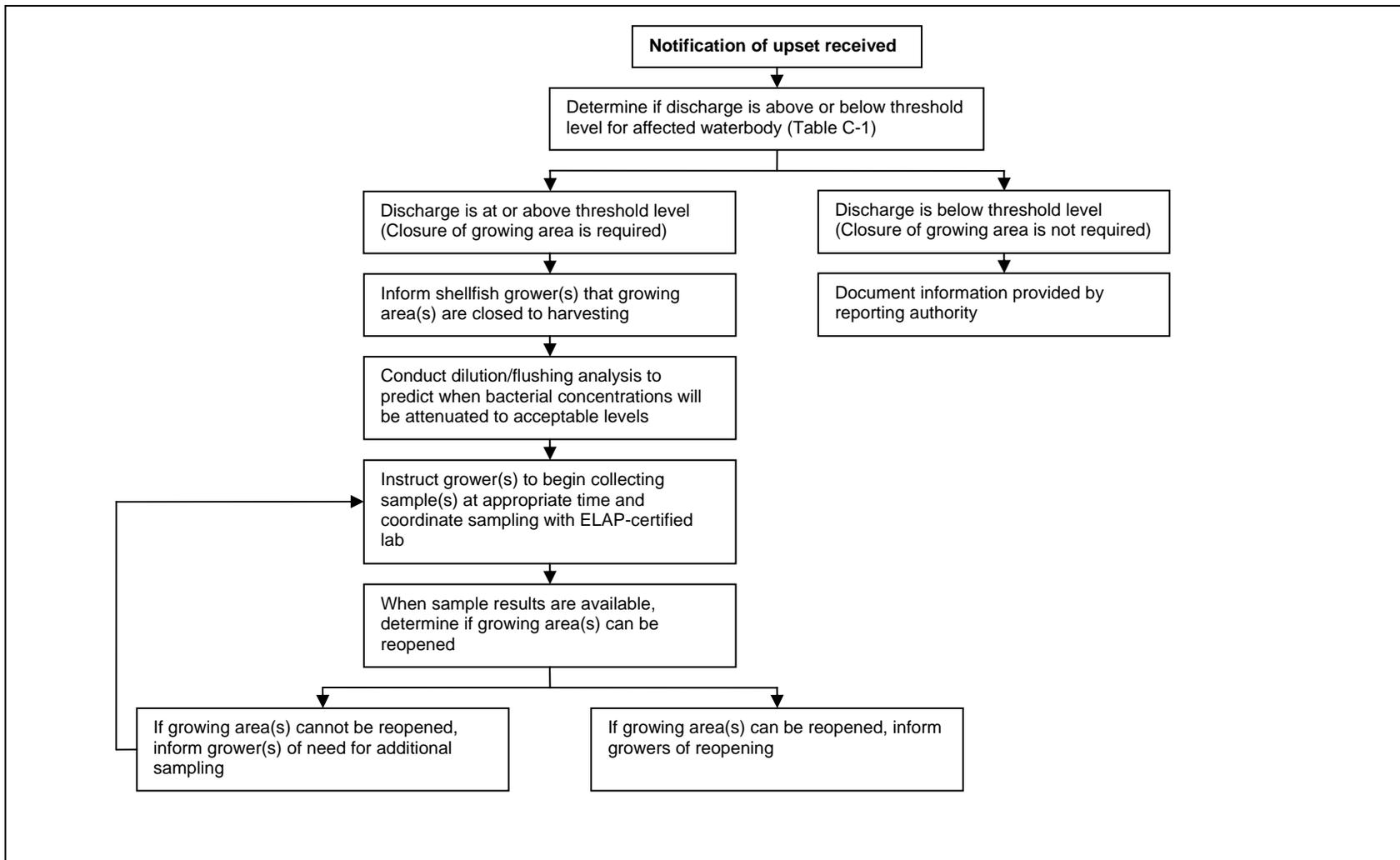


Figure C-1. Wastewater upset decision tree for California Department of Public Health.

MANAGEMENT PLAN FOR DRAKES ESTERO, JANUARY 2012

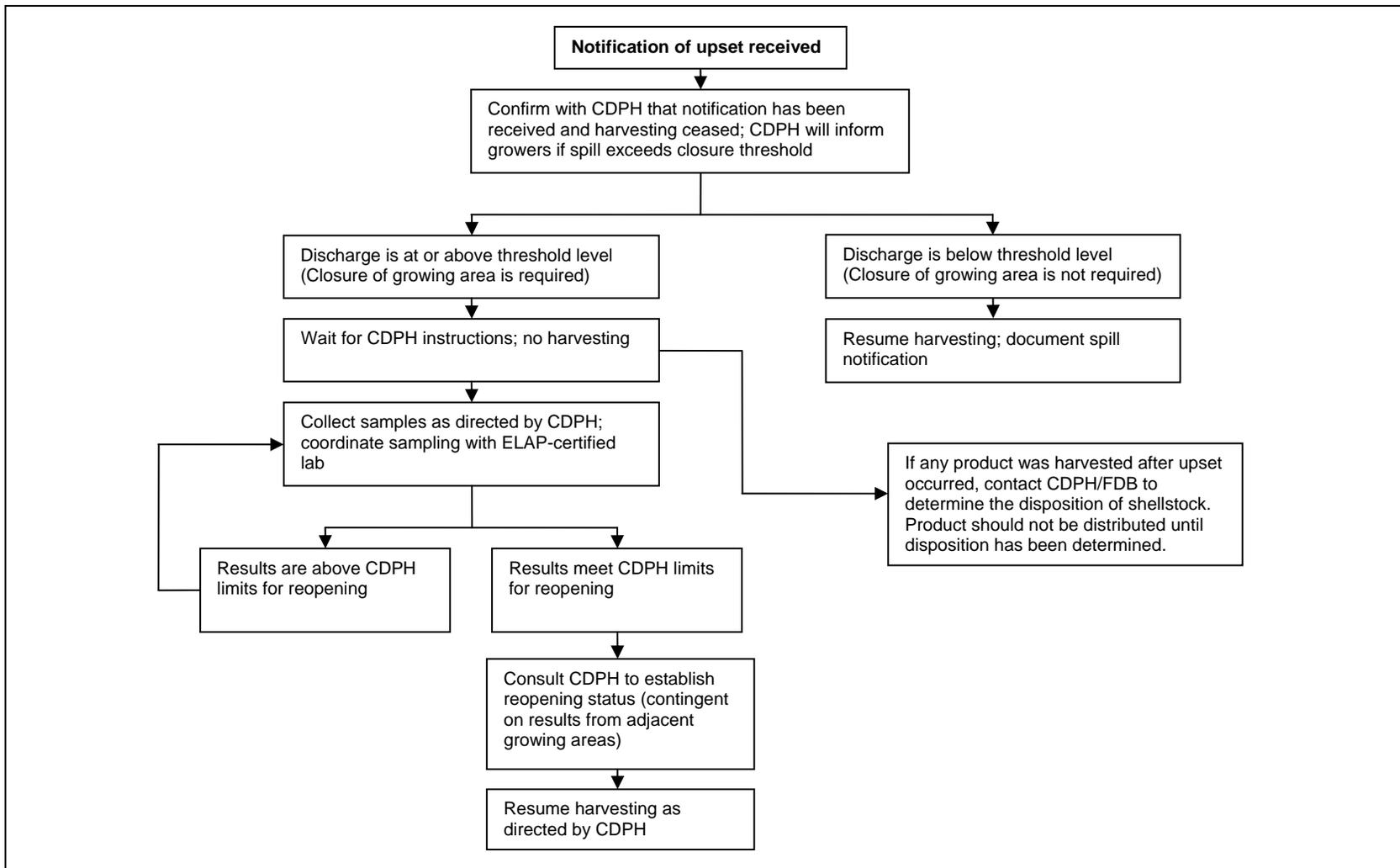


Figure C-2. Wastewater upset decision tree for growers.

MANAGEMENT PLAN FOR DRAKES ESTERO, JANUARY 2012

Appendix D. Harvester's Monthly Report of Rainfall and Harvest Operations

HARVESTER \_\_\_\_\_  
 GROWING AREA \_\_\_\_\_

MONTH/YEAR \_\_\_\_\_  
 RAIN GAUGE LOCATION \_\_\_\_\_

This form is for the use of California certified shellfish growers who harvest from conditionally approved areas. Growers are required to complete and file this form in accordance with the Management Plan for the conditionally approved area in which they conduct harvesting operations.

Day	Rainfall in inches	Closure & Reopening Dates and Times	Harvest Times & Amounts
1			
2			
3			
4			
5			
6			
7			
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## Appendix E. Standard Operating Procedure for Responding to Elevated Levels of Paralytic Shellfish Poisoning Toxin in Shellfish from Drakes Estero

The purpose of this Standard Operating Procedure (SOP) is to set forth guidelines for actions to be taken by the California Department of Public Health (CDPH) and the Drakes Bay Oyster Company (DBOC) at any time during which DBOC holds a valid certificate to harvest oysters in Drakes Estero (the Estero) and when paralytic shellfish poisoning (PSP) toxin is detected in shellfish samples taken from the Estero or Drakes Bay. The protocol set forth in this SOP is based on the requirements of the National Shellfish Sanitation Program and the laws provided for Drakes Estero in recognition of the fact that DBOC harvests and markets oyster exclusively, and that it takes mussels from the Estero only for use as indicators of PSP activity.

This SOP does not alter the responsibility of DBOC to comply with all terms and conditions specified by CDPH in connection with its issuance of DBOC's Shellfish Growing Area Certificate.

This SOP does not limit the authority of CDPH to take any action it deems necessary to protect and preserve the public health, including closure of the Estero to commercial shellfish harvesting, notwithstanding the terms of this SOP.

Nothing in this SOP restricts CDPH or any agency assisting CDPH from engaging in sampling, public information, or patrol activities pertaining to sanitation of shellfish or PSP prevention. Nothing in this SOP precludes CDPH from taking any other necessary actions it is otherwise legally authorized to take to ensure sanitation of shellfish after harvest, including embargo and confiscation, to prevent human illness due to consumption of shellfish.

CDPH shall notify DBOC of any decision made pursuant to this SOP that results in a closure to harvesting of any part of the Estero. Such notice may be accomplished by oral communication with an officer of DBOC, as specified in Attachment 1. DBOC waives its right to written notice regarding closure of specified parts of the Estero that do not include the entire growing area. DBOC retains its right to written notice and hearings when the entire growing area is closed by CDPH. CDPH shall provide written confirmatory notice following oral communications when the entire growing area is closed.

### Definitions:

1. "The inner parts of the Estero" means the upper end of Schooner Bay including Beds 1 through 3 and 33 through 35, inclusive, and the upper end of Creamery Bay including Beds 25 through 27, inclusive, as shown on the map of Drakes Estero included as Attachment 2 to this SOP.
2. "The outer parts of the Estero" means all parts of Drakes Estero not included in the definition of the inner parts of the Estero.
3. "Micrograms" means millionths of a gram of PSP toxin per 100 grams of meat in a shellfish sample, as determined by laboratory analysis.
4. A "harvest" means a collection of oysters taken from the Estero from a single numbered bed, as shown on Attachment 2, during a 24-hour period.

SPECIAL PSP MANAGEMENT PROCEDURES (Also see summary, Table 1)

**Regular sampling:** Early warning of possible PSP problems in Drakes Estero shall be provided by mussel samples taken from Drakes Bay and from within the Estero itself. The PSP sentinel station maintained by CDPH at the former Coast Guard lifeboat station near Chimney Rock, Drakes Bay, shall serve as a primary early-warning station outside the Estero. Two primary early-warning stations within the Estero shall be the buoy located in the main channel and Bed 12 (see attachment 2). Once each week when oyster harvesting is being conducted in the Estero, DBOC shall submit one sample of mussels from the buoy station and Bed 12, and one sample of oysters from Bed 12 and the principal harvest bed currently in use.

**Increased sampling:** If, during a non-alert period when PSP toxin has been below detection levels, a shellfish sample from either Drakes Bay or the Estero has a detectable level of PSP toxin, indicating the possible start of a bloom event, DBOC shall submit follow up samples: a mussel sample from the buoy station, mussel and oyster samples from Bed 12 and an oyster sample from all harvest beds currently in use. Sampling activities within the Estero shall otherwise be increased as directed by CDPH.

**First stage alert:** If a mussel sample from Bed 12 or any other location in the Estero has from 80 to 400 micrograms, and no oyster sample from the Estero equals or exceeds 80 micrograms, the Estero shall be in a first stage alert. A mussel sample shall be taken twice a week from the buoy station and Bed 12, and oyster samples shall be taken twice per week from Bed 12 and all beds from which oysters are harvested. Frequency and locations of sampling shall be increased if so directed CDPH.

A first stage alert shall be continued until either (a) a second or third stage alert is declared, or (b) two successive samples of mussels from both locations taken over a minimum period of three days, and all other mussel samples taken from the Estero within the same time period, have PSP toxin levels lower than those specified above as requiring a first stage alert.

**Second stage alert:** If an oyster sample from the outer parts of the Estero has from 80 to 200 micrograms, or a mussel sample from Bed 12 or any other location in the Estero exceeds 400 micrograms, the Estero shall be in a second stage alert. The outer parts of the Estero shall be closed to oyster harvesting.

Oysters may be harvested during a second stage alert only from the inner parts of the Estero. DBOC shall obtain clearance from CDPH for each harvest before marketing oysters harvested during a second stage alert. This harvest clearance shall be based upon PSP toxin analysis of shellfish samples performed by CDPH's Microbial Disease Laboratory (MDL) at Richmond, California. DBOC shall be responsible for shipping or delivering the shellfish samples to the MDL.

If DBOC harvests during a second stage alert, one oyster sample shall be taken from each harvest, samples of mussels shall be taken twice per week from the buoy station, and samples of mussels and oysters shall be taken twice per week from Bed 12. If toxin levels are declining at all sampling stations in the Estero, CDPH may reduce the frequency of such sampling for harvest clearances.

A second stage alert shall be continued until either (a) a third stage alert is declared, or (b) two successive samples of mussels from the buoy station and mussels and oysters from Bed 12, taken over a minimum period of three days, and all other oyster samples taken from the Estero during the

same period, have PSP toxin levels lower than those specified above as requiring a second stage alert.

Third stage alert: If an oyster sample from any location in the Estero exceeds 200 micrograms, the Estero shall be in a third stage alert. In such a case, CDPH may as its sole option either (a) impose the controls described for a second stage alert, or (b) close the entire Estero to shellfish harvesting.

A third stage alert shall be continued until two successive samples of oysters from Bed 12, taken over a minimum period of three days, and all other oyster samples taken from the Estero during the same period, have PSP toxin levels lower than 200 micrograms.

**Table 1. Summary of special PSP Management procedures for Drakes Estero.**

Status	PSP Levels <sup>1</sup>	Procedures
Regular Sampling	No toxin detectable in any sample	No constraints on harvesting. Weekly mussel sample from Bed 12 and weekly oyster sample from the principal harvest bed.
Increased Sampling	A shellfish sample from Drakes Bay or Drakes Estero begins to show detectable toxin.	No constraints on harvesting. Follow up samples of mussels and oysters from Buoy station, Bed 12 and oysters from all harvest beds in use. Further sampling as directed
First Stage Alert	Mussel sample from Estero 80 to 400; all oyster samples less than 80.	No constraints on harvesting. Twice-weekly mussel sample from Buoy station, Bed 12 and oyster samples from all harvest areas in use.
Second Stage Alert	Oyster sample from outer part of the Estero 80 to 200 or mussel sample from any location in the Estero exceeds 400.	Oyster harvesting is restricted to inner parts of the Estero, and PSP clearance is required for each harvest. Oyster sample from each harvest, twice-weekly mussel sample from Buoy station and oyster and mussel samples from Bed. 12.
Third Stage Alert	Oyster sample from any location in the Estero exceed 200.	CDPH may impose Second Stage Alert controls, or it may close the Estero to all harvesting.

<sup>1</sup> PSP toxin levels are expressed in micrograms of toxin per 100 grams of shellfish meat.

## Appendix F. Marine Biotoxin Monitoring Procedures

This appendix contains two protocols for marine biotoxin monitoring. Procedure 1 is to be used for collecting shellfish samples to be submitted to the California Department of Public Health for biotoxin analysis. Procedure 2 should be used when performing field biotoxin analysis using Jellett test strips and when collecting phytoplankton samples. Training in both procedures will be provided to the grower by CDPH.

Procedure 1 was developed by the California Department of Public Health. Procedure 2 was developed by the California Department of Public Health and the University of California Santa Cruz as part of the Cal-PreEMPT Program, with support from the National Oceanographic and Atmospheric Administration's Monitoring and Event Response for Harmful Algal Blooms (MERHAB).

## PROCEDURE 1: COLLECTING SHELLFISH SAMPLES TO BE SENT TO CDPH FOR BIOTOXIN ANALYSIS (NOT ANALYZED IN THE FIELD)

Prepared By

California Department of Public Health  
Environmental Management Branch  
and  
Environmental Microbial Diseases Laboratory

### INTRODUCTION

**The following field sampling protocol will accommodate analysis for both paralytic shellfish poisoning (PSP) toxins and domoic acid (DA). Because a preservative cannot be used at the time of sample collection, it is imperative that the field collectors take care to ensure the integrity of each sample.**

1. **SAMPLING:** A sample should consist of a single species of bivalve shellfish (mussels, oysters, clams, etc.) collected randomly from the sampling site. Each sample should include a **minimum of 15 individuals and at least 250 grams of drained shellfish meat**; this provides adequate material for both analyses with a reserve as insurance against a possible lab accident. This is equivalent to a volume of about one (1) cup of shucked meats. It takes up to 40 small sea mussels (about 2 inches shell length) to produce 250 grams of meat. Avoid collecting only a few very large specimens: this may provide misleading information on the presence or absence of toxin.
2. **FIELD PREPARATION OF SAMPLES:**
  - a. Shucked samples.
    - (1) Thoroughly clean the outside of shellfish with water.
    - (2) Open shell by cutting the adductor muscle(s). Do not use heat or anesthetic before opening shell. **Cut carefully to avoid damage to body of mollusk.**
    - (3) Rinse the opened shellfish to remove sand or other foreign materials if needed.
    - (4) For mussels, cut off byssal threads (attachment hairs) with scissors and discard, saving all meat.
    - (5) Open shell and drain off excess liquid. Remove meat from shell without damaging tissue.
    - (6) Drain shucked meat on a #10 mesh sieve without layering for five (5) minutes.
    - (7) Place drained meat into a wide-mouthed, 16-ounce sample bottle. About 1/2 to 2/3 of a sample bottle of shellfish meat provides the desired amount. NOTE: Do not overfill; be sure to leave an air space to accommodate expansion upon freezing.
    - (8) Tighten cap securely. Refrigerate immediately in the field.
    - (9) **Freeze sample** as soon as possible; ensure that sample is frozen prior to shipment.
    - (10) Fill out sample submission slip; be sure to record sample **bottle number** and **type of shellfish** (e.g., Pacific oyster, bay mussel, etc.). A list of representative sample types and their associated codes is presented in Table 1. In addition, please record the **sample location and sampling date**, and **include your name and telephone number** so that we may contact you immediately. The presence of high toxin concentrations may necessitate immediate resampling.
  - b. Unshucked samples: If you have been instructed or authorized to send unshucked shellfish samples, clean the outside of shellfish, wrap in newspaper to cover sharp edges, place in a heavy gauge plastic bag and seal, double bag the sample, and check for leaks. Refrigerate immediately.
3. **SHIPPING:** Rapid testing of samples for PSP and DA is extremely important. Samples should be shipped as soon as possible by the most rapid means available, while taking care that they arrive at the laboratory in an unspoiled condition.

MANAGEMENT PLAN FOR DRAKES ESTERO, JANUARY 2012

- a. Place frozen sample(s) in an insulated shipping container with an adequate quantity of frozen ice packs and sandwiched in absorbent materials to soak up any leakage or condensation.
- b. Place sample submission slip(s) on top of the Styrofoam lid; close and seal the shipping container.
- c. Containers returned to you from the laboratory will have mailing labels inside a plastic mailing envelope taped onto the lid or side. Remove the label addressed to you and reverse labels so that the box is addressed to the laboratory. Remove or cover any old UPS or other shipping label(s) that could cause confusion.
- d. Package should be addressed to:
 

California Department of Public Health  
MDL/EMDS  
ATTN: Specimen Receiving MS B106  
850 Marina Bay Parkway  
Richmond, CA 94804
- e. Send package by Courier Service. In accordance with prior arrangements.
  - (1) Next-day courier service may be provided in some locations by EMB: call (510) 412-4635 for information; or
  - (2) You may use your own courier at your own expense.
- f. Avoid sending samples at the end of the week or just before holidays. Prolonged transit time causes increased risk of spoilage.
- g. All questions regarding this protocol should be directed to the EMB office at (510) 412-4635.

SAMPLE TYPE	CODE
Wild Sea Mussels ( <i>Mytilus californianus</i> )	WSMU
Sentinel Sea Mussels	SSMU
Wild Bay Mussels ( <i>Mytilus edulis</i> )	WBMU
Sentinel Bay Mussels	SBMU
Cultured Bay Mussels	CBMU
Cultured Pacific Oysters ( <i>Crassostrea gigas</i> )	CPOY

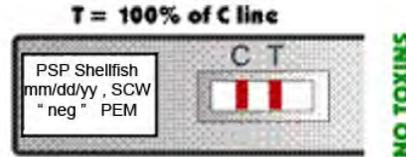
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Table 1. Common sample types and their respective codes.

## PROCEDURE 2: PHYTOPLANKTON SAMPLING AND FIELD BIOTOXIN ANALYSIS

### Labeling

Label Jellett test strips and shellfish extract vial with the following information: toxin, sample type (e.g. mussel, oyster or phytoplankton), date, location, test strip results (+/-), and your initials. Use the back of the test strip for more space, if needed. See example:



### Phytoplankton Samples

#### **Collecting & Observing Phytoplankton Sample:**

1. Use plankton net to obtain 300 mL sample: retrieve net very slowly
2. Record total length of the tow (depth x number of repetitions, e.g. 30 feet x 5 tows = 150 feet)
3. Swirl net sample to resuspend, and fill 125 mL bottle containing formalin just to the shoulder
4. Pour the remaining sample into a clean bottle without formalin
5. Allow live sample to settle for 15 minutes
6. Pipette several drops of the settle material to a microscope slide and place a coverslip on the drops, or use a small flat glass capillary tube to pull up a quantity of the settle material
7. Observe the slide/capillary for the presence of *Pseudo-nitzschia* or *Alexandrium* and record estimate of percent composition or relative abundance (Absent, Rare, Present, Common, Abundant).
8. Note other most common species along with an estimate of percent composition or abundance.
9. Fill out data sheet with observations and percentages
10. Repeat steps 6 through 9 for a total of three separate observations
11. Field sheets should be photocopied before shipping to CDPH

### Shellfish Samples

#### **Collecting Shellfish Sample:**

1. Collect a minimum of 15 large mussels, more if they are small
2. Rinse outside of shell, remove byssal threads, and shuck mussels placing tissue in #10 sieve and allow to drain for 5 minutes
3. Fill 600 mL beaker to at least 300 mL with shucked meat and thoroughly puree meat using blender
4. Pour approximately 10 mL pureed meat into 50 mL tube and pour remainder into 500 mL sample collection jar and refrigerate immediately

#### **Preparing the Shellfish Extract:**

1. Add 10 mL Jellett *Extraction Liquid* to tube containing 10 mL pureed shellfish and shake vigorously to ensure complete mixing
2. Place paper paint filter over a 500 mL beaker and pour shellfish mixture into filter. Allow to filter for 5 minutes
3. Transfer shellfish extract filtrate from beaker into small vial, cap, label with date, location, and initials

**★ This extract can be used for BOTH the ASP and PSP tests ★**

**Testing the Shellfish Extract: Domoic Acid/ASP** (also refer to green Jellett instructions):

## MANAGEMENT PLAN FOR DRAKES ESTERO, JANUARY 2012

1. Open sealed envelope containing Domoic Acid test strip: ensure desiccant pouch is blue (discard test strip if desiccant is pink).
2. Add 1 mL of water to the vial provided (white cap).
3. Add 100  $\mu$ L of shellfish extract to vial containing 1 mL of water. Cap and shake thoroughly. Discard pipette.
4. Number the two buffer vials (red cap, green cap) "1" and "2" to avoid mixing them up
5. Tap small vials of buffer 3 times on hard surface. Place in rack and remove cap (red) from vial #1.
6. Add 100  $\mu$ L of the shellfish extract to the buffer solution using the new pipette provided (fill to black line).
7. Mix shellfish extract and buffer: insert pipette and fill and empty into buffer vial 3 times.
8. Add 100  $\mu$ L of the buffer/extract solution to the buffer vial #2 (green cap) using the pipette provided (black line).
9. Mix contents of second vial thoroughly: insert pipette and fill and empty into buffer vial 3 times.
10. Fill pipette to black line (100  $\mu$ L) with solution from second buffer vial.
11. Dispense into sample well of test strip (S). Discard pipette.
12. Record start time and wait 45 - 75 minutes before reading results.
13. Label front of diagnostic kit as shown at beginning of this protocol.

### **Interpreting Test Strip (also refer to Jellett instructions):**

1. When time interval has expired, record current time on shellfish field sheet and observe diagnostic kit.
2. Use the Jellett strip control card with sample strips (included in the Jellett test kit package) to interpret the test results. The T-line becomes fainter as the toxin level increases.
3. Test strip **C-line** is **equal to or fainter** than Invalid test on Control Card: your test is **Invalid**.
4. Test strip **T-line** is **darker** than Positive T-line on control card: test is **Negative**.
5. Test strip **T-line** is **equal to or fainter** than Positive T-line on control card: test is **Positive**.
6. Record results and any observations on the field sheet. Record results on front of strip.
7. Take a digital photo of the Jellett test strip.
8. Place diagnostic kit in Ziploc bag, seal, and place in envelope with shellfish field sheet.

### **Documentation**

1. make copies of all field sheets and retain copies; ship originals as described below
2. email a digital photo of all completed test strips to [gregg.langlois@cdph.ca.gov](mailto:gregg.langlois@cdph.ca.gov)

### **Shipping Samples:**

- ◆ Place plankton field sample bottle in a Ziploc bag. Place plankton field sheet and all test strips in another Ziploc bag. Enclose both in a third bag and label "For EMB".
- ◆ Place shellfish field sheet in a Ziploc. Put all bags, the small vial of extract (when requested), and the 500 mL bottle of pureed shellfish in a shipping box with blue ice for shipment to CDPH via Next Business Morning delivery.

Appendix G. Statements of Agreement

STATEMENT OF AGREEMENT FOR  
COOPERATING REGULATORY AGENCIES

The undersigned has read and understands the purpose of the *Conditionally Approved* classification of the commercial shellfish growing area in Drakes Estero and the conditions of its Management Plan, dated January 2012, and agrees to comply with the conditions and procedures set forth in the Management Plan

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Signature

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Name (print or type)

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Agency

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Date

Mail completed form to:

California Department of Public Health, EMB  
850 Marina Bay Parkway, # G165  
Richmond, CA 94804

STATEMENT OF AGREEMENT FOR HARVESTER

The undersigned has read and understands the purpose of the *Conditionally Approved* classification of the commercial shellfish growing area in Drakes Estero and the conditions of its Management Plan, dated January 2012, and understands that compliance with the conditions and procedures set forth in the Management Plan is mandatory as a condition of the Shellfish Growing Area Certification issued by the California Department of Public Health.

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Signature

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Name (print or type)

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Agency

---

Date

Mail completed form to:

California Department of Public Health, EMB  
850 Marina Bay Parkway, # G165  
Richmond, CA 94804

Appendix H. Record of Changes

TECHNICAL REPORT #	DATE	PAGE	REASON FOR CHANGE
04-04	2/1/2004	24, 43	Added section on Marine Biotoxin Monitoring and added Appendix C – Marine Biotoxin Monitoring
06-05	12/2005		Mr. Kevin Lunny purchased lease M-438-01 and M-438-02 from Johnson Oyster Company and is doing business as Drakes Bay Oyster Company
06-05	1/1/06	15	Modified the extreme environmental conditions criteria
06-05	1/1/06	15, 16	Added to the requirements for movement of shell stock during closure
06-05	1/1/06	24	Refined the water quality monitoring requirements
06-05	1/1/06	24	Specified grower responsibility in the event of a change to the water sampling plan
06-05	1/1/06	25	Water samples exceeding NSSP criteria
06-05	1/1/06	25	Shellfish meat samples exceeding market standards
06-05	1/1/06	Appendix E, page 46	Notification of shell stock movement during a growing area closure
08-05	1/1/08	15	Rainfall closure rules for Conditionally Approved areas have been changed, specifying one additional day of closure following 7-day cumulative rainfall totals of 2.0 inches
08-05	1/1/08	16	Extreme environmental condition procedures have been changed to specify immediate closure of both Conditionally Approved and Approved areas following 7-day cumulative rainfall totals of 2.5 inches or greater.
08-05	1/1/08	18-19	Modified procedures for responding to sewage spills
08-05	1/1/08	28-29	Modified procedures for water samples exceeding NSSP standards
08-05	1/1/08	30	Added requirements for domoic acid and phytoplankton monitoring
08-05	1/1/09	28-29	Minor clarification of protocol for samples exceeding NSSP criteria
11-05	1/1/11	37	Added rainfall closure table.
11-05	1/1/11	47-50	Moved wastewater upset procedures to new Appendix C.
12-05	1/1/12	24	Clarification of field audit requirement

