Government of **Western Australia**
Department of **Health**

Marine Biotoxin Monitoring and Management Plan

WESTERN AUSTRALIA SHELLFISH QUALITY ASSURANCE PROGRAM

Version 2

2020

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Marine Biotoxin Monitoring and Management Plan

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Version Control

Version	Date	Author	Reason	Sections
Draft Marine Biotoxin Monitoring and Management Plan 2015	May 2015	WASQAP	Updating Biotoxin Management Plan from WASQAP Manual 2011 following Biotoxin Risk Assessment carried out in 2014	All
Draft Marine Biotoxin Monitoring and Management Plan 2015	July 2015	WASQAP	Amendments following consultation	All
Marine Biotoxin Monitoring and Management Plan 2016	May 2016	WASQAP	Updated plan following outcome of Department of Agriculture and Water Resources Review. Annual Review	All
Marine Biotoxin Monitoring and Management Plan version 2 2020	September 2020	DOH, DPIRD and Industry	Review of document following changes to ASQAP Operations Manual Version 5 2019 and increased monitoring data	All

Contents

Marine Biotoxin Monitoring and Management Plan

1.0 Introduction

This document should be read in conjunction with the Western Australia Shellfish Quality Assurance Program (WASQAP) Industry Manual/User Guide, the Australian Shellfish Quality Assurance Program (ASQAP) Operations Manual and the Sampler Manual.

Toxic shellfish poisoning is a health risk to consumers and damages consumers' confidence and trade. These risks can be reduced through the application of suitably developed marine biotoxin management plans.

Naturally occurring marine biotoxins can result in well documented human illnesses following ingestion of raw or cooked shellfish. The four major classes of illness are Paralytic shellfish poisoning (PSP), Diarrhetic shellfish Poisoning (DSP) Amnesic Shellfish Poisoning (AST) and Neurotoxic Shellfish Poisoning (NSP). The toxins causing these illnesses are identified as Paralytic Shellfish Toxins (PSTs) Diarrhetic Shellfish Toxins (DSTs) , Amnesic Shellfish toxin (AST or domoic acid) and Neurotoxic Shellfish toxins (NSTs).

1.1 Purpose

This Marine Biotoxin Monitoring and Management Plan (MBMMP) has been developed under the WASQAP to ensure regular industry monitoring within shellfish growing areas to gain a better understanding of the risk level and to mitigate the risk of contaminated shellfish. The management plan takes into account the inherent risk, the cost of managing the risk, whilst considering the legislative and financial burden on seafood producing businesses.

1.2 Scope

This MBMMP applies to all bivalve molluscan shellfish species commercially harvested or handled for the purpose of human consumption regardless if they are harvested from the wild or from marine or land-based aquaculture facilities. It includes bivalve molluscan shellfish harvested for domestic and export markets.

1.3 Requirement for Marine Biotoxin Monitoring and Management Plan

Section four of the ASQAP Operations Manual requires that a marine biotoxin risk analysis has been established for a harvest area and an appropriate marine biotoxin management plan is in place which is approved by the Shellfish Control Authority (SCA). Additionally, it also provides required content for the MBMMP including:

a) the responsibilities of all parties involved in the biotoxin management plan

b) hydrographic details describing predominant currents and circulatory patterns (detail is provided in the respective harvesting area annual review reports)

c) species of shellfish cultured/harvested (detailed within the Harvest Controls Surveillance and Management Plan HCSMP)

d) sample sites (specific details within the HCSMP)

e) sampling frequencies (detailed within the sampling program)

f) sampling methods (specific details are contained within the Sampler Manual)

g) methods of analysis for water and shellfish samples (specific details are contained within the Sampler Manual)

h) laboratories used for sample analysis (detailed within Sampler Manual)

i) alert level/s and/or closure levels for toxic/potentially toxic algal species

j) potentially toxic algal species list

k) closure levels for toxins in shellfish flesh

l) actions to be taken by SCA when either alert levels are exceeded or toxins are found in shellfish below closure levels

m) closure procedures including closure criteria, notification of closures to marine farmers and relevant authorities, public announcements, management during closures, product recall

n) opening procedures including opening criteria, notification of opening to marine farmers and relevant authorities, public announcements, procedures for opening inactive or seasonal harvest areas

o) procedures for dealing with relayed and recalled product potentially (or known to be) contaminated with biotoxins

p) case definitions of toxic syndromes

q) an annual review

Most of the above information is included within this document and further detailed information is referenced above from the other WASQAP documents.

1.4 Biotoxin Risk in WA

The biotoxin risk analysis in the previous MBMMP was based on information provided in Part B of the Cawthron report (No. 645) entitled Australian Marine Biotoxin Management Plan for Shellfish Farming and the Report prepared by Curtin University at Centre of Excellence for Science, Seafood and Health (CESSH) in 2014 entitled "Review the Tasmanian paralytic shellfish toxin (PST) event and Safefish recommendations to determine an interim risk management approach for WA".

CESHH report acknowledged that whilst filter feeding bivalve shellfish species (e.g. mussels, oysters) have a high capacity to accrue biotoxins, the report concluded that there is a low putative biotoxin risk in Western Australia's commercially harvested areas. Additionally, following the implementation of routine biotoxin sampling during 2015/16 (carried out as part of the biotoxin review) only one sample was found to be on the regulatory limit. Therefore, the sampling frequencies for phytoplankton and biotoxin testing were set accordingly for all current harvest areas (i.e. twice monthly for phytoplankton testing and once a month for biotoxin testing) reflecting a low risk rating at that time.

However, since 2015 there has been an established routine biotoxin monitoring plan in place for each harvesting area that enables an improved ongoing biotoxin risk assessment for each growing area. This is reviewed annually as part of the harvesting area annual review and MBMMP.

It is worth noting however the recent and persistent bloom activity in WA in the Swan/Canning and Peel /Harvey for *Alexandrium minitum* and *Dinophysis acuminta* respectively. These blooms can present a future risk to shellfish farming and should be considered in the context of the overall harmful algae bloom risk in WA.

1.5 Roles and Administrative Responsibilities

Roles and administrative responsibilities for the MBMMP are the same as those documented in the WASQAP Industry Manual. However, Table 1 provides specific detail on the roles and responsibilities in respect of biotoxin monitoring and management.

Table 1 Roles and Responsibilities for the Marine Biotoxin Monitoring and Management Plan

DOH	Industry	DPIRD
Has oversight of the phytoplankton and biotoxin sampling program	Shellfish farmers and wild harvesters sample water and shellfish species within harvesting areas and submit samples to appropriate phytoplankton and biotoxin laboratories	DPIRD to assist with review of information and research on biotoxins
Confirms closures and re-openings initiated by industry and notifies all parties concerned.	Ensure sampling schedule is implemented and staff undertaking samples are appropriately trained	To provide information and advice on rapid testing kits and the progress of the biotoxin testing facility in WA
Reviews phytoplankton and biotoxin results in the annual review reports	Maintain a food recall plan that covers biotoxins and capability to implement it	Provides input to any revision of the MBMMP
Reviews the MBMMP	Provides input to any revision of the MBMMP	

1.6 Growing Areas and Sampling Sites:

Phytoplankton sampling sites have been selected with consideration given to depth, predominant currents, tidal and riverine influences and the practical issues of accessing the sites. Phytoplankton sample site locations are mapped and provided in the HCSMP for each harvesting area. Shellfish samples are provided from those parts of the growing area that are currently being harvested.

Harvest areas and sampling sites are contained within the HCSMP. Phytoplankton and biotoxin sampling protocols and procedures for sample collection and dispatch to the analytical laboratory are also detailed in the Sampler Manual and are covered in the on-line sampler training module.

2.0 Phytoplankton and Shellfish Monitoring and Sampling Procedure

(This procedure applies to routine sampling and sampling undertaken in the event of an exceedance).

2.1 Overview of sampling

All sampling is performed in accordance with section 4 of WASQAP Industry Manual/User Guide. Biotoxins are sampled routinely (monthly), and when phytoplankton levels are over threshold levels (refer to Table 2). Biotoxins PST, DST AST, are tested in flesh via validated screening methods (when risk is considered low) or confirmatory analysis in approved laboratories with recognised methods (refer to section 10 ASQAP). Flesh samples are provided from current harvest areas and where more than one species of shellfish are harvested from a lease all species must be tested for biotoxins.

Phytoplankton in the water is screened by identification and enumeration of target toxin producing species (see list in Table 2). Phytoplankton samples are provided from designated sampling locations. These samples are analysed by a laboratory that meets the laboratory and analytical requirements of section 10 of ASQAP. While potential Neurotoxic Shellfish Toxins (NST) producers have been identified occasionally they have never been detected at significant levels. Therefore, NSP toxins are currently not routinely tested for in WA, however the NSP phytoplankton risk in WA waters is continuously monitored.

Industry is responsible for managing the turnaround time between the time of sampling to the time at which results are available.

Biotoxin events are notoriously unpredictable, even when the best routine monitoring program is actively implemented it is possible that new biotoxin events and challenges will arise. Therefore, aside from the mandatory sampling programs, environmental factors should also be considered as useful indicators to a pending food safety biotoxin event. Such clues can be drawn from, but should not be limited to, fish kills, meteorological data, pollution spills (especially those involving nutrients) and obvious blooms (which may be noted on the WASQAP Sampling Program Information Sheet – refer to WASQAP Industry Guide Appendix 1).

Phytoplankton sampling should be undertaken frequently and regularly, with the frequency remaining constant throughout the year, as potentially harmful species can occur at any time of the year (Cawthron Report No.645, Nov 2001). Therefore, phytoplankton water samples are collected bimonthly throughout the year as per the sampling program for growing areas. However, the frequency of phytoplankton sampling may increase in response to results of the regular monitoring program. (N.B. For seasonal start-up two phytoplankton samples taken two weeks apart and one biotoxin sample is taken prior to the commencement of harvesting).

2.2 Sample Frequency

Routine samples

Based on the current biotoxin risk for existing WA shellfish harvesting areas - monthly meat samples and twice monthly phytoplankton samples are required when a growing area is in the open status.
Areas that solely produce juvenile oysters for relay/on-growing elsewhere will be sampled monthly (for water or flesh), at a minimum.

Event samples

During the closure of a harvest area due to biotoxins, sampling is required to confirm biotoxin levels. During biotoxin events phytoplankton sampling will be varied to provide increased surveillance.

It is acknowledged that the use of flesh testing is the cornerstone of the regulatory approach (FRDC Project 2012/060), and whilst phytoplankton provides a support role, (particularly in the early identification of impending blooms) together they provide a good risk management tool. Concurrent (meat and phytoplankton) sampling improves the knowledge of biotoxin risk and is recommended.

2.3 Sampling methods

Samples are taken from designated sampling stations in accordance with the sampling plan for the harvest area and biotoxin risk rating. Details on methods can be found in the Sampler Manual.

2.3.1 Phytoplankton samples

A water sample is taken by industry representatives using the integrated tube sample method for water depth greater than 2 m and a bucket/bottle method for

waters less than 2m. Samples are sent to the Laboratory for phytoplankton analysis for target species identification and enumeration. Sample result turn-around times are important for industry because if a phytoplankton result is not received within one week of its submission/scheduled date the food businesses operating in the harvesting area should consider cessation of harvesting (unless prior arrangements have been made with DOH Food Unit). Water samples are analysed within 72 hours of arrival at the laboratory. At the same time water samples are taken, a flesh sample is also collected and frozen (unless part of routine biotoxin analysis whereby it would be sent straight away for analysis).

2.3.2 Shellfish flesh samples

Samples are collected from the leases in a manner that ensures the samples represent those shellfish most likely to be harvested.

A minimum of 100g shellfish meat is required (of each species authorised on a licence to be marine farmed or harvested) from each sample site and submitted frozen to the laboratory for routine monthly sampling or kept frozen for 6 weeks pending phytoplankton test results.

Appropriately validated qualitative marine biotoxin screen methods can be used in the following situations:

a) To determine if a quantitative method should be undertaken on a sample from a closed area for re-opening purposes (i.e. to test the first of two samples collected to re-open areas);
b) For routine testing of harvest areas in the open status when risk is considered low.

2.4 Closure management

Triggers for phytoplankton levels in the water to alert management actions i.e. initiate flesh testing are listed in Table 2 and regulatory closure thresholds for biotoxins in shellfish flesh are listed in Table 3.

The phytoplankton trigger levels documented in Table 2 were developed based on the WA biotoxin risk assessment (CESHH report 2014) and consideration of phytoplankton levels used internationally and in various states of Australia. They should be revised as further monitoring and research is undertaken that supports a

change. The Laboratory remains vigilant for the wider spectrum of potentially toxic species and any novel species.

Table 2: Summarises the phytoplankton levels (in cells/L) that trigger management action.

Micro-algae species	Type of Toxin	Alert Level	Alert level to initiate flesh testing (cells/L)
***Alexandrium catenella*[1]**	PSP	100	200
***Alexandrium minutum*[1]**	PSP	100	200
***Alexandrium ostenfeldii*[1]**	PSP	100	200
***Alexandrium tamarense*[1]**	PSP	100	200
Gymnodinium catenatum	PSP	500	1,000 mussels 2,000 (other shellfish)
Dinophysis acuminate	DSP	1,000	1,000
Dinophysis acuta	DSP	500	1,000
Dinophysis caudata	DSP	500	1,000
Dinophysis fortii	DSP	500	1,000
Prorocentrum lima	DSP	500	500
***Pseudo-nitzschia* seriata group (*P.multiseries* and *P.australis*)[2]**	ASP	50,000*	500,000
***Pseudo-nitzschia* delicatissima group[2]**	ASP	500,000	500,000
Karenia brevis	NSP	500	1,000
Karenia/Karlodinium/ Gymnodinium group[3]	NSP	100,000	250,000

*** At 50,000 weekly flesh testing will commence**

N.B. The cell levels within each toxin group are cumulative. (e.g. 600 cells/L of both D.acuta and D. fortii would mean a total count of 1200 cells/L exceeding the critical level to initiate flesh testing).

[1] *Alexandrium* species may be difficult to identify when numbers are low. If any doubt exists, they should be treated as potentially toxic.

[2]Species within the *Pseudo-nitzschia* groups are difficult to identify. The toxic species of most concern in each group are listed for those laboratories that have capacity to identify these algae to species level. Otherwise all algae within these groups should be considered potentially toxic. The *Pseudo-nitzschia seriata* group includes *P. australis, P. pungens* and *P. multiseries.* The *Pseudo-nitzschia delicatissima* group includes *P. turgidula, P. fraudulenta, P. delicatissima, P. pseudodelicatissima* and *P. multistriata*.

[3]The *Karenia/Karlodinium/Gymnodium* group includes *Karenia bidigitata, Karenia brevisulcata, Karenia mikimotoi, Karenia papilionacea, Karenia selliformis, Karlodinium micrum* and *Gymnodinium impudicum*. If there is evidence of fish kills near the growing area, NST testing should be considered.

Prorocentrum rathymum presence is currently recorded on Laboratory reports - trigger levels have not been established and under review as DSP risk uncertain.

If potentially toxic phytoplankton species are identified at levels that exceed the alert levels ('to initiate flesh testing' in Table 2) the analyst will immediately notify (by phone and/or email foodsafety@health.wa.gov.au) the DOH Food Team. Additionally, notification containing the specified subject heading is also to be sent to the following email address: algalblooms@health.wa.gov.au

Subject: Algal Bloom Shellfish Hazard
Importance: High

If the phytoplankton count reaches the alert level to 'initiate flesh testing' for the particular species, the food business must arrange for the chilled/frozen sample of shellfish to be tested for biotoxins.

Another water and flesh sample will be taken and the water sample submitted for phytoplankton analysis and the flesh sample stored for possible biotoxin testing. The food business may decide to voluntary cease harvesting pending the biotoxin results.

If the subsequent sample shows that the phytoplankton levels for the particular phytoplankton species again exceed the 'alert levels to initiate flesh testing' the flesh sample must again be submitted for biotoxin analysis.

If algal biotoxins are determined to be present in the flesh samples at levels which exceed the maximum permitted concentrations specified in the Australia New Zealand Food Standards Code (*the Code*) Standard 1.4.1 Contaminants and Natural Toxicants (Table 3), the food business must close the harvesting area.

Under ASQAP section 4.1.9 a harvest area may also be placed in the closed status when:

- Phytoplankton levels exceed the closure trigger levels provided in the management plan in absence of shellfish flesh toxicity data
- Or samples as required by the SCA have not been taken

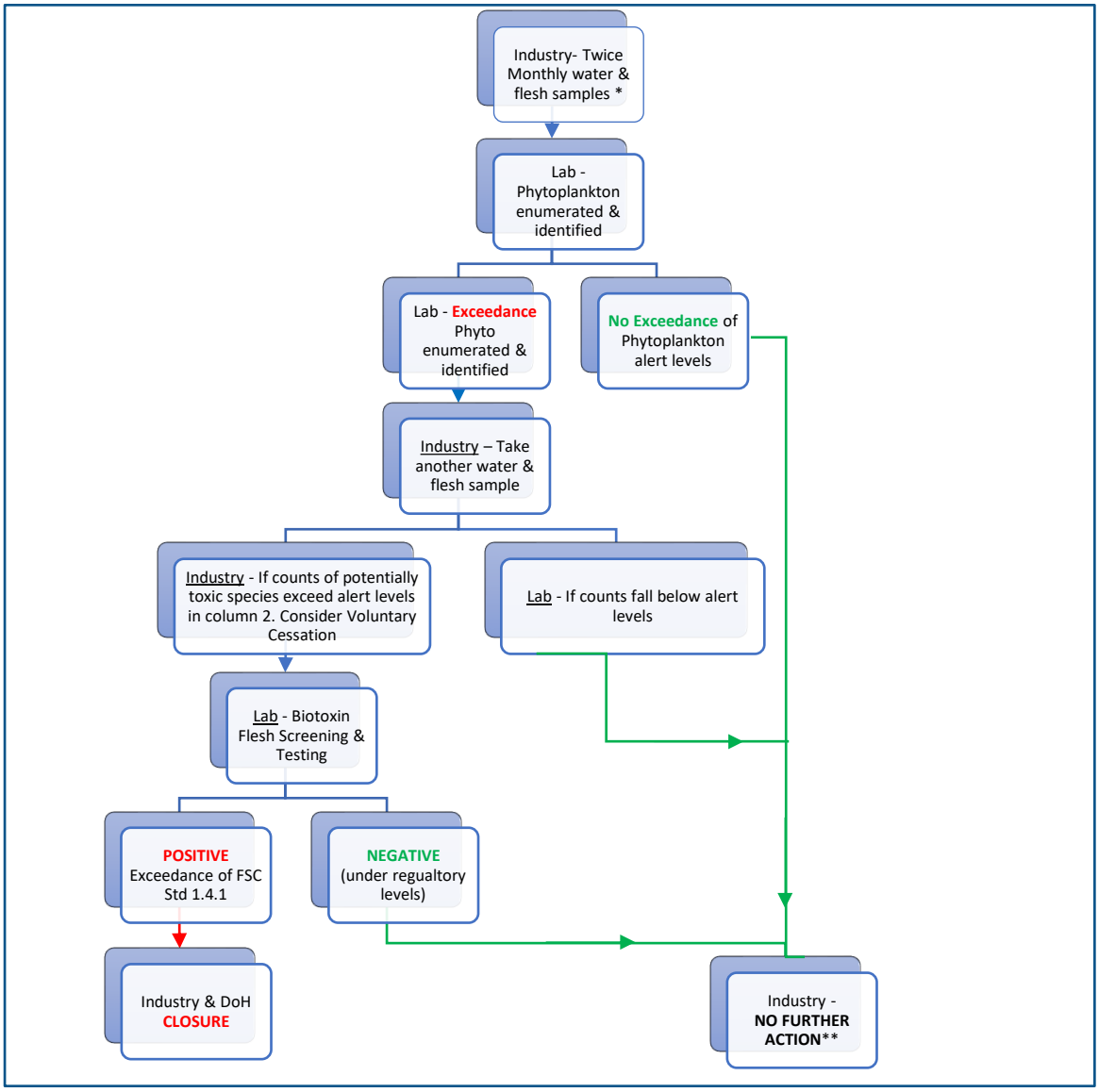
Phytoplankton samples taken during closure are used to monitor bloom status and to confirm if toxic algae concentration is rising or falling.

Where a harvesting area is not closed the Department of Health would consider the provisions contained within its Compliance and Enforcement Policy to ensure no harvesting takes place.

The protocols detailed in the WASQAP for surveillance, communication, media release and product recall will be carried out.

A formal closure (Prohibition Order under the Food Act 2008) of a harvesting area may be considered appropriate following a food-borne disease outbreak investigation after the reporting of cases of human illness consistent with the case definition for PSP, NSP, DSP, and/or ASP that have resulted from the consumption of shellfish from a particular area. Additionally, a formal closure may be considered appropriate by the DOH where necessary for other reasons (e.g. toxins present in neighbouring areas, reporting of a potentially toxic phytoplankton species not previously reported from the harvest area etc.).

Figure 1 Flowchart illustrating actions required when phytoplankton levels are above trigger levels



*one flesh sample submitted routinely each month for biotoxin testing, the other sample held frozen for 6 weeks

**however, phytoplankton levels considered; possible increased monitoring

Table 3 Marine Biotoxin Regulatory Closure Levels

A harvest area must be closed for the harvesting of shellfish when toxins in shellfish are found to be above the levels prescribed in the Australian and New Zealand Food Standards Code, Contaminants and Natural Toxicants Standard 1.4.1 (Schedule 19) as detailed below.

Analysis	Frequency	Maximum Level
Paralytic Shellfish Toxin (PST) (saxitoxins equivalent) High Performance Liquid Chromatography (HPLC) Fluorescence Detector HPLC-FLD	Phytoplankton over trigger levels or routine biotoxin testing	0.8mg mg/kg saxitoxin equivalent
Amnesic Shellfish Toxin (AST) (domoic acid equivalent) Liquid Chromatography coupled with Mass Spectrometry (LCMSMS analysis)	Phytoplankton over trigger levels or routine biotoxin testing	20mg/kg Domoic acid equivalent
Neurotoxic Shellfish Poisoning (NSP toxins*)	Phytoplankton over trigger levels	200 MU/kg
Diarrhetic Shellfish Toxin (DST) (okadoic acid equivalent) (LCMSMS)	Phytoplankton over trigger levels or routine biotoxin testing	0.2 mg/kg Okadaic acid equivalent
YTX YESSOTOXINS (LCMSMS) **AZP Azaspiracids** (LCMSMS)		YTX is not regulated in Australia and although it is toxic to mice when applied intraperitoneally, its oral toxicity is questionable (Cawthron Institute, 2001).

N.B. DSP toxins include Okadaic acid (OA), Dinophysistoxins (DTXs), Pectenotoxins (PTXs) (PTX2-sa is currently regarded as non-toxic) , Yessotoxins (YTXs) and Azaspiracids (AZAs).N.B. the human toxicity of pectenotoxins and yessotoxins is currently unknown, until proven non-toxic to humans they will continue to be regulated for as DSP toxins. Azaspiracids are not yet confirmed to be in this group.

*NSP toxins may now also be measured using chemical methodology (LCMS/MS). However, no mg/kg equivalence value or guidance is provided within the ANZFSC for this method. The US Food and Drug Authority acknowledge that 0.8 mg/kg brevetoxin-2 is equivalent to 200MU/kg.

Biotoxin quantitative methods must meet criteria for the Determination of marine biotoxins listed in Codex Standard 292: Standard for Raw and Live Bivalve Molluscs, and use current FAO toxicity equivalency factors (TEFs).

3.0 Harvesting Area Re-Opening

Reopening Criteria

Phytoplankton results may be used to qualify meat testing requirements (refer to 3.3 below and Figure 2).

If biotoxin tests on at least two successive meat samples* taken a week apart show that the concentrations of biotoxin in the bivalve shellfish tissue are below the maximum level (ML) in the Code;

- AND water samples collected during the same period show levels of toxic algae at or below the alert levels; AND
- the algal levels are not increasing in number,

then re-opening of the harvest area may occur.

N.B. *Appropriately validated qualitative marine biotoxin screen methods can be used to determine if a quantitative method should be undertaken on a sample from a closed area for re-opening purposes (i.e. to test the first of two samples collected to re-open areas). Refer to section 10 of ASQAP).

(For seasonal start-up following closure unrelated to biotoxins or phytoplankton levels e.g. for commercial reasons two phytoplankton samples taken two weeks apart and one biotoxin sample must be taken prior to the commencement of harvesting).

3.2 Should there be a toxin event in a harvest area then each individual shellfish species harvested shall be sampled. This will assist in determining the food safety risk of each species.

3.3 However, in the event that two consecutive shellfish meat samples taken a week apart are found to comply with the ML but phytoplankton samples collected during the same period show levels of toxic phytoplankton above the alert levels, re-opening may only occur after a 3rd consecutive compliant meat test result (quantitative result) - which may be taken a further 48 hours or more after the second bivalve shellfish meat sample.

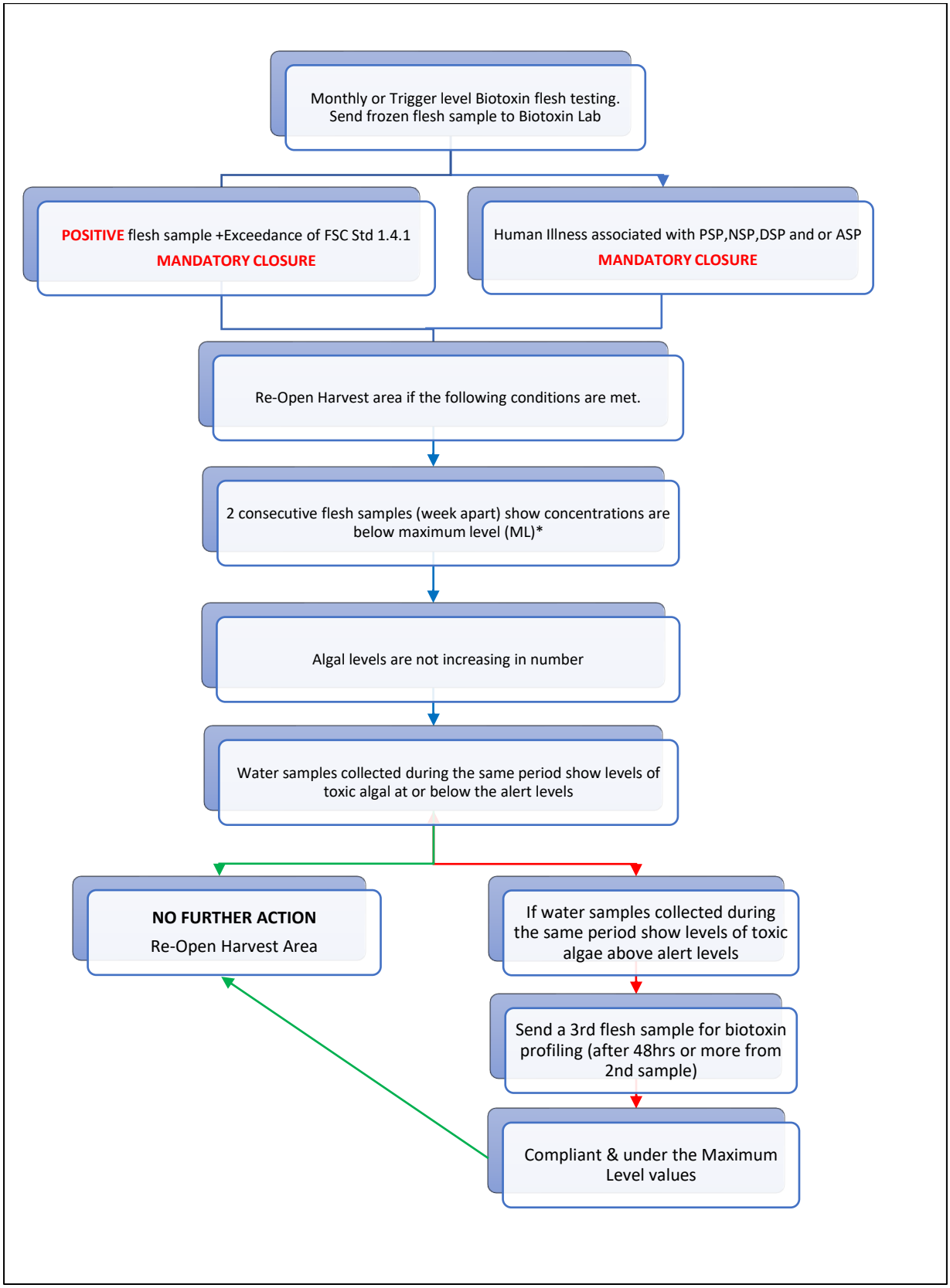
3.4 Following the re-opening of a harvest area additional sampling may be required for example minimum weekly bivalve shellfish and phytoplankton samples for at least 2 weeks to monitor risk.

All those notified of the closure will be notified of the re-opening. (Refer to opening procedure in HCSMP).

IF A SHELLFISH HARVESTING AREA IS CLOSED FOR OTHER REASONS BESIDES PHYTOPLANKTON/BIOTOXIN EXCEEDANCES (I.E. HIGH BACTERIOLOGICAL COUNTS) THE FOOD BUSINESSES SHOULD CONTINUE TO COLLECT PHYTOPLANKTON AND FLESH SAMPLES.

A summary of the WASQAP biotoxin detection and action process relevant to commercially produced shellfish is displayed below.

Figure 2: Procedures for re-opening commercial harvesting areas after experiencing an exceedance of the FSC standard 1.4.1 (Schedule 19) for biotoxins in the flesh of shellfish.



*First flesh sample can be a validated qualitative biotoxin screen

4.0 Recreational Shellfish Samples

It should be noted that recreational collection of shellfish is not within the scope of WASQAP. It is impossible to guarantee the safety of eating wild shellfish without having a comprehensive monitoring program that tests the waterway concerned for harmful microorganisms and toxins. Such programs are extremely expensive and difficult to undertake. The DOH therefore recommends only eating shellfish harvested commercially under strict monitoring programs.

5.0 Review

This manual will be reviewed biennially in consultation with relevant stakeholders to reflect changes in scientific knowledge, shellfish culture techniques, processing technology and changes in legislation.

Appendix 1- Phytoplankton species

Some name changes have occurred since original publication of the Cawthron report. These have been included in the list below and the list will be updated as new information is provided on toxigenic genera. The IOC (UNESCO) has a comprehensive and regularly updated list of harmful microalgae http://www.marinespecies.org/hab/. (Cawthron Report No 645 and NSW Shellfish Program Marine Biotoxin Management Plan 2015)

Category A – Species known to be present in Australian waters and proven to produce toxins either in Australia or internationally:

Alexandrium catenella (saxitoxin and derivatives)
Alexandrium minutum (saxitoxin and derivatives)
Alexandrium ostenfeldii (saxitoxin and derivatives, also produces spirolides in Canada)
Alexandrium tamarense (saxitoxin and derivatives, also has non-toxic strains)
Dinophysis acuminata (pectenotoxin, okadaic acid?, dinophysis toxins? and diol esters?)
Dinophysis acuta (pectenotoxin, okadaic acid?, dinophysis toxins? and diol esters?)
Dinophysis caudata (pectenotoxin, okadaic acid?, dinophysis toxins? and diol esters?)
Dinophysis fortii (pectenotoxin, okadaic acid?, dinophysis toxins? and diol esters?)
Dinophysis hastata (okadaic acid?, dinophysis toxins? and diol esters?)
Dinophysis mitra (okadaic acid?, dinophysis toxins? and diol esters?)
Dinophysis rotundata (okadaic acid?, dinophysis toxins? and diol esters?)
Dinophysis tripos (some strains produce okadaic acid, dinophysis toxins and diol esters)
Gymnodinium catenatum (saxitoxin and derivatives)
Gymnodinium cf breve (Karenia cf brevis) (brevetoxins)
Prorocentrum lima (okadaic acid?, dinophysis toxins? and diol esters?)
Pseudonitzschia australis (domoic acid)
Pseudonitzschia delicatissima (domoic acid)HNTA
Pseudonitzschia fraudulenta (domoic acid) HNTA
Pseudonitzschia multiseries (domoic acid)
Pseudonitzschia pseudodelicatissima (domoic acid) HNTA
Pseudonitzschia pungens (usually non-toxic, but toxic strains produce high concentrations of domoic acid per cell)
Pseudonitzschia turgidula (domoic acid)
Pyrodinium bahamense var. compressum (in tropical habitats) (saxitoxin and derivatives)
Note: HNTA Historically non-toxic in Australia

Category B – Potential toxin producing species (ie toxicity untested/unclear) known to be present in Australian coastal waters:

Alexandrium pseudogonyaulax (possible STX and derivatives, goniodomin)
Chattonella marina/antiqua (possible brevetoxins)
Fibrocapsa japonica (possible brevetoxins)
Heterosigma akashiwo (possible brevetoxins)
Pseudonitzschia cuspidata (possible domoic acid)
Pseudonitzschia heimii (possible domoic acid, non-toxic in New Zealand)
Pseudonitzschia lineola (possible domoic acid)
Pseudonitzschia multistriata (possible domoic acid, non-toxic in New Zealand)
Pseudonitzschia subfraudulenta (possible domoic acid)
Pseudonitzschia subpacifica (possible domoic acid)

Category C – Other potential toxin producing species world-wide that may be present in Australian waters:

Alexandrium angustitabulatum (possible saxitoxin and derivatives, identified in New Zealand waters)

Alexandrium acatenella (possible saxitoxin and derivatives)
Alexandrium cohorticula (possible saxitoxin and derivatives)
Alexandrium fraterculus (possible saxitoxin and derivatives)
Alexandrium fundyense (possible saxitoxin and derivatives)
Alexandrium lusitanicum (possible saxitoxin and derivatives)
Alexandrium tamiyavanichi (possible saxitoxin and derivatives)
Coolia monotis (produces cooliatoxin)
Dinophysis norvegica (Major DSP producer in Europe)
Gymnodinium aureaolum (possible brevetoxins)
Gymnodinium bidigitatum ((possible brevetoxins) found in New Zealand waters)
Gymnodinium galatheanum (Karlodinium micrum) (possible brevetoxins)
Gymnodinium impudicum (possible brevetoxins)
Gymnodinium mikimotoi (Karenia mikimoto) (possible brevetoxins)
Gymnodinium papillionaceceum Karenia papillonacea) (possible brevetoxins)
Gymnodinium pulchellum (Takayama pulchella) (possible brevetoxins)
Gymnodinium selliforme (Karenia selliformis) (gymnodimine, found in New Zealand waters)
Lingulodinium polyedra (yessotoxin producer in Japan)
Nitzschia navis-varingica (domoic acid was recently confirmed for an isolate from brackish Vietnamese waters)
Ostreopsis siamensis (produces palytoxin)
Pfiesteria piscicida Not possible to identify with routine monitoring. Culturing and immunolabelling required
Prorocentrum concavum (okadaic acid?, dinophysis toxins? and diol esters?)
Prorocentrum elegans (okadaic acid?, dinophysis toxins? and diol esters?)
Prorocentrum hoffmannianum (okadaic acid?, dinophysis toxins? and diol esters?)
Prorocentrum maculosum (produces prorocentrolides)
Prorocentrum minimum (Prorocentrum cordatum) (The toxin linked to this organism (185 fatalities in Japan) has not yet been elucidated, and the role of P. minimum is still in question)
Protoceratium reticulatum (yessotoxin producer in New Zealand)
(? Indicates this toxin has not been confirmed at the time of this report as being produced by Australian strains of this species)
Gonyaulax spinifera (possible yessotoxin)
Pseudonitzschia calliantha (domoic acid)

Numerous Karenia species have recently been described. Toxicity and applicability to the Australian program require more investigation.

Appendix 2 - Toxic Shellfish Poisoning Case Definitions

Paralytic Shellfish Poisoning (PSP)

Causative toxins: Saxitoxins (STX's), Gonyautoxins (GTXs) and C toxins (CTXs)

Microalgal sources: Gymnodinium catenatum, Alexandrium species (including A. minutum, A. catenella, A. tamarense, A. fundyense, A. ostenfeldii, plus others), Pyrodinium bahamense var. compressum, also freshwater species such as Anabaena spp., and Microcystis spp.

Common Symptoms:
•STXs block nerve conduction, manifesting as respiratory distress due to partial paralysis of the muscles necessary for breathing.
• Mild neurological symptoms encompass tingling or numbness around the lips or in fingers and toes (paraesthesias), sensations of floating or weightlessness (dysaesthesias), or gastrointestinal upset (nausea, vomiting, diarrhoea, gut pains).
• More severe poisoning may present with functional weakness (impaired grip strength, staggering gait), difficulty breathing and signs of acute respiratory insufficiency, e.g. cyanosis of the lips or fingernails.
• Severe STX intoxication can cause catastrophic acute respiratory failure and death by asphyxiation

Clinical Case Definition: The following neurological symptoms occurring within 12 hours of consuming shellfish:

- neurosensory;
- paraesthesia, i.e. numbness or tingling around the mouth, face or extremities;
- and one of the following neuromotor/neurocerebellar symptoms:
    - weakness such as trouble rising from seat or bed
    - difficulty in swallowing
    - difficulty in breathing
    - paralysis
    - clumsiness
    - unsteady walking
    - dizziness/vertigo
    - slurred/unclear speech
    - double vision

Probable case

- Meets the case definition,
- and detection of PSP biotoxins at or above the regulatory limit in shellfish obtained from near or at the same

site (not leftovers) within 7 days of collection of shellfish consumed by the case (current level: 80µg/100g
shellfish).

Confirmed case

- Meets the clinical case definition, and detection of PSP biotoxins in leftover shellfish at a level that meant the case consumed a dose likely to

cause illness (current level: 10MU/kg body weight, about 2µg/kg body weight).

Amnesic Shellfish Poisoning (ASP)

Causative toxins: Domoic acid (DA)

Microalgal sources: *Pseudo-nitzschia* species including *P. australis, P.multiseries, P. delicatissima, P.fraudulenta, P. pseudodelicatissima* plus others.

No reports of illness attributable to DA poisoning have been received in Australia.

Common Symptoms:
• Mild intoxication may involve only gastro-intestinal upset (nausea, vomiting, diarrhoea, gut pains).
• Symptoms of neuro-intoxication include headache, convulsive seizures, myoclonus (involuntary, irregular muscle contractions), cognitive impairment and disorientation, anterograde amnesia (inability to lay down new memories following neurological damage), respiratory difficulty and coma.

Clinical Case Definition: Vomiting or diarrhoea or abdominal cramps within 24 hours of consuming shellfish;

- and no other probable cause identified by microbiological examination of a faecal specimen from the case or microbiological testing of left-over food;
- and/or one or more of the following neurological signs/symptoms occurring within 48 hours of consuming shellfish:

  - confusion
  - memory loss
  - disorientation
  - seizure
  - coma

Probable case

- meets the clinical case definition, and
- detection of ASP biotoxin at or above the regulatory limit in shellfish obtained from near or at the same site

(not leftovers) within 7 days of collection of shellfish consumed by the case (current level: 20ppm domoic
acid/100g shellfish).

Confirmed case

- meets the clinical case definition, and
- detection of ASP biotoxins in leftover shellfish at a level resulting in the case consuming a dose likely to
- cause illness (current level: 0.05 mg/kg body weight).

Diarrhetic Shellfish Poisoning (DSP)

Causative toxins: Okadaic acid (OA), Dinophysistoxins (DTXs), Pectenotoxins (PTXs)(PTX2-sa is currently regarded as non-toxic), Yessotoxins (YTXs) and Azaspiracids (AZAs).N.B. the human toxicity of pectenotoxins and yessotoxins is currently unknown, until proven non-toxic to humans they will continue to be regulated for as DSP toxins. Azaspiracids are not yet confirmed to be in this group.

Microalgal sources: DSTs are produced by marine microalgae known as dinoflagellates. In Australia the known causative species are *Dinophysis acuminata*, *D. acuta*, *D. caudata*, *D. fortii* and *Prorocentrum lima*. DST producing species are found in all states in Australia at various levels.

Common Symptoms:

• Nausea, diarrhoea, vomiting, abdominal pain and headache are the characteristic symptoms. The symptoms usually start between 30 minutes to a few hours after consumption.
• Usually resolves by three days following consumption of contaminated shellfish.
No fatalities have been reported.
• May present a risk of dehydration requiring fluid and electrolyte replenishment, particularly in young children or the elderly.
• *Okadaic acid* is a potent tumour promoter, which raises concerns about the possibility of harmful effects from chronic, low-dose exposure. Such exposures are difficult to measure, so the concerns of public health agencies are currently directed toward concentrations of OA in shellfish that cause acute gastro-intestinal illness.

There is no epidemiological evidence of human health effects from yessotoxin. However it is lethal to mice when administered intraperitoneally, and causes damage to heart muscles and livers in mice. Azaspiracids cause vomiting and diarrhoea in humans. In animal tests, these toxins have caused neurotoxic effects and severe damage to the intestine, spleen and liver tissues. The microalgal source of azaspiracids is Azadinium spinosum..

Clinical Case Definition: Vomiting or diarrhoea occurring within 24 hours of consuming shellfish and no other probable cause identified by microbiological examination of a faecal specimen from the case or microbiological testing of leftover food.

Probable case

- meets the clinical case definition, and
- detection of DSP biotoxin at or above the regulatory limit in shellfish obtained from near or at the same site

(not leftovers) within 7 days of collection of shellfish consumed by the case (current level: 20 µg/100g
shellfish or 5 MU/100g)

Confirmed case

- meets the clinical case definition, and
- detection of DSP biotoxins in leftover shellfish at a level resulting in the case consuming a dose likely to
- cause illness (current level: ingestion of 48 µg or 12 MU).

Neurotoxic Shellfish Poisoning (NSP)

Causative toxins: Brevetoxins (BTX's)

Microalgal sources: Karenia brevis (=Gymnodinium breve), K. cf brevis (=Gymnodinium cf breve), plus potentially K. papilionacea (=Gymnodinium papilionaceum), K. mikimotoi (=Gymnodinium mikimotoi) and similar species; Chattonella species, Heterosigma akashiwo and Fibrocapsa japonica.

Common Symptoms: The symptoms occur within 3-5 hours and are chills, headache, diarrhoea, muscle weakness, joint pain, nausea and vomiting. There can be altered perceptions between hot and cold, difficulty in breathing, double vision, trouble in walking and swallowing.

Clinical Case Definition: Two or more of the following neurological symptoms occurring within 24 hours of consuming shellfish:

- neurosensory:
  - paraesthesia, i.e. numbness or tingling around the mouth, face or extremities
  - alternation of temperature sensations such as a prickly feeling on the skin during a bath/shower or exposure to sun, or difficulty distinguishing hot or cold objects
- neuromotor/neurocerebellar:
  - weakness such as trouble rising from seat or bed
  - difficulty in swallowing
  - difficulty in breathing
  - paralysis
  - clumsiness
  - unsteady walking
  - dizziness/vertigo
  - slurred/unclear speech
  - double vision

Probable case

- meets the clinical case definition, and
- detection of NSP biotoxin at or above the regulatory limit in shellfish obtained from near or at the same site

(not leftovers) within 7 days of collection of shellfish consumed by the case (current level: 20MU/100g
shellfish).

Confirmed case

- meets the clinical case definition, and
- detection of NSP biotoxins in leftover shellfish at a level resulting in the case consuming a dose likely to cause

illness (current level: 0.3MU/kg body weight

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