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

Marine biotoxin monitoring and management plan

Western Australia shellfish quality assurance program

Version 3

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Prepared by the WA Department of Health (the department)

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Version Control

Version	Date	Author	Reason	Sections
Draft marine biotoxin monitoring and management plan (MBMMP) 2015	May 2015	WASQAP	Updating MBMMP from WASQAP manual 2011 following biotoxin risk assessment carried out in 2014	All
Draft MBMMP 2015	July 2015	WASQAP	Amendments following consultation	All
MBMMP 2016	May 2016	WASQAP	Updated plan following outcome of Department of Agriculture and Water Resources review. Annual review	All
MBMMP version 2 2020	September 2020	The department, DPIRD, and industry	Review of document following changes to ASQAP operations manual version 5 2019 and increased data monitoring	All
MBMMP version 3 2022	July 2022	The department, DPIRD, and industry	Unpublished market access	All

Version	Date	Author	Reason	Sections
MBMMP version 4 2024	February 2024	The department, DPIRD, and industry	Annual review	All
MBMMP version 5 2025	April 2025	The department	Annual review	All

Contents

Marine biotoxin monitoring and management plan

Introduction

This document should be read in conjunction with:

- Western Australian shellfish quality assurance program (WASQAP) industry manual
- Australian shellfish quality assurance program (ASQAP) operations manual
- WASQAP sampler manual.

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

Naturally occurring marine biotoxins can result in human illnesses following ingestion of raw and cooked shellfish. The four major classes of illness are:

1. paralytic shellfish poisoning (PSP)
2. diarrhetic shellfish poisoning (DSP)
3. amnesic shellfish poisoning (AST)
4. neurotoxic shellfish poisoning (NSP).

The toxins causing these illnesses are identified as paralytic shellfish toxins (PSTs) diarrhetic shellfish toxins (DSTs), amnesic shellfish toxins (AST or domoic acid) and neurotoxic shellfish toxins (NSTs).

Purpose

This marine biotoxin monitoring and management plan (MBMMP) has been developed under the WASQAP to ensure regular industry monitoring in shellfish harvest areas for better understanding and to mitigate the risk levels of contaminated shellfish. The management plan considers the inherent risk, the cost associated with managing the risk, and the legislative and financial burden on seafood producing businesses.

Scope

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

The recreational collection of shellfish is not in the scope of WASQAP. It is impossible to guarantee the safety of eating wild shellfish without having a comprehensive monitoring program. Such programs are extremely expensive and difficult to undertake. The department therefore recommends only eating shellfish harvested commercially under strict monitoring programs.

Requirement for MBMMP

It is a requirement of ASQAP, shown in section 4, that each harvest area establishes a marine biotoxin risk analysis and implements a marine biotoxin management plan. This is approved by the Shellfish Control Authority (SCA). Additionally, ASQAP outlines the required content for the MBMMP, which includes:

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

b) hydrographic details describing predominant currents and circulatory patterns detailed in the respective harvesting area annual review reports

c) species of shellfish cultured and harvested that are detailed in the HCSMP

d) sample sites detailed in the HCSMP

e) sampling frequencies detailed in the sampling program and the HCSMP

f) sampling methods detailed in the WASQAP sampler manual

g) methods of analysis for water and shellfish samples detailed in the WASQAP sampler manual

h) laboratories used for sample analysis detailed in the WASQAP sampler manual

i) alert or closure levels for toxic or 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 if 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, and 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.

Further information on each of the above listed points can be found within the MBMMP, the WASQAP industry manual, the ASQAP manual and the WASQAP sampler manual.

History of biotoxins in WA

The biotoxin risk analysis in the previous MBMMP was based on information provided in part B of the Cawthron report (number 645) as well as the 2014 Review the Tasmanian paralytic shellfish toxin (PST) event and SafeFish recommendations to determine an interim risk management approach for WA report prepared by Curtin University at Centre of Excellence for Science, Seafood and Health (CESSH).

The CESHH report acknowledged that while filter feeding bivalve shellfish species leads to a high capacity of accruing biotoxins, there is a low putative biotoxin risk in Western Australia's commercially harvested areas. There have been a limited number of detections since routine biotoxin sampling commenced in 2015. Therefore, the sampling frequencies for phytoplankton and biotoxin testing remain twice monthly for phytoplankton testing and once a month for biotoxin testing, reflecting a low-risk rating.

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

Roles and administrative responsibilities

Roles and administrative responsibilities for the MBMMP are the same as those in the WASQAP industry manual.

The department	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	Assists with risk assessment and threshold reviews and to lead research and development relevant to biotoxins
Confirms closures and re-openings initiated by industry and notifies all parties concerned.	Ensures sampling schedule is implemented and staff undertaking samples are appropriately trained	Informs about current research and development opportunities
Reviews phytoplankton and biotoxin results in the annual review reports	Maintains 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	

Table 1 roles and responsibilities for the marine biotoxin monitoring and management plan.

Harvest areas and sampling sites

Phytoplankton sampling sites are 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 individual management plans. Phytoplankton and biotoxin sampling protocols and procedures for sample collection and dispatch to the analytical laboratory are also detailed in the WASQAP sampler manual and are covered in the online sampler training module.

Phytoplankton and shellfish monitoring and sampling procedure

These are the procedures that apply to routine sampling and sampling undertaken in the event of an exceedance.

Overview of sampling

All sampling is performed in accordance with the WASQAP sampler manual and the WASQAP industry manual. Biotoxins are sampled monthly and when phytoplankton levels are above threshold levels, seen in table 2.

However, it should be noted that individual importing countries may have further requirements, for example. for the EU market, export listed harvest areas require weekly biotoxin analysis. For further information on export requirements, refer to Department of Agriculture, Fisheries and Forestry (DAFF)[1].

Biotoxins such as PST, DST, and AST are routinely tested in shellfish flesh by confirmatory analyses by approved laboratories with recognised methods (refer to ASQAP section 10). Flesh samples are provided from current harvest areas, and where more than one species of shellfish is harvested from an area, all species must be tested for biotoxins.

Phytoplankton are screened in water samples through the identification and enumeration of target toxin producing species, seen in table 2.

Phytoplankton samples are provided from predetermined sampling locations. Samples must be analysed by a laboratory that meets the laboratory and analytical requirements outlined in 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 Western Australia. 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, including liaising with samplers, laboratories, and transport providers.

Biotoxin events are notoriously unpredictable. It is possible that new biotoxin events and challenges will arise even when the best routine monitoring program is actively implemented. Therefore, environmental factors should also be considered as useful indicators to a pending food safety biotoxin event aside from the mandatory sampling programs. Such clues can be drawn from, but should not be limited to, fish kills, meteorological data, nutrient-involved pollution spills and obvious blooms These are

[1] Australian Government Department of Agriculture, Fisheries and Forestry website

noted on the WASQAP sampling program information sheet. Refer to WASQAP industry manual appendix 1.

Phytoplankton sampling should be undertaken on a regular basis, with the frequency remaining consistent throughout the year, as potentially harmful species can occur at any time of the year. Therefore, phytoplankton water samples are collected bimonthly throughout the year as per the sampling program for harvest areas. However, the frequency of phytoplankton sampling may increase in response to results of the regular monitoring program.

Where the harvesting area has been in a closure unrelated to regulatory triggers, two phytoplankton samples are taken two weeks apart and one biotoxin sample is taken prior to the commencement of any harvesting.

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 harvest area is in the open status. weekly biotoxin samples are required if the harvest area is EU listed.

Event samples

Sampling is required to confirm biotoxin levels during the closure of a harvest area. 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 seen in the FRDC Project 2012-060. Whilst phytoplankton provides a support role, particularly in the early identification of impending blooms, they provide a robust risk management tool. Concurrent meat and phytoplankton sampling improves the knowledge of biotoxin risk and is required.

Sampling methods

Samples are taken from predetermined sampling stations in accordance with the harvest area sampling plan and the demonstrated biotoxin risk rating. Further details on approved sampling methods can be found in the WASQAP sampler manual.

Phytoplankton samples

A water sample is taken by industry representatives using the integrated tube sample method for water depths greater than 2 metres and a bucket or bottle method for waters less than 2 metres. Samples are sent to the laboratory for phytoplankton to be counted and identified for target species.

The turnaround time for sample results needs to be strictly managed by industry to limit harvest closures.

Phytoplankton results not received within one week of its submission or scheduled date will result in a harvest area closure unless prior arrangements have been made with the department’s food unit. Water samples are to be reported within 72-hours of

arrival at the laboratory, with the total time not exceeding 8[2] days from the scheduled sampling date unless prior approval is granted by the SCA. 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 directly for analysis.

Sample Type	Maximum time to get sample to lab	Maximum time for notification of results*	Maximum time for lab report be issued
Phytoplankton water sampling	24 to 48 hours	72 hours	7 days

*Refers to the early notification of results.

Shellfish flesh samples

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

A representative sample for each species grown in the harvest area must be taken and analysed monthly at a minimum. Samples are stored and transported in accordance with the requirements of the analytical laboratory. A subsample is to be taken alongside phytoplankton samples and held frozen for 6 weeks pending on the phytoplankton test results.

For the EU market, weekly biotoxin testing is required. 4.5.2 to 4.5.4 of the WASQAP manual does not apply.

Appropriately validated qualitative marine biotoxin screening methods can only be used to determine if a quantitative method should be undertaken on a sample from a closed area for reopening purposes in consultation with the SCA.

Summary of sampling frequency

Determinant service	Product	Minimum frequency
Biotoxins (PST, AST, and DST)	Shellfish flesh	Monthly*
Phytoplankton (ID and cell counting of toxin producing species)	Water	Twice monthly

*Samples are taken twice monthly alongside phytoplankton samples, with samples being sent to the laboratory at a minimum of monthly for biotoxin analyses. The alternate sample is to be held frozen for 6 weeks pending phytoplankton test results.

[2] Not applicable to export listed areas.

Closure management

Phytoplankton trigger levels that alert management actions, such as a closure, are listed in table 2 and regulatory closure thresholds for biotoxins in shellfish flesh are listed in **Error! Reference source not found.** The phytoplankton trigger levels documented in were developed based on the WA biotoxin risk assessment in the 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.

If potentially toxic phytoplankton species are identified at levels exceeding those in table 2 below the laboratory analyst will:

- immediately notify the department's food team by phone or email
- ensure notification containing the specified subject heading is also to be sent to their email address with high importance with the subject title 'Algal Bloom Shellfish Hazard'.

The food business must:

- arrange for the chilled or frozen sample of shellfish to be tested for biotoxins
- collect another water and flesh sample for phytoplankton or biotoxin analysis
- submit the water sample for phytoplankton analysis
- freeze the flesh sample as per section 2.3.2.

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, shown in table 3, the food business must close the harvesting area.

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

- phytoplankton levels exceed the levels provided in the management plan in absence of shellfish flesh toxicity data
- samples as required by the SCA have not been taken
    - for EU listed harvest areas, any sampling area not sampled for either phytoplankton or biotoxin in exceedance of 3 days over their scheduled sampling frequency must be closed unless prior approval has been granted by the SCA.

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

Where a harvesting area is not closed, the department 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, and product recall will be implemented.

A formal closure, detailed in the 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, or ASP that have resulted from the consumption of shellfish from an identified area. Additionally, a formal closure may be considered appropriate by the department where necessary for other reasons, such as toxins present in neighbouring areas or reporting of a potentially toxic phytoplankton species not previously reported from the harvest area.

For export listed areas, if there are two or more confirmed cases of food-borne illness, the harvest area is promptly placed in the closed status and DAFF are notified. For more details refer to exports standards.

Microalgae species	Type of toxin	Closure and flesh testing level
Alexandrium catenella[1]	PSP	100
Alexandrium minutum[1]	PSP	100
Alexandrium ostenfeldii[1]	PSP	100
Alexandrium tamarense[1]	PSP	100
Gymnodinium catenatum	PSP	1,000 mussels 2,000 other shellfish
Dinophysis acuminate	DSP	1,000
Dinophysis acuta	DSP	1,000
Dinophysis caudata	DSP	1,000
Dinophysis fortii	DSP	1,000
Prorocentrum lima	DSP	500
Prorocentrum rathymum	DSP	*
Pseudo-nitzschia seriata group (P.multiseries and P.australis)[2]	ASP	500,000
Pseudo-nitzschia delicatissima group[2]	ASP	500,000
Karenia cf.brevis	NSP	1,000
Karenia, karlodinium, and *gymnodinium* group[3]	NSP	250,000

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

*Reportable for presence and cell density only, as no evidence to set up action levels.

N.B. The cell levels within each toxin group are cumulative. (e.g. 600 cells per 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*, and *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 harvest 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.

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) Saxitoxin dihydrochloride equivalent High performance liquid chromatography (HPLC) Fluorescence detector HPLC-FLD	Monthly routine sampling or phytoplankton over trigger levels EU market as per EU regulation 853\2004 and 2019/627. Weekly testing to include all species	FSC, 0.8 mg/kg saxitoxin dichloride equivalent EU market as per EU regulation 853\2004 – 800 µg per kilogram
Amnesic shellfish toxin (AST) domoic acid equivalent Liquid chromatography coupled with mass spectrometry (LCMSMS analysis)	Monthly routine sampling or phytoplankton over trigger levels EU market as per EU regulation 853\2004 and 2019/627. Weekly testing to include all species	FSC – 20 mg/kg domoic acid equivalent EU market as per EU regulation 853\2004 – 20 mg of domoic acid per kilogram
Neurotoxic shellfish poisoning (NSP toxins*)	Monthly routine sampling or phytoplankton over trigger levels Testing to include all species	FSC - 200 MU/kg
Diarrhetic shellfish toxin (DST) okadoic acid equivalent (LCMSMS)	Monthly routine sampling or phytoplankton over trigger levels EU market as per EU regulation 853\2004 and 2019/627 – weekly testing to include all species	FSC - 0.16 mg/kg okadaic acid equivalent EU market as per EU regulation 853\2004 - for okadaic acid, dinophysistoxins and pectenotoxins together,160 µg of okadaic acid equivalents per kilogram
YTX yessotoxins (LCMSMS) AZP azaspiracids (LCMSMS)	EU market as per EU regulation 853\2004 and 2019/627 testing to include all species EU market as per EU regulation 853\2004	YTX is not regulated in Australia and although it is toxic to mice when applied intraperitoneally, its oral toxicity is questionable (Cawthron Institute, 2001). EU market as per EU regulation 853\2004 – 3.75 mg of yessotoxin equivalents per kilogram EU market as per EU regulation 853\2004 – 160 µg of azaspiracid equivalents per kilogram

Table 3: marine biotoxin regulatory closure levels

N.B. DSP toxins include okadaic acid (OA) and dinophysistoxins (DTXs).
For EU listed harvest areas, include pectenotoxins (PTXs) (PTX2-sa is currently regarded as non-toxic) 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 or 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 milligram per kilogram brevetoxin-2 is equivalent to 200 MU per kilogram.

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).

Harvesting area reopening

Reopening criteria

Phytoplankton results may be used to determine meat testing requirements. Refer to 3.3 and figure 2.

The reopening of the harvest area may occur if biotoxin tests on at least two successive meat samples* taken a week apart show that the following concentrations of biotoxin in the bivalve shellfish tissue are below the maximum level (ML) in the Code:

- water samples collected during the same period show levels of toxic algae at or below the levels in table 2
- algal levels are not increasing in number.

NB *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 reopening purposes to test the first of two samples collected to reopen areas. Refer to section 10 of ASQAP.

For seasonal start up following closure unrelated to biotoxins or phytoplankton levels, such as commercial reasons, two phytoplankton samples must be taken two weeks apart and one biotoxin sample must be taken prior to the commencement of harvesting.

1. For reopening due to elevated toxin levels in a harvest area, all species must comply with the food standards code, with two tests sampled not less than one week apart. This will assist in determining the food safety risk of each species.
2. 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 increasing toxic phytoplankton within 80 per cent of levels in table 2, reopening may only occur after a third consecutive compliant meat test result which may be taken an additional 48 hours or more after the second bivalve shellfish meat sample.
3. Following the reopening 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 reopening. Refer to opening procedure in HCSMP.

If a shellfish harvesting area is closed, you must continue to collect the necessary samples to maintain classification.

A summary of the WASQAP biotoxin detection and action process relevant to commercially produced shellfish is displayed below in figure 2.

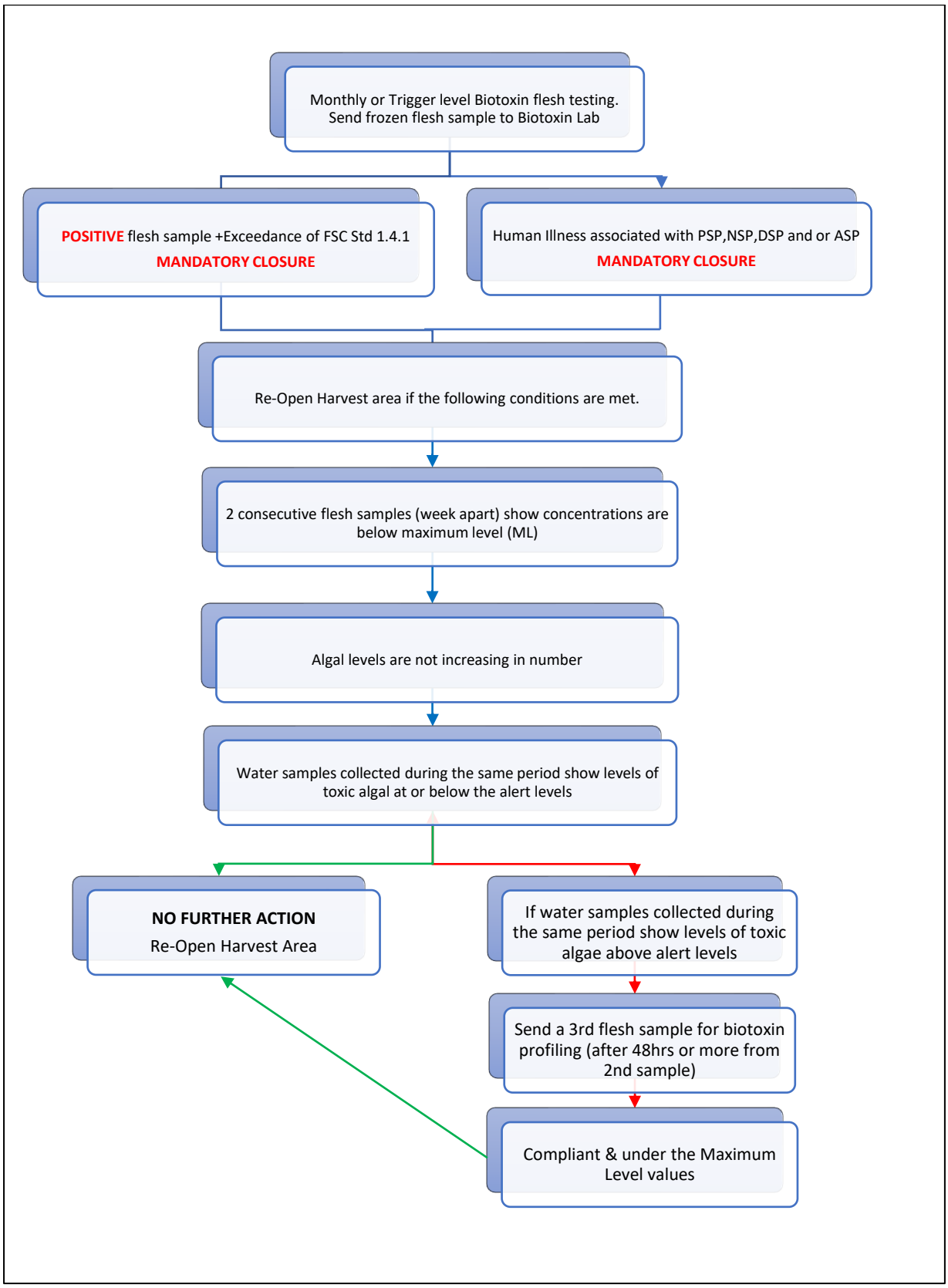

Figure 2: procedures for re-opening commercial harvesting areas after experiencing an exceedance of the levels in the FSC standard 1.4.1 (Schedule 19) for biotoxins in the flesh of shellfish.

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 (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 is historically nontoxic in Australia

Category B – potential unclear or untested toxin producing species 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 m*onotis (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 is 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)
- *gonyaulax spinifera* (possible yessotoxin)
- *pseudonitzschia calliantha* (domoic acid).

? – indicates this toxin has not been confirmed at the time of this report as being produced by australian strains of this species.

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)
- C toxins (CTXs)

Microalgal sources:

- *Gymnodinium catenatum*
- *Alexandrium* species (including *alexandrium minutum, alexandrium catenella, alexandrium tamarense, alexandrium fundyense, alexandrium ostenfeldii*)
- *Pyrodinium bahamense var. compressum*, also freshwater species such as anabaena spp.
- Microcystis spp.

Common symptoms include:

- STXs that block nerve conduction, manifesting as respiratory distress due to partial paralysis of the muscles necessary for breathing
- mild neurological symptoms, including 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, including functional weakness (impaired grip strength, staggering gait), difficulty breathing, and signs of acute respiratory insufficiency, such as cyanosis of the lips or fingernails
- severe STX intoxication, which 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, such as numbness or tingling around the mouth, face or extremities
- any of the following neuromotor or neurocerebellar symptoms:
  - weakness such as trouble rising from seat or bed
  - difficulty in swallowing
  - difficulty in breathing
  - paralysis
  - clumsiness
  - unsteady walking
  - dizziness or vertigo
  - slurred or 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, excluding leftovers, within 7 days of collection of shellfish consumed by the case (current levels are 80 µg per 100 grams of 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 are 10 MU/kg body weight, about 2 µg/kg body weight).

Amnesic shellfish poisoning (ASP)

Causative toxins:

- domoic acid (DA).

Microalgal sources:

- pseudo-*nitzschia* species including:
    - pseudo-*nitzschia australis*
    - pseudo-*nitzschia multiseries*
    - pseudo-*nitzschia delicatissima*
    - pseudo-*nitzschia fraudulenta*
    - pseudo-*nitzschia pseudodelicatissima*.

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

Common symptoms include:

- mild intoxication, which may involve only gastrointestinal upsetting such as nausea, vomiting, diarrhoea, and gut pains.
- symptoms of neuro-intoxication. including headaches, convulsive seizures, myoclonus (involuntary, irregular muscle contractions), cognitive impairment and disorientation, anterograde amnesia (the inability to lay down new memories following neurological damage), respiratory difficulties, 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 leftover food
- one or more of the following neurological signs or symptoms occurring within 48 hours of consuming shellfish:
    - confusion
    - memory loss
    - disorientation
    - seizure
    - coma.

Probable case

Meets the clinical case definition, and detection ASP biotoxin at or above the regulatory limit in shellfish obtained from near or at the same site excluding leftovers, within 7 days of collection of shellfish consumed by the case (current levels are 20 ppm domoic acid or 100 grams 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 causes illness (current levels are 0.05 mg/kg body weight).

Diarrhetic Shellfish Poisoning (DSP)

Causative toxins:

- okadaic acid (OA)
- dinophysistoxins (DTXs)
- for EU listed harvest areas, pectenotoxins (PTXs).

PTX2-sa is currently regarded as non-toxic

NB. 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*
- *dinophysis acuta*
- *dinoph*ysis caudata
- *dinophysis fortii*
- *prorocentrum lima.*

DST producing species are found in all states in Australia at various levels.

Common symptoms:

- include nausea, diarrhoea, vomiting, abdominal pain and headache 30 minutes to a few hours after
  consumption
- usually resolves by three days following consumption of contaminated shellfish.
- 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, therefore the concerns of public health agencies are currently directed toward concentrations of OA in shellfish that cause acute gastrointestinal illness.

No fatalities have been reported.

There is no epidemiological evidence of human health effects from yessotoxin. 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, excluding leftovers, within 7 days of collection of shellfish consumed by the case (current levels are 20 µg/100 g shellfish, or 5 MU/100 g)

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 levels are 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),
- potentially k. *papilionacea* (=*gymnodinium papilionaceum*)
- k. mikimotoi (=gymnodinium mikimotoi)
- *chattonella* species
- *heterosigma akashiwo*
- *fibrocapsa japonica*.

Common symptoms include:

- chills, headache, diarrhoea, muscle weakness, joint pain, nausea and vomiting within 3 to 5 hours
- altered perceptions between hot and cold
- difficulty in breathing
- double vision
- trouble in walking
- trouble with swallowing.

Clinical case definition

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

- neurosensory:
  - paraesthesia (numbness or tingling around the mouth), face or extremities
  - alternation of temperature sensations such as a prickly feeling on the skin during a bath or shower or during exposure to sun, or difficulty distinguishing hot or cold objects
- neuromotor or neurocerebellar:
  - weakness such as trouble rising from seat or bed
  - difficulty in swallowing
  - difficulty in breathing
  - paralysis
  - clumsiness
  - unsteady walking
  - dizziness or vertigo
  - slurred or 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, excluding leftovers, within 7 days of collection of shellfish consumed by the case (current levels are 20 MU/100 g of 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 levels are 0.3 MU/kg of body weight

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