Ministry for Primary Industries
Manatū Ahu Matua

Submissions Template: Proposed amendments to the:

Proposed Animal Products Notice: Regulated Control Scheme - Bivalve Molluscan Shellfish for Human Consumption

Questions MPI would like feedback on			MPI Response
1.	Is the level of detail appropriate?	More detail is needed in some areas – see comments	
2.	Are the technical aspects correct?	Some anomalies – see comments	
3.	Are the procedures practical and achievable for the seafood sector?	See comments related to verification	
4.	Are there any areas that need more guidance?	See comments	

Section Reference	3. Comment	4. Proposed amendment	MPI Response
Definitions: Prohibited Zone Selective area			Noted Have changed “selective” to “limited”
Definitions: Epidemiological association (Also see Section 8.6- 8.8)	Due to the importance given to epidemiological association in subsequent clauses, it is important that guidance is provided on what this means, and how it should be assessed.		Agree to add definition back in. It is used 3 times. Twice relating to suspected illness. The other in 2.12 b) is when there is a confirmed epidemiological association, the APO needs to ensure ongoing review of implicated sources.
1.1 (1)	Definitions	All definitions should remain in the new Specifications. It is important that this document stands alone so that other documents/regulations don’t have to be accessed or referred to for interpretation. In particular there are definitions that need to be included to ensure that a particular response/action is not open to broad interpretation for example;	BMS RCS Regulations definitions will not be added back. The Notice and Regulations need to be jointly used whenever considering the standards. This encourages readers to go back to the regulations. Note 1.1 (2) refers to definitions in the regulations: (2) Any term or expression that is defined in the Animal Products Act 1999, Animal Products (Ancillary and Transitional Provisions) Act 1999, or Animal Products Notice: Regulated Control Scheme – Bivalve Molluscan Shellfish for Human Consumption, and used but not defined in this Notice has the same meaning as in those Acts or Regulations.

Section Reference	3. Comment	4. Proposed amendment	MPI Response
		• Anniversary (date, year, season?)	Anniversary used once:- On an annual basis, and within 60 working days of the anniversary of the date of the current sanitary survey, an APO must review each growing area to reflect any changes in the growing area catchment. No change as word carries its ordinary English meaning. Added clause in schedule 1 Table 1A, 9. Conclusions new "(4) Anniversary date".
		• Immediate (what time frame?)	Immediate used in 4 places. 3.4 (2) & 4.2 (1) g) & 7.2 (1) & 8.8 (3) a) - Do not recommend changing because "immediately" carries its ordinary English meaning, implies more urgency than "within 24 hours", and for the 24 hour wording to make sense you'd need to identify the start of the period, which is impractical in these cases.
		• Unusual Event (what is an unusual event? Examples?, see comment below)	Unusual event used once. The rationale for determining it as an unusual event has to be acceptable to a Shellfish Specialist. Better to provide more information in a Guidance Ddocument with examples. Disagree adding to definitions.
		• Critical measurement	Where critical measurement used in 16.1 it is explained. Disagree adding to definitions.

Section Reference	3. Comment	4. Proposed amendment	MPI Response
		• Temperature control	Where temperature control used in part 13 explained. Where used in section 12 can refer to "temperature controls" in section 13. E.g. *(3) Sorting sheds may be provided with a refrigeration facility or some other means by which BMS can be subjected to temperature control to ensure compliance with schedule 4 time-temperature requirements.*
		• Indirect impact (what is an indirect impact? Examples?)	Disagree adding to definitions.Better to provide Guidance because 2006 definitions was unclear.
		• Unacceptable (based on what?)	Where unacceptable used 4 times, 3 times it is unacceptable to Shellfish Specialist and once to APO. They use professional judgement and justify decision. Disagree adding to definitions.
		• Allow discovery of	Used "allow discovery of" in 14.7 (2) b). No definition needed where used self-explanatory.
		It is agreed that definitions that are not used anywhere in the BMS RCS should be deleted. The inclusion of the 'New definitions' is supported.	Noted

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		The changes to definition's to read better and to improve clarity are also supported.	
1.1 (1)	**Formatting:** adverse pollution conditions definition no longer includes acronym APC. Why was the acronym removed from previous version?	Keep Acronym i.e. **adverse pollution conditions (APC)**, in relation…..	Added APC after "adverse pollution conditions" in definitions. Added "strategy" after APC use in 14.3 (3) t). Where APC is used in schedule 3 it is defined.
1.1 (1)	**Formatting:** Global positioning system acronym not in bold	Update Global positioning system acronym to be bold i.e. **global positioning system (GPS)** is a system….	Changed to: **GPS** means the global positioning system, a system for determining position on the Earth's surface
1.1 (1)	**Formatting:** The organism names listed under the pathogen definition are no longer start with capital letters or in italic font	Update organisms to read as per the BMS Notice 2006 e.g *Salmonella*	Changed to capitalise and italics.
1.1 (1)	Prohibited zone definition could be worded more clearly.	Update to read "**prohibited zone** means part of a growing area in which commercial harvesting of BMS is	Disagree - we need "except" because sometimes we may allow harvest from prohibited zones.

Section Reference	3. Comment	4. Proposed amendment	MPI Response
		prohibited, as outlined in Part 3	
1.1 (1)	**TYPO:** recognised laboratory definition refers to "the Act" but would be better to include the name of the Act	Include the name of the Act in the definition	Notice issued under the Animal Products Act. Act defined in the BMS RCS Regulations. – it's only used once, and to define it would be inconsistent with the principle that we're not defining terms that are defined in the Regulations. But where used written in full.
1.1 (1)	**TYPO:** Spat definition sub list starts at c) instead of a)	Update numbering to start at a)	Noted.
1.2	Period of time that records need to be kept for.	We suggest that records need to be kept at minimum for the 12 year cycle required for the Sanitary Survey for each growing area. Some records need to be kept even longer e.g. phytoplankton and biotoxin results from 1993. If there are certain types of records that can be kept for a shorter period of time then these could/should be specified.	4 years was stipulated 2006 BMS RCS. Still applicable. Does say "at least" 4 years. MPI administratively holds all records for growing areas and archives very old documents. None are destroyed. Original 1970s documents still available. For other records, e.g. harvest declarations, depot records etc. - 4 years is adequate.

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Spat definitions	Need a re-evaluation of the objectives and rationale for the need to specify spat sizes, and if needed to determine appropriate spat size limits in association with industry and Fisheries legislation.	Editorial change required before industry will support.	Where Fisheries legislation have spat definition we try to follow but Fisheries have 10mm and 40mm for GSM spat in differing legislation. Scallop one place 50mm. Discussed with industry at meeting. No change.
2.1 (4)	Opportunity to improve wording to be clearer.	Every listed classified growing area is reviewed annually by an APO to check whether it has the right classification, but the classification may also be reviewed as described in clause 2.12.	Agree. Changed to: (4) Every listed classified growing area must be reviewed annually by an APO to check whether it has the right classification, and the classification may be reviewed at other times as set out in clause 2.12.
Section 2.3 (1) b) BMS spat may be harvested … of growing on for a minimum of six months….	Request addition of language… for a minimum of six months or a lesser period as approved by the Shellfish Specialist.	Editorial change required before industry will support.	Agree. b) BMS spat may be harvested from the area for the purpose of growing on for a minimum of 6 months, or any shorter period determined by a shellfish specialist, before harvest for human consumption.
Section 2.4 (2)	Sanitary survey every 12 years is no longer necessary in today's age of electronic	Industry wishes to discuss this concept framework further.	May conflict with USA, but if same outcome can be met MPI is open to industry's suggestions on how to achieve same outcome.

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	reports. The report should be updated as information comes to hand or at least on an annual basis.		Discussed at industry meeting. No change.
2.6 (3)	Opportunity to improve wording to be clearer.	For growing areas under the APC strategy, an APO must use no less than 15 of the most recent samples covering a minimum of 3 years from each primary sample station to calculate the bacteriological standard described in clause 2.6 (2) b).	Agree Wording is unclear, because the idea of "the most recent" conflicts with the idea of "the last 3 years". Changed to: (3) For growing areas under the APC strategy, in order to calculate the bacteriological standard described in clause 2.6 (2) b), an APO must use no less than 15 of the most recent sample results.
Section 2.6 Remote Approved growing area	SRS sampling requirements should also be listed.	Editorial change required before industry will support.	Not in favour at this stage. SRS requires minimum of 6 sampling events per year so no benefit for industry (can be 5 or less samples per annum). Discussed at industry meeting. No change.
2.7 (2) c)	Opportunity to improve wording to be clearer as well as align with section 2.8 (2) c)	Where the APC strategy is used, at each primary sample station:	Agree for 2.7 (2) c) i) and ii), and 2.8 (2) c). Changed to: (2)c) i) where the APC strategy is used, at each primary sample station:

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			ii) where the SRS strategy is used, at each primary sample station:
2.7 (2) c) ii)	**TYPO:** The word 'and' is included at the end of the criteria but a growing area would be using a APC or a SRS strategy so it should be 'or'	… the samples exceed an MPN of 700 per 100 grams; or	If use 'or" then infers it excludes clauses a) and b). No change
2.7 (2) d)	Opportunity to improve wording to be clearer as well as align with section 2.8 (2) d)	Where the SRS strategy is used, at each primary sample station:	Agree as above for 2.7 (2) c) and d).
2.7 (3)	Opportunity to improve wording to be clearer.	For growing areas under the APC strategy, an APO must use no less than 15 of the most recent samples covering a minimum of 3 years from each primary sample station to calculate the bacteriological standard described in clause 2.7 (2) c).	Agree, changed to: (4) For growing areas under the APC strategy, in order to calculate the bacteriological standard described in clause 2.7 (2) c) i), an APO must use no less than 15 of the most recent sample results.
2.8 (2) c) ii)	**TYPO:** The word 'and' is included at the end of the criteria but a growing area	… 10% exceed 14,100 per 100 grams; or	If use 'or" then infers it excludes clauses a) and b). The "and" is ok if we have the "where" in front. Have re-formatted 2.7 and 2.8 to make the intention clearer.

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	would be using a APC or a SRS strategy so it should be 'or'		
2.8 (3)	Opportunity to improve wording to be clearer.	For growing areas under the APC strategy, an APO must use no less than 15 of the most recent samples covering a minimum of 3 years from each primary sample station to calculate the bacteriological standard described in clause 2.8 (2) c).	Agree changed to: (5) For growing areas under the APC strategy, in order to calculate the bacteriological standard described in clause 2.8 (2) b) i), an APO must use no less than 15 of the most recent sample results.
Section 2.8 (2) (b) …not impacted by sewage discharges etc.	What is the purpose of this section? It should read as per the NSSP requirement: Restricted Classification. (1) General (a) A growing area may be classified as restricted when: (i) A sanitary survey indicates a limited degree of pollution; and (ii) Levels of fecal pollution, human pathogens, or poisonous or deleterious substances are at such	Clarification sought before industry can support or object.	2006 RCS clause 17 (2) (b) had same statement. This is for "non-point" impacted areas. Discussed at industry meeting. Agree clause needs modified to apply to potential depurated product only. Have reworded and added subclause (3): (3) However, if the limited pollution is non-point source but arises from discharges from sewage treatment facilities or combined sewerage overflows, the area may be classified as restricted only if the BMS is subject to relay or other processing (and not merely to depuration).

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	levels that shellstock can be made safe for human consumption by either relaying, depuration or low acid-canned food processing. Maybe this relates to sampling numbers? In which case it should appear in that section.		
Section 2.9(1) Conditionally approved areas	2.9(1) needs reworded as: (1) BMS may be commercially harvested from a growing area for human consumption that is classified as conditionally approved or conditionally restricted: a) only in accordance with the conditional area management plan for the area; or and b) unless when the area is not closed in accordance with Part 7.	Editorial change required before industry will support.	Changed to: (1) BMS may be commercially harvested from a growing area for human consumption that is classified as conditionally approved or conditionally restricted: a) only in accordance with the conditional area management plan and the marine biotoxin management plan for the area; and b) if the area is not closed under Part 7 Opening and closing growing areas.

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Section 2.9 (2)	The word here should be 'may' not 'must' - these are requirements that can add to ability to classify CA but are not imperative.	Editorial change required before industry will support.	Agree, changed to 'may'.
Section 2.10 need for scallop areas to have sanitary surveys	We Oppose; There is insignificant food safety gain in requiring sanitary surveys for scallop areas**.**		This is to tidy up a legal issue, we need the areas to be a classified area so can list them and open and close the areas legally. Solution proposed in schedule 1 (see below) to address.
Section 2.10 (3) Selective growing area	We Seek Amendment; Suggested language change: (1) A growing area may be classified as selective **if an assessment and/or** sanitary survey of the area finds that the only BMS that may be harvested for human consumption are those where the final product is the: a) adductor muscle; or		This is to tidy up a legal issue, we need the areas to be a classified area so can list them and open and close the areas legally. Solution proposed in schedule 1 (see below) to address. Noted have changed "selective" to "limited"

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	b) roe; or c) adductor muscle and roe (e.g. scallops). (2) That kind of BMS may be commercially harvested from a growing area classified as selective unless the area is closed in accordance with Part 7. (3) Other BMS must not be harvested.		
Section 2.10 need for scallop areas to have sanitary surveys	There is insignificant food safety gain in requiring sanitary surveys for scallop areas.	Industry does not support and wishes to discuss this concept framework further.	Discussed at industry meeting. Understand legal requirements. When explained an administrative issue which can be done without extra cost to industry. File current marine biotoxin plans.
Section 2.10 (3) Selective growing area	Suggested language change: (1) A growing area may be classified as selective if a sanitary survey of the area finds that the only BMS that may be harvested for human consumption are those	Editorial change required before industry will support.	Discussed with industry. No change. Except changed "selective" to "limited".

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	where the final product is the: a) adductor muscle; or b) roe; or c) adductor muscle and roe (e.g. scallops). (2) That kind of BMS may be commercially harvested from a growing area classified as selective unless the area is closed in accordance with Part 7. (3) Other BMS must not be harvested.		
Section 2.11 (2) a) iv) Annual review of growing areas…. In the case of sources implicated in illness outbreaks, a thorough re-evaluation	Add the words "previously implicated" and "as appropriate" (it may that the source no longer exists).	Editorial change required before industry will support.	Agree changed to: (2) The annual review involves all of the following (where applicable): a) a field observation and evaluation of the pollution sources identified in the sanitary survey and their performance standards, if any. This may include: i) a drive through survey; or ii) observations made during sampling; or iii) information from other sources; or

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			iv) in the case of sources **previously implicated** in illness outbreaks, a thorough re-evaluation;
2.12 (1) d) Growing area classification review (links with Part 8.8)	Human pathogens or chemical contaminant of themselves are not sufficient to cause a classification review – it is when they are reaching or breach tolerance levels. (e.g. concepts in Chapter II Risk Assessment/Management NSSP)	Editorial change required before industry will support.	The clause requires the APO to determine therefore have to justify and needs to breach a recognised tolerance level. Discussed at industry meeting. No change.
2.13	Opportunity to improve wording	….supported by a sanitary survey conducted in the 12 months prior to the reclassification.	Agree changed to: Any revision of a growing area classification to a less restrictive classification must be supported by a sanitary survey, which may be done by way of updating the most recent sanitary survey of the area.
2.13 Upward revision of classification must be	Don't concur – it must just be an 'adequate' survey.	Industry does not support current language.	It is a serious process going from say a restricted classification to conditionally approved classification. This is a current requirement under the 2006 RCS. The NSSP does use language "adequate sanitary survey" therefore

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supported by a 12- year sanitary survey			MPI open to suggestions though from Industry to meet same outcome. Agree after Industry meeting to achieve outcome of "adequate" The concern is that people should be able to simply update the latest sanitary survey. Changed clause to reflect that outcome.
Part 3 –Prohibited zones	Gives industry new choices.	Support	Noted
Part 3	Prohibited Zone Classification. We do not support this change. "Prohibited", clearly defines "no harvest" in its present classification. Three (3) growing areas in Northland do have areas(zones) within the defined/managed Growing Area, that operate under different rainfall/ salinity criteria and these have also been opened separately on individual(zone) biotoxin testing.	Keep the existing classifications. Allow for "Temporary" reclassification to, restricted/conditionally restricted and use "temporary" conditions to manage harvesting within a given "zone" (this exists in some GAs already) "Temporary conditions" could also be used as a management tool for "approved" (classification) GAs.	Do not support. An area is either open or closed. Legally, we cannot close part areas as we have been doing under the 2006 RCS.

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	This seems an over complication and somewhat confusing use of classifications. The Reasons given for 3.2(2) reads as per a "conditionally restricted" classification. Management plans need to be flexible on any "conditions" imposed, as the environment changes and management of a growing area develops.	Allow for short term promotion/relegation between classifications, as a management tool (More than 1 month and less than 1 year). Classification shifts could be under the same guidelines as for , 8.4(1) "Sampling when a growing area is closed for a prolonged period"	
3.2 (2) a)	We do not support the authorisation of harvesting from a prohibited zone/area for the purposes of 'processing'. Depending on the type of 'processing' (heat treatment for example) it may be insufficient to inactivate/kill human pathogens particularly viruses. See: Richards GP *et al*. 2010. Processing	Recommend removing 'processing' and that only the relay of shellfish from a prohibited zone/area be allowed.	Disagree. This decision is controlled by a Shellfish Specialist. It would have to go to an approved process in a premises that will be effective for the hazard of concern. Example a norovirus contaminated area we could allow harvest for canning. Need to allow flexibility for industry.

Section Reference	3. Comment	4. Proposed amendment	MPI Response
	Strategies to Inactivate Enteric Viruses in Shellfish. Food and Environmental Virology 2:183-193.		
Section 4.2 (1) Content of conditional area management plan. j) i) & ii) where relevant a statement that BMS must remain in growing area for a period acceptable to an APO if BMS are removed from water for farm management purposes and the area closes to conditions before BMS are placed back into water	What determines 'relevant'? This is overly punitive – the product should simply go back into the water and be managed under the normal plan.	Industry does not support.	Current clause is in 2006 RCS 26 (1) (e) (ii) Can see no NSSP requirement for this. Would apply mainly to oysters. So if oysters out of water and area closes, the oysters will be better off because they will miss the initial contamination slug. Product when placed back in the water then fits in with normal management plan conditions. Same principle could apply for biotoxin events. Agree, deleted.
Section 4.3 (1) … under which an APO may or must open or close….	Why both may and must – should it be 'must'? We would want to keep the 'must' as it also refers to opening an area, and industry needs certainty over	Clarification sought before industry can support or object.	Agree delete "may or" Adequate provisions for other closures "may" in section 7.2.

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	when an area will reopen under routine rainfall criteria etc. It may be possible to specify where it is appropriate to say "may" (where APO discretion is needed) and where it is appropriate to say "must" (where the management plans provide very clear triggers)		Section 4.3 is for conditional management plans and where an area must be closed.
Section 4.3 (3) 'wastewater treatment plant'	Do we need a definition for 'wastewater treatment plant?' The listed criteria are appropriate for significant municipal systems, but not for smaller package systems or even septic tanks.	Clarification sought before industry can support or object.	This is where the WWTP affects the growing area. So yes if it is a small system that discharges those items not onerous and need consideration. Not a new clause. 2006 RCS 26 (1) (a) had same clause. But understand need clarity around not an individual domestic septic system. Package system that cater for multiple sources need to be covered. The clause is about known impact. Considered adding a definition for WWTP. But no suitable definition therefore best dealt with guidance.

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4.5 & 5.4	It is agreed that consultation among all stakeholders (APO, Technical Expert Assistants, Shellfish Specialist, Growers & Harvesters, Consultants etc) should occur for Management Plans. However, in its current form, the Specification allows for a process with limited boundaries and no timeframe. This could essentially put growing areas in limbo or closure if all parties cannot agree.	Recommend that clear parameters, process, and timeframe be included in the Specification to ensure the consultation and decision making process happens in a timely manner. It should also be specified that consultation and decision making must be data and best practice driven and be consistent with the BMS RCS/Specifications.	Consider more guidance but believe enough in 4.5 (2) & 5.4 (2) and have timeframe stated. No change.
Section 4.5 Consultation on conditional area management plan	New section. In principle good but suggested change "representatives nominated by growers and harvesters"	Editorial change required before industry will support.	Agree
Section 5.3 (2) e) a summary of the BMS monitoring plan….	Isn't this just a summary of the implementation of the BMSMB monitoring plan over the last year? Does this mean r the whole monitoring plan to be re-iterated every Annual Review, or is it more helpful (and concise) to just	Clarification sought before industry can support or object.	Same clause as 2006 RCS. But see clarity is needed and will reword to ensure clearer. Reflect that it is a summary and to confirm was the plan implemented correctly and was it effective. We can update current guidance for annual reviews to demonstrate what is meant.

Section Reference	3. Comment	4. Proposed amendment	MPI Response
	summarise the management of the programme?		
Section 5.5 (2) a) …information from adjacent coastal marine areas	Is the intent of this to review the other official sample sites that might relate to growing area? Is there any intention to require industry do investigations outside of their intended region of responsibility?	Clarification sought before industry can support or object.	Yes to both questions especially new areas where no or limited data available then need to consider activity in adjacent areas. Discussed with industry. To help clarify add words as per below. (5) The selection of sample stations must be based on the consideration of all of the following: Or words to that effect.
Section 5.5 Marine Biotoxin Monitoring Programme (2) e) need to provide spatial and depth coverage.	Recommend inserting word 'potential need to provide spatial and depth coverage' because not everywhere will require this.	Editorial change required before industry will support.	Agree to improve clarity a. the potential need to provide spatial and depth coverage of BMS and toxigenic phytoplankton.
Section 5.5 Removal of Yessotoxin	Good move	Support	noted
Section 5.6 Frequency of sample testing (2) APO may authorise a reduced programme based in following sampling frequencies.	Industry recommends removing prescriptive sampling intervals. Each area should have a programme designed on risk based principles using factors such as geography,	Do not support in the current form. Industry wishes to discuss this concept framework further.	Discussed in Industry meeting. MPI needs to ensure same outcome met. Current frequencies can be altered with good justification via a DG application. MPI agreed to improve DG application guidance document. No change proposed to clauses.

Section Reference	3. Comment	4. Proposed amendment	MPI Response
(3) Required sampling frequencies.	shellfish species, and history of relationship between phytoplankton and toxin presence.		
5.6 (4) APO may decrease frequency of testing for seasonality based on five annual events	Industry recommends removing prescriptive sampling intervals. Each area should have a programme designed on risk based principles using factors such as geography, shellfish species, and history of relationship between phytoplankton and toxin presence.	Do not support.	Discussed at Industry meeting. MPI agree to delete "on at least 5 annual occasions" in clause 5.6 (4)
Section 5.7 Marine Biotoxin action plan	This figure does not add anything to document. The figure is simply the same process used throughout the programme as any analytes of concern increase/decrease. One could argue that there is only Triggers 1 & 2 – the rise and fall of the overall event.	Recommend deleting this section.	MPI preferred to leave because very good guidance to escalation (de-escalation) of responses but after industry meeting agreed to delete section 5.7 and ensure concept of change of sampling frequency and extra sites and or species is captured in 5.2 (1) g) Also removed references to marine biotoxin action plan in 5.2(1)(g) and 5.3(2)(g). Deleted section 5.7.

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	This section contains the same intent as Section 5.2 Content of marine biotoxin management plan. Suggest removing this section.		
5.7 Fig. 1	**Question:** Is it possible to go from closure state to routine state if results meet the trigger 4 criteria? If yes, can Fig. 1 please be reviewed		Technically yes Now deleted 5.7.
5.7 Fig. 1 a)	**TYPO:** Colon at the end of the definition not required.	Update to full stop	Noted editorial Now deleted 5.7.
5.7 Fig. 1 c)	**TYPO:** Colon at the end of the definition not required.	Update to full stop	Noted editorial Now deleted 5.7.
5.7 Fig. 1 d) f) g)	The use of "trigger level" when describing toxic phytoplankton is confusing because it does not relate to the values specifically associated with the trigger 1/2/3/4 but instead the levels in table 2.	Instead of using the word "trigger" use the word "action" as a reference to the title used for table 2. e.g. toxic phytoplankton are present above action level.	Noted editorial Now deleted 5.7.

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Section 6.2(1) i) and (1) s) iv)	Why is it necessary to record where 'wet storage' occurs? (is it to enable trace-back from to areas for biotoxin purposes etc). All product on the farm is generally wet stored and there are no food safety risks associated with 'wet stored' product i.e. harvested in accordance with growing area conditions. If there is a requirement for traceability of all lots of BMS, then that should be a separate requirement applicable across all Notice clauses and is not therefore necessary to include in each and every management plan.	Clarification sought before industry can support or object.	Traceability is a critical requirement for BMS. Discussed at industry meeting. Agreed - no change. Wet storage important for trace back during events when BMS taken from other growing areas or even within an area. E.g. Norovirus event may only impact part of an area. If BMS shifted from part where event occurred need to know where they are.

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Section 6.2 r) transport route to get BMS from source to place of relay etc	Do you mean transport 'method' – why is it essential to nominate route? Route can easily change e.g. road closures in Coromandel and will industry be penalised for doing so?	Editorial change required before industry will support.	Agree. Intent changed when present clause in current BMS RCS 54 (1) (b) was moved. *The harvest control plan must include surveillance activities ……. and the transport of BMS from the source growing area for the purposes of relay, depuration or post harvest treatment.* Recommend we change "r" to *identify surveillance activities for the transport route to get BMS from the source growing area to the place where it is taken for relay, depuration or post-harvest treatment;*
Section 6.3 Surveillance requirements (2) a) Surveillance requirements at least once every 30 days.	These section needs to be edited to say "… at least once every 30 days when the area is closed for harvest" For example, NSSP states shall patrol harvest areas classified as restricted, conditionally restricted, or prohibited, or conditionally approved and approved when in the closed status at sufficient intervals to deter illegal harvesting.	Editorial change required before industry will support.	Issue is mistake in clause 6.3 see RCS 2006 clause 54 (2) which is poorly worded. To align intent and with NSSP recommend. (1) Harvest control plans must require that surveillance is carried out on all growing areas that are: a) closed; or ~~b) conditional; or~~ ~~c) restricted; or~~ d) have prohibited zones; or e) used for relay. Then the new (2) clause is clear "where surveillance needed"

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			(6) Where surveillance is required, the harvest control plan must require surveillance of the area: a) at least once in every 30 day period; The USA require area to which shellfish relayed to be put in closed status until relay period is finished. We do not do that. Therefore in USA relayed shellfish needs surveillance hence our clause includes relay surveillance. New 9.3 (7) do not harvest until end of period. We could drop need for surveillance for relays and rely on annual review by verifier of the relaying as we will require. If MPI APO thinks an issue a condition of a relay permit can be added to require surveillance. Discussed at industry meeting and we will include only surveillance for when closed or has prohibited zone. Not relay.
Section 7.1 Non-emergency growing area closures (1) An APO must close a conditional area as soon as the criteria for closure is identified	This section suggests new administration duties for APO. (2006 BMRCS stated 'may' under certain conditions) For routine conditional management conditions, acceptable to all parties, the area should automatically	Do not support in the current form.	The BMS RCS regulations are clear. This DG exemption is delegated down to shellfish specialists. SS has approved several in the country. Reg 32 (4) For the purposes of subclause (3),— (a) the Director General may approve systems for the automatic issue of notifications; and (b) any such automatic notification is deemed to be issued by the Director General or an animal product officer.

Section Reference	3. Comment	4. Proposed amendment	MPI Response
	open and close according to harvest criteria. We lack an explicit clause to permit closing/ re-opening via automated systems and this should be inserted too in 7.3(1).		MPI add a clause in 7.1 (4) to highlight Regulation concept wrt automatic notification systems.
7.1 (3) a)	"Inactivity" probably better describes a trend in some GAs to harvest within a shorter period. Presumably "inactivity" is between 1 month and 1 year. Is Part 8, section 8.4 "inactivity"? (1 year +) Does the extended closure require application each year?	For 8.4(1) Add (c) determine the nature of any survey that may be required before the area may be opened.	Agree add clause as suggested.
7.2 (1) b)	Opportunity to improve wording to be clearer.	In the opinion of the APO, any event that may affect the public health quality of the BMS in the area, such as:	Agree change "emergency" to "event".

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Section 7.2 Emergency reasons for growing area closures (1) a) An APO must close an area immediately if an investigation confirms pathogens responsible for an outbreak.	This should be amended to clarify that it is when a growing area is implicated. Outbreaks can be caused by post-harvest contamination issues.	Editorial change required before industry will support.	Agree amend to reflect this and clarify. Added a reference to pathogens or biotoxins "from the growing area".
7.2 (1) b) iv) storm or flood.	This should be qualified to say storm or flood conditions beyond the bounds of the harvesting criteria.	Editorial change required before industry will support.	Disagree. The whole tone of clause is about emergency/extreme events. And clause has "in the opinion of the APO….." therefore APO needs to justify such an event. If include 'beyond the bounds of the harvest criteria" would limit APO. E.g. we have upper criteria e.g. clos1e seven days is >100mm in 24 hour period. From experience extreme weather bombs can drop >200mm in the Sounds in a short period and MPI have invoked this "storm' event clause to extend until APO has samples showing area OK. If we amend as suggested this would technical limit APO doing this. Discussed at industry meeting no change.
7.2 (2) b) & (3) keep an area closed for 28 days	NSSP successfully uses 21 days for viral events. Do we	Concept requires further discussion.	We would need to see the science first to justify taking from 28 to 21 days. MPI would consider change if the science rationale is provided.

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from end of contamination event	have adequate NZ information to reduce?		Discussed at industry meeting if information provided to justify change - MPI will do so.
7.2. (2) c) implement ongoing evaluation process for implicated pollution sources	This should be qualified to 'until the source has been adequately mitigated or eliminated.'	Editorial change required before industry will support.	Agree, changed to: c) implement an ongoing evaluation process for any implicated pollution sources until the pollution source has been eliminated or its effects adequately mitigated.
7.3 (and 7.1 (1)) When closed growing area may be opened (1)	This section suggests new administration duties for APO. (2006 BMRCS stated 'may' under certain conditions). For routine conditional management conditions, acceptable to all parties, the area should automatically open and close according to harvest criteria.	Industry does not support. Further technical clarification requested.	As above no need to change because the DG approval for the automatic system covers this. Discussed at industry meeting no change.
7.3 When closed growing area may be opened (4) b) requirement that intertidal growing areas have been sampled at	There is unlikely to be a variance between low and high tide. Needs to be justification for high and low tide sampling.	Industry does not support. Further technical clarification requested.	Clause was in 2006 BMS RCS - would need to see the science that justifies this. Would only apply to wild species because farmed oysters invariably farmed at one level of the tide. But outcome may be met by 7.3 (4) d. Discussed at industry meeting no change.

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low and high tide mark after biotoxin closure.			
7.3 When closed growing area may be opened (4) d) spatial sampling has been conducted to consider patchiness of bloom…	Whilst the wording "to the extent that patchiness of the causative harmful algae bloom has been adequately addressed" may addresses the need or otherwise to sample at different points in the GA, and whilst the wording of the spatial sampling may refer to flesh testing, the clause can be read ambiguously. This should be clarified	Editorial change required before industry will support.	Discussed at industry meeting no change.
7.3 (4) g)	This requires biotoxin to be below regulatory limit and static or declining, AND phytoplankton to be below trigger levels in Table 2 (part 5) and static or declining. However, this results in an area remaining in the closed state on the tail end of an event (when risk is	Editorial change required before industry will support.	2006 RCS has this clause. MPI understand issue though and good point. Not sure why has not raised as issue historically. We think could amend to this below because 7.3 (5) is catch all. a) cell counts of toxigenic phytoplankton listed in Table 2 (Part 5) are decreasing or static ~~and below the trigger level stated in Table 2~~; and

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	declining) when phytoplankton levels and biotoxin levels may both be below levels in the build up to an event (when risk is increasing) and yet the area is open because it hasn't closed yet. We should be clear, within sensible reason, that if phyto levels and biotoxin levels are ok for an area to be open (before it closes) then they should be ok for an area to be open again on the way down.		
Section 8.2.2 Remote approved areas (1) b) or samples must be collected based on alternative sampling plan accepted by shellfish specialist	Clarification required on what this section means.	Clarification sought before industry can support or object.	Was used in 2006 BMS RCS e.g. queen scallop area have approved to only take 2 BMS per annum and no water. Pointless doing water when 10-20km offshore and in 100-200m of water depth. Discussed at industry meeting no change.
Section 8.2.4 reduction from monthly samples to 5 per annum	Positive change for industry – but need to discuss implementation process.	Support	It is for areas impacted by non-point sources only. Maybe debate around this. Comes back to what sanitary survey finds. Key thing though is the sampling must be very APC

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			focussed. Historically APC sampling has been poor and too many" nice day" sampling (pointless results other than showing when fine OK). Discussed at industry meeting no change.
8.2.4(1)	Reduction in cost is always desirable, but not a reason in itself to reduce the number and frequency of bacteriological sampling. The current sampling programme is a very good "Insurance scheme" alerting the growers before harvesting from "unsafe" water, which can result in costly recall or even loss of product. Historically, harvesting in many of Northland's GA's was confined to the winter 6 months of the year, whereas now, many GA's harvest 12 months of the year. Growing Areas in Northland may experience many rainfall closure events, often more	1. Retain the current monthly (open) sampling programme for those GA's open more than 5 months each year 2. Retain a minimum of 5 APC samples / year for areas harvesting less than 6 months each year. 3. That there is a more vigilant approach to targeting APC opening days. i.e. within 24hrs of opening unless unsafe. If sampling frequency is reduced to 5 sample sets per year for all harvesting schedules, then the following guidelines be used, to include those GA's already on 5 samples /year.	Noted but aligning with NSSP. See comments section above. Note this is a minimum number and can do more which historically has happened.

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	than 1 per month and these events are destined to increase with the climatic changes that are predicted. After an area has had more than 100mm per 30days (as noted in management plans) then a "saturated soil condition" exists creating a bigger risk for microbial pollution. Harbour margins continue to be developed. How will change of land use be monitored at a frequency to meet these changes? Reducing sampling from monthly to 5 samples per year will allow for polluted water to go unnoticed for a longer period of time. A reduction to 5 samples per year will reduce the historical data available to accurately and confidently produce food-safe, growing area management plans.	Suggest 6 sample sets/year as per SRS sampling. This and the following guides will allow for ease of management and auditing. Sampling must be of a frequency to be representative of all harvesting for the year. 1) Sampling must be within 24hrs of opening after an APC closure, unless unsafe conditions. 2) If harvesting is for more than 6 months of the year then the minimum sampling frequency is 30 days and the maximum sampling frequency is 60 days. 3) If harvesting is done over less than 6 months of the year, then the minimum sampling frequency is 7 days and the maximum sampling frequency is 30 days. 4) Sampling is done when a growing area is "open" or would "otherwise be open" if	

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	As the aquaculture industry is increasing production this would be false economy and a backward step in the desire to confidently produce a food product that is safe for consumption in NZ and Internationally.	the GA harvests for less than 6 months of the year.	
8.5 (2)	We do not support that elevated bacteriological result(s) be excluded from growing area compliance/risk assessment if it can be attributed to an "unusual event". The designation of an "unusual event" is fraught with interpretation. This parallels the scenario that occurred with the recent drinking water outbreak at Havelock North where intermittent positive *E. coli* results were explained away as being 'unusual'. In hindsight these results were providing valuable information as to	Recommend removing 8.5 (2). **All data** to be considered for compliance and risk assessment purposes.	Strong criteria around this, it is rare (in fact 3 historical applications where the rationale was not accepted) for Shellfish Specialist to "exclude". The result is not lost and has to be reported accompanied by very good documented rationale as to why it is an unusual event. Important MPI develops guidance for Shellfish Specialists. No change.

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	the potential public health risk facing the drinking water supply. Therefore it is important that **all data** (which are generated by a recognized laboratory using validated methods) be considered for compliance and risk assessment purposes for a growing area, both during annual reporting and the 12 year Sanitary Survey. One or two high results within a 15 sample (or more) dataset is unlikely to impact compliance criteria but may provide valuable information about risk to shellfish safety in a particular growing area.		
Section 8.6 Investigation of outbreaks of illness (1) …APO must determine if an epidemiological association exists	This requires sufficient technical expertise to do the epidemiological association assessment. Who does MPI envisage will carry out this task? (this is a technical field and usually undertaken by	Concept requires further discussion before it is supported.	This is about APO determining whether the association exists. Expertise not with APO but with relevant public health authorities who will determine this. APO is expected to stay in close contact with the public health official and depending on their investigations take appropriate action. From MPIs experience this has happened. We can provide

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between the illness and the BMS consumption.	regulatory health authorities). We also need clear standards for assessing epidemiological association. Note that 2006 BMRCS definition for 'epidemiological association' and the NSSP refer to the current edition of *Procedures to Investigate Foodborne Illness* published by the International Association of Milk, Food and Environmental Sanitarians Inc. This important reference has been dropped in new draft BMRCS. We need to have an epidemiological technical standard. MPI need to table replacement for above or reinsert.		more guidance if needed. Definition for epidemiological association has been added to the document as above. Discussed at industry meeting no change.
Section 8.7 Results of investigation of outbreak of illness	This requirement is overly prescriptive. It should simply say 'initiate a growing area	Industry does not support.	Good point recommend amend as follows. e) initiate a growing area review including where applicable:

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(1) e) ii) analysis of at least the last 3 years bacteriological results to determine classification, and if, applicable harvest criteria is appropriate.	review'. The illness events, which may in fact be chemical, Vibrio or biotoxin, may have nothing to do with 3 years of micro data.		i. a thorough field review of all actual or potential pollution sources; and ii. analysis of at least the last 3 years bacteriological results to determine if the classification and, if applicable, harvest criteria are appropriate.
Section 8.8 Investigation where human pathogen or chemical contaminants present (2) & (3)	The actions required here are too drastic for immediate action. Theoretically all measures can be triggered by the presence of any pathogen or chemical even at levels considered harmless. With improving testing methodologies there is increased risk of "discovering" contamination that was previously below the limit of detection. There must be some trigger levels specified, or at least a requirement for a risk assessment which looks at	Industry does not support in current form. Concepts requires further discussion.	MPI can develop better wording to reflect outcome "…a type of level that may impact on human health…" The APO (Shellfish Specialist would be involved) would take action based on known tolerance levels e.g. in FSANZ or MPI MRLs, or overseas market concern (e.g. suspect Hep A or Salmonella found in NZ BMS). Any action would need to be justified. Discussed at industry meeting no change.

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	risks from the specific concentration of chemical or titre of pathogen. There needs to be some risk assessment undertaken first as required by Sections 79 & 80 of 2006 BMRCS and Chapter II Risk Assessment and Risk Management of NSSP		
Section 9.5 Contaminant reduction studies (2) iii) iv) four corners of relay area and in the middle of square	This sampling regime is overly prescriptive - samples should just be representative of the relay lot. For example, many oyster relay lots are placed along a rack or line.	Editorial change required before industry will support.	Disagree. This clause also used for after pathogens found in growing areas and to clear an area. Have to get n=5 and therefore best to get spatial coverage over the area as best as possible. But we note editorial mistake 9.5 (2) b) iv) needs to be split after the "or" so the Shellfish Specialist can consider an acceptable coverage if it is believed no difference. Discussed at industry meeting and MPI agreed to amend to reflect outcome that samples are taken that represent the whole area or lot. Changed to: (2) The contaminant reduction study must: a) address environmental and spatial factors which may affect the cleansing of the BMS; and b) include a study of a minimum of 5 samples that: i) are taken by a certified sampler; and

Section Reference	3. Comment	4. Proposed amendment	MPI Response
			ii) each sample must contain at least 12 individual BMS; and iii) **between them are representative of the whole area or lot being sampled**; and
Section 9.5 Contaminant reduction studies (2) e) include details of depth of water and stratification in the relaying area	To add words 'where appropriate' – this information is not necessary for intertidal oyster lots (who likely do most of NZ's relays)	Editorial change required before industry will support.	Added in "where appropriate"
Section 10.2 Operation of wet storage (5) Wet storage may only take place in growing areas that meet the requirements of the classification of the area	Is this sentence necessary? It has already been established that all shellfish must be harvested in accordance with their classification	Clarification sought before industry can support or object.	Agree delete (5)
Section 11.3 Requirements for harvest vessels vehicles and BMS containers	Loss of DG exemption is a concern for small harvesting vessels e.g. for small oyster/clam harvesting	Do not support.	Clause was not used in BMS RCS 2006. 39(4) of the Act applies s 166A(1)(e) to Notices, which has the effect of meaning that a Notice can confer a discretion

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(2) marine sanitation devices must be provided on all harvesting vessels	vessels that are not off-shore.		on the Minister, DG, or an APO. Given that the DG can have a discretion to allow an exception. DG exemption added in.
Section 11.9 Content of harvest declaration	Good change – dredge industry no longer required to add GPS details of harvest zone. (Will be covered by the selective area requirements).	Support.	Noted
Section 12.1 Sorting sheds and BMS depots to be verified.	New? requirement that application for sorting sheds/depots to be made to DG – to clarify with MPI	Clarification sought on the risks MPI is trying to address before industry can support or object.	Not new just consolidated previous 2 sections in 2006 RCS. No new requirements. Regulations require application/listing. Has always been the case. Discussed at industry meeting no change.
Section 12.2 Requirements applying to both sorting sheds and depots (1)	The requirements for sorting sheds have been increased. 2006 BMRCS only requires that BMS are held in a room, compartment or container that complies with construction requirements. In other words, it was acceptable to have a sorting shed that contained storage	Do not support.	Not new requirements just consolidated messy previous 2 sections. Discussed at industry meeting no change.

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	unit meeting specifications. Now it seems the sorting shed must meet the same requirements as a depot.		
Section 13.1 Verification of transportation units (1)	New? requirement to apply to DG for listing transporters – to clarify with MPI.	Clarification sought before industry can support or object.	Always needed to list. See BMS RCS regulations. Discussed at industry meeting no change.
Section 13.1 Verification of transportation units (5)	New? requirements for delisting transporter unit or operators.	Clarification sought before industry can support or object.	Not new always required annual transporter verification. What we have improved on is now annual verification of transport operator and not ever unit every year. What is proposed is verifiers do a selection of units listed under operator's name. Improvement for industry less cost. Discussed at industry meeting no change.
Section 13.4 Couriers	New section setting out industry requirements for using a courier. Whilst the use of couriers is important to some sections of industry, and addressing that is valued, some industry members have expressed concern about interpretation, meaning and implications.	Clarification sought before industry can support or object.	Discussed at industry meeting agreed mistake made in clause. Change as follows or similar wording. (1) A courier who transports BMS is not a transport operator for the purposes of the RCS (and therefore does not have to be listed) if: c) all BMS transported by the courier are transported in a transport unit provided by a listed transport operator or harvest operator; and d) the transport operator or transport operator is satisfied that the courier can and will ensure that:

Section Reference	3. Comment	4. Proposed amendment	MPI Response
			i) the BMS are kept in an ambient temperature of 7°C or cooler; and ii) the BMS are protected from damage and contamination; and iii) opportunities for substitution are prevented.
Schedule 4 Changes to time temperature management	The suggested changes to this schedule will cause industry unnecessary hardship. There is no evidence of any food safety issues with the current NZ post- harvest time temperature standards. The BMRCS needs to take account of NZ conditions, for example regarding industry practices, along with biophysical and epidemiological data.	Industry does not support.	This has aligned with USA. A check of EU standards could not find any time temperature parameters. Discussed at industry MPI agreed to change back to table currently in 2006 BMS RCS.
Part 14 Sample Taking	14.3 (2)(a) and 14.3(3) Are the procedures practical and achievable for the seafood sector.	Establish nationally, 2 levels of sampler training; a) A "sampling manager", a requirement for each growing area, who meets the existing	Not in favour of lowering standard. NZ allowing industry and non-regulator personnel to take samples needs to be closely controlled.

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	Each growing Area needs to have a "sampling manager" who fully understands all aspects of the sampling programme. Farm workers can be intensively trained in all the practical aspects of collecting samples, completing forms and packaging samples. It isn't necessary to have a scientific knowledge to be able to follow correct procedures. "Sampler Management" full training could require a day or more, "sampler assistant" training half a day. A saving for industry. Along with onsite auditing this can improve the efficiency of the sampling programmes and reduce non-compliance.	requirements and competencies, plans for sampling under direction from the APO and can direct the collection of samples by; b) A "sampler assistant". These samplers, sampling only under directions from the "manager", would be trained in all of the practicalities to be able to collect samples aseptically, complete the sampling forms and despatch to the Labs.	

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Part 14	14.7 Labels of samples. Are the procedures practical and achievable for the seafood sector? 14.7(2)(a)(b). i) ii) iii) If a sample has a **unique number** and as in 14.6 (2) a) ….e) has a sample submission form that supplies all detail, then repeating this information on the bag is unnecessary. Time is particularly difficult to write on a bag after the sample has been collected and cannot be recorded accurately prior to collecting the sample. A number of non-conformities arise from sample labelling.	That the unique number and date be the only requirements on the sample bag or bottle. That a smudge proof label is available to use for this purpose.	This is the purpose of "state, or allow the discovery of:" Can use a unique number to do this. Previously we had "…other forms of labelling acceptable." i.e Shellfish Specialist approval. No change.
14.4 (6)	Refers to "the Act" but would be better to include the name of the Act	Include the name of the Act in the wording	Agree. Put full name of Act in clause.
14.4 (6)	**TYPO:** Colon at the end of the definition not required.	Update to full stop	Noted editorial.

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15.3	Receipt of samples (h) exemption for >10□C This is open to wider interpretation; maybe out to 24hrs? What is the temperature guide?	Suggest that the section could read; h(i) the sample reaches the laboratory in less than 12 hrs and add h(iii) that the sample temperature is not higher than the seawater temperature from where and when the sample was taken.	No change. Adding suggested iii) will not work because not required to take seawater temperature.
15.3 (1) h) ii)	**Question:** Criteria states "has not had adequate time." Would it be possible to put a timeframe rather than being left to the discretion of the laboratory	The sample has been collected within 10 hours of delivery to the laboratory.	MPI will work on wording to improve clarity but not in favour of strict timeframes.
15.3 (2) a)	States "decide whether to analyse the sample" but if the criteria is not met or the lab considers the samples may be unsuitable why would there need to be a decision made.	Update to "Contact the APO responsible for the growing area to notify them of the discrepancy and request replacement samples; and"	Biotoxin samples we may accept because temperature not critical. No change.

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15.6 Table 4	A lot of repeated information included in sample column	Group and merge like information (see table below)	Agree good improvement.
15.6 Table 4	Start time information in top row references "clause 15 (1) (b)" but that doesn't exist	Review and update	Yes agree.
15.6 Table 4	**TYPO:** The use of the word "must" in relation to the testing time for samples is contradictory to the next point which states testing may occur within 48 hours.	Replace with "Every effort must be made to ensure testing is started within 24 hours of sample collection. In the event of significant transport delays, testing may be extend to no more than 48 hours from sample collection provided:…."	Agree need to amend wording to improve clarity although the "subject to" does cover this.
15.8 (6) a) to d)	**TYPO:** This items in this list are independent and any of them would trigger the action outlined in 15.8 (6) therefore they do not require an "and"	Remove "add" from the end of points a), b) and c)	Agree remove "and"
Schedule 1 Sanitary Surveys	1. Sampling for Sanitary Survey before classification	For a new GA with no prior classification, 30 sets of samples should be taken over a full 12 month period	Disagree. Professional will have a good idea of actual or potential pollution sources in an area after doing a shoreline surveys and "paper" based research. Therefore

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	" 1(1) Samples must be collected……. to provide adequate results to form a profile for periods defining APC conditions." 1(2) and 1(4) set the number of samples to be taken "where pollution sources have an impact (30 sets)" and "where no pollution sources have an impact (15 sets)" It would be scientifically unsound to adequately assess the potential impact of any pollution sources before sampling has been completed as per 1(1).	targeting potential APC conditions. If the classification is for a new GA which is an extension of a currently classified GA, then sampling could be 15 sets over the full 12 months, or the period of time where the existing GA experiences regular closures. To meet the requirements of 2.14(1)	for more remote areas have an idea of potential pollution events and time the 15 sampling events to see if actually impacts significantly. Prefer to level 2.14 (1) open ended as it is for sampling (APO decision) because have variable situations e.g. a marine farm group alongside but further away from pollution sources brought into the area may need little or no sampling.
Old Schedule 3 and new Schedule 4	Deleting Schedule 3 and deleting guidance material for Schedule 4 is not supported. As indicated above, the Specifications should stand alone without the need to access, or refer to, other documents or	Northland DHB Include Schedule 3 and guidance material for Schedule 4 in the Specification so that other documents do not need to be accessed or referred to.	A BMS RCS guidance document is planned to be produced to capture many guidance issues like 10% rule, SRS etc.

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	guidance material. Not all guidance material is publically available e.g. Guideline for Changes to Marine Biotoxin Management.		
5.4 (2)(d)	The laboratory is sometimes omitted from communications notifying of changes to minimum required testing, which can result in updates not being implemented.	To add a clause: e) Communication to the laboratory of any changes relevant to the minimum testing required.	Not necessary. If a frequency has changed will have to contact laboratory to implement changes.
Table 2	*Alexandrium catenella* and *A. pacificum* refer to the same species.	To remove the line referring to *A. catenella*.	Agree But left A catenella in case if found.
Table 2	Recommendation for 30 000 c/L of *Azadinium* spp. had been established from limited preliminary research on the emerging toxin producer. Now, international experience suggests that blooms of *A. spinosum* are	Discussions and potential refinement of this trigger level are required. This results from recent overseas on-farm results in Ireland suggesting there are difficulties correlating *Azadinium* spp. cell numbers to accumulated toxin levels in shellfish	Have discussed and at this stage MPI agreed to keep level as proposed and when further research comes available will amend accordingly.

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	difficult to detect by spot sampling for microscopy analysis (Pers. Comm.). Although there is still limited data available, 30 000 c/L may be too high to provide early warning.	monitored weekly in a farming context.	
Table 4	Water samples for phytoplankton analysis can sometimes be taken on Friday and received at the laboratory on Friday pm or Saturday morning. Testing on such samples will be initiated first thing the following Monday, unless urgent testing is requested.	To add a footnote to the table, stating that: "These turnaround times at the laboratory apply to working days unless special arrangements are made."	MPI would prefer to use 15.6 (3) clause to cover this issue. We need to drive sampling timing so not arriving at lab late in week or weekend. Only do this if urgent and if urgent need to test urgently and pay for weekend service. The other situation is transport delays e.g. Nelson fog bound then use Shellfish Specialist approval. (7) A recognised laboratory may extend a test timeframe for a particular sample or group of samples in accordance with any written approval given by a shellfish specialist on the grounds that: a. a technical failure has been encountered in the laboratory; or b. there were transport difficulties with the sample.

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Table 4	Refers to clause 15 (1) (b).	There is no clause 15 (1) (b) in draft document.	Noted as above will amend.
Table 3	Yessotoxin removed from Maximum Permissible Levels for Marine Biotoxins in BMS.	Add footnote to table to indicate yessotoxin testing will be required for export due to continuing regulation overseas.	This is domestic standard. Will do separate export requirement for YTX.
Table 3	DSP toxin group includes Okadaic acid, Dinophysis toxins and Pectenotoxins.	Disuse re PTX that it should not be regulated). There is no evidence that Pectenotoxins have the same mode of action and act synergistically with other 'DSP toxins' (Okadaic acid and Dinopysistoxins). We suggest an updated risk evaluation of Pectenotoxins in bivalve molluscs to determine if they should be included as part of the DSP toxin group, or if they warrant regulation at all. Also, it is recommended that a consistent approach is used	Agree on issue. EFSA do recommend not to regulate with DSP group (Scientific opinion for PTX and the OA group). PTX is a bit like YTX and no human health illnesses reported. Need to commission a report to deal with these and this could be a year or more so leave as we have and work through issues. • do we regulate PTX • If regulate PTX what analogues and what regulatory level. • If regulate do we have PTX separately • If do not regulate will need export requirement like YTX • Do we better define DTX group analogues?

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		when specifying those toxins included within a toxin group. For example, there is currently a broad definition for dinophysistoxins (no DTX analogues detailed) and a specific definition for pectenotoxins (which include PTX1 and + PTX2). Note: The most commonly observed PTX analogues in NZ shellfish are PTX2, PTX6 and PTX11.	Note EU still regulate PTX and combine PTX in the DSP group for the 0.16 mg/kg regulatory OA level.
Table 4	In line with the long established routine testing schedule, samples received before Thursday 10 am will have results reported within the timeframes stated. NOTE: This applies to a normal 5 days working week.	An addition to clause 15.6 (2) b) there were transport or sampling difficulties resulting in the sample arriving in the laboratory late in the week. These must be reported within 4 working days unless special arrangements are made.	As above prefer not to add. MPI would prefer to use 15.6 (3) clause to cover this issue. We need to drive sampling timing so not arriving at lab late in week or weekend. Only do this if urgent and if urgent need to test urgently and pay for weekend service. The other situation is transport delays eg Nelson fog bound then use Shellfish Specialist approval. (8) A recognised laboratory may extend a test timeframe for a particular sample or group of samples in accordance with any written approval given by a shellfish specialist on the grounds that:

Section Reference	3. Comment	4. Proposed amendment	MPI Response
			a. a technical failure has been encountered in the laboratory; or b. there were transport difficulties with the sample.
Table 4	Some commercial customers may not be / are not interested in receiving non-urgent results in format other than a report summarising all results generated and sent at the end of the week.	No improvements recommended, but a record that in a discussion with Brian Roughan, it was agreed that the term "reporting" means sending results to the MPI database. In the majority of cases, it also implies sending results to customers.	Noted.
15.8 (6)	Must give verbal notification of results within 1hour of confirmation and written results within 24hours.	Change to: must give verbal notification of results exceeding specifications within 1hour of confirmation and written results within 24hours.	If read whole clause it says 'if any of the following results…." And then lists them. See no need to change clause.
Table 3	The units for the PSP toxin group are stated as 0.8 milligrams saxitoxin equivalent per kg ("mg STX	Replace the units "milligrams saxitoxin equivalent per kg" with "milligrams saxitoxin	Agreed

Section Reference	3. Comment	4. Proposed amendment	MPI Response
	eq./kg"). Cawthron currently reports PSP toxin results in saxitoxin dihydrochlride equivalents, which is in-line with the Codex standard (CODEX STAN 292-2008; ≤0.8 milligrams (2HCL) of saxitoxin equivalent).	dihydrochloride equivalent per kg"	
Table 3	The limit for the NSP toxin group is set to 0.8 mg brevetoxin-2 equivalents per kg. Currently, there is no approved method to allow this maximum permissible level to be enforced. Therefore, NZ is currently poorly placed to monitor NSP levels in bivalve shellfish should an event occur.	Research through the Safe NZ Seafood Programme will allow the development and implementation of an approved method for NSP detection and quantification in bivalve shellfish in NZ. We are aware of an analytical instrumental method validation for several brevetoxins in bivalve shellfish being undertaken by the US FDA. This will become prioritized research once the 'PSP by LC-MS' collaborative study is completed.	Noted no change needed. Once validated method available MPI will approve.

Section Reference	3. Comment	4. Proposed amendment	MPI Response
Part 15:Laboratories		To include a table showing the approved tests.	Agreed MPI will put a list together and find suitable location.
14.5 (2) e)	States: pack the sample using packaging that is durable, leak proof and free from contamination.	Change to: double bag the sample in packaging that is durable, leak proof and free from contamination.	Agreed but clause covers water and flesh sampling. Do not double bag water samples. MPI will amend to ensure concept covered.
2.4 (4)	Selective areas need guidance as to exactly what in schedule 1 they need to cover.	New clause in schedule 1 2. (2) Despite clause schedule 1 2. (1) selective areas meet the requirements for a sanitary survey report by the completion of a marine biotoxin management plan in accordance with clause 5.2.	Agree will help with concerns. These documents already exist. Therefore no new requirements for industry and this was the intent of the selective inclusion and bring programme into compliance with the regulations. MPI may amend schedule 1 to make clear. Noe idea is to include clause 3 Selective minimum requirements for sanitary survey. Then list elements currently needed for a marine biotoxin management plan. New subclause added to clause 2, specifying the only parts of Table 1A that need to be completed for an area that is proposed to be classified as selective. Noted changed “selective” to “limited”
2.12	Heading uses “May’ then clause 2.12 (1) uses “must”	Review	MPI will consider and improve if not clear. Changed “may” to “to”
2.12 (1) a)	“of” editorial	review	Agree editorial delete “of”

Section Reference	3. Comment	4. Proposed amendment	MPI Response
			area has been closed following ~~of~~ an outbreak of illness caused by something other than naturally occurring pathogens or biotoxins; or
4.1 and 5.1	Management plans need to be subject to each other.	4.1 (3) add end of clause "subject to marine biotoxin management plan conditions" 5.1 (3) b) add to end of clause "subject to conditional management plan requirements"	Agree good improvement. Have adjusted the wording to more clearly cover the fact that there may be other grounds on which an area is opened or closed.
5.6 (5)	Make clear DG reduced frequency relates to 5.6 (3) & (4)	Add "subclause (3) and (4)	Agree Adjusted these subclauses. The power to authorise reduced sampling is in sub (2), and sub (3) then sets out the requirements for the reduced sampling. So sub (4) refers to the reduced sampling authorised under sub (2).
5.6 (3)	Make clear clause (3) relates to clause (2)	Add "clause (2)"	Agree The clause (2) reduced programme that an APO may authorise must comply with the following:

Section Reference	3. Comment	4. Proposed amendment	MPI Response
7.2 (1) b)	Make clearer that not limited to the listed examples	Change “such as” to “including but not limited to”	“such as” - means not limited to.
8.1	Make clearer that require samples on boundary of growing areas.	review	MPI think adequate with wording already present “effective evaluation” and “adjacent to …”. Something that could be covered with guidance.
14.3 (3) d)	Needs to include “marine biotoxin” sampling	“and biotoxin”	Agree the correct method for taking water and BMS samples for microbiological and biotoxin analyses

Supplementary information for 15.6 Table 4 point 1 [AsureQuality]

Sample	Tested for	Start Time
Microbiological and marine biotoxin samples	• Microbiological purposes. • Phytoplankton monitoring. • Marine biotoxins, using bioassay methods. • Marine biotoxins, using non-bioassay methods.	Testing must start within 24 hours from sample collection, subject to clause 15 (1) (b). Testing may start within 48 hours, but only if: • significant transport delays have occurred; and • the delay is documented; and • the temperature requirements in clauses 15.3 (1) h) and 15.5 (1) are met; and • if the sample is of BMS, the sample is live.
Sample	**Tested for**	**Completion Time**
BMS	Marine biotoxins, using non-bioassay methods	Testing and reporting must be completed within 2 working days after sample received by laboratory
	Marine biotoxins, using bioassay methods	Testing and reporting must be completed within 4 working days after sample received by laboratory
	Microbiological purposes	Testing and reporting must be completed within 3 working days after sample received by laboratory
Seawater	Microbiological purposes	Testing and reporting must be completed within 5 working days after sample received by laboratory
	Phytoplankton monitoring	Testing and reporting must be completed within 24 hours after sample received by laboratory