

Primary Production of Bivalve Molluscs Guidance Document Consultation Feedback Summary			
Consultation period: Thursday 29 June 2023 – Friday 7 July 2023			
Number of submissions received:	4		
Proposers:	ShellMAP Regulatory Services Oysters Tasmania Mark Boulter Shellfish QA Specialist – IMAS Michel Bermudes Ma Bruny Oysters Pty Ltd		
ShellMAP submission			
Reference	Type	Details	Assessment
P6	Definition	Scallop – adductor v abductor	Response ASQAP definition of shellfish used in Guide
P 11	Process	Relay authorisation and whether it needs to be included here or not	Response Relay authorisation is issued under PPSA, FSC and conditions of accreditation Needs to be mentioned as it is part of the whole system for accredited producers
P 14	Process	Council statutory approvals	Response DA's are not the legal instrument to require permits. This is an advice on planning permits, not a requirement of the planning permit process.
P 15	Terminology	MF lease and licences	Accepted Updated in the Guide to reflect accurate terminology
P 15	Process	NCC applicability to wild fish fish processors	Response Applies to all 'regulated fish' and seafood processors that are required to hold accreditation under the PPSA
P 21	Process	Is ShellMAP the relevant contact point?	Response ShellMAP is the pre harvest contact point for accredited BM primary producers under the PPSA, in the first instance and this may be a valuable first contact with potential new industry entrants. Wider queries from other commodities would contact Aquaculture Ops in the first instance.
P 25	Definitions	Carted water – approved source	Accepted Will be added to definitions section to cover water sources carted from a ShellMAP approved harvest area or Public Health Act 1997 approved

			source for water carters and re-wording of text in Guide to provide clarity around 'approved sources'.
P 25 and 26	Process	ShellMAP roles	<p>Response</p> <p>Clarify that applications will be referred to ShellMAP for comment.</p> <p>Conditions of authorisation will be included as part of the Certificate of Accreditation which is issued by PPSP along with environmental criteria to be included in Harvest Area Management Plans through collaboration with ShellMAP Scientific Officers.</p> <p>This is supported through the NRE Tas 'How we work' corporate strategy that facilities and promotes principles and behaviours to build on existing collaborative relationships within the State Service and beyond.</p>
P 26	Process	Limits – wet storage v depuration	<p>Accepted</p> <p>Presentation of this information is not clear and text will be re-written and re-organised to address the lack of clarity.</p> <p>All limits are adopted from ASQAP and relate to source water classification.</p>
P 28	Process	Malfunction – does this apply to wet storage and depuration?	<p>Accepted</p> <p>Presentation of this information is not clear and text will be re-written and re-organised to address the lack of clarity.</p>
P 29	Layout	Source water and shellfish contamination table	<p>Accepted</p> <p>Re-configuration of table to improve readability</p>
P 29	Definitions	Limits - wet storage v depuration	<p>Accepted</p> <p>Presentation of this information is not clear and text will be re-written and re-organised to address the lack of clarity.</p> <p>All limits are adopted from ASQAP and relate to source water classification.</p>
P 29	Definitions	Limits – treated water – ND in 100 ml	<p>Response</p> <p>ASQAP limit is ND in 100ml as opposed to the more</p>

			contemporary lab reporting of <1 cfu/100ml
P 29	Process	Validation study iv – does this mean every 3 months?	Response Validation will be conducted at a frequency determined by the Chief Inspector s 15 (1) of the PPSA may vary depending on the process proposed and operational performance.
P 29	Process	ShellMAP roles	Response Conditions of authorisation will be included as part of the Certificate of Accreditation which is issued by PPSP.  Conditions of authorisation will be included as part of the Certificate of Accreditation which is issued by PPSP along with environmental criteria to be included in Harvest Area Management Plans through collaboration with ShellMAP Scientific Officers.
P 33	Process	GMP - Testing	Response Verification is a process that forms part of the FSMS of the accredited producer. Frequency TBD by PPSP as part of the assessment of the FSMS and acceptance of proposed verification.
Appendix 1 Application Checklist P 35	Process	Relay authorisation and whether it needs to be included here or not?  Application for accreditation and variation to accreditation	Response Relay authorisation is issued under PPSA, FSC and conditions of accreditation. Needs to be mentioned as it is part of the whole food safety scheme and regulations.  Note: Relay is mentioned in the FSC and therefore needs to form part of the whole system.
Appendix 2 Water Quality Parameters P 43	Definitions	Water used for depuration – biological requirements table 2a – not exceeding 70 cfu/100ml	Response Conditions of authorisation will be included as part of the Certificate of Accreditation which is issued by PPSP along with environmental criteria to be included in Harvest Area Management Plans through

			<p>collaboration with ShellMAP Scientific Officers.</p> <p>The limits outlined in Appendix 2 are from ASQAP, validation (disinfection) studies will provide baseline data for system performance and ShellMAP water monitoring to verify harvest area classification will inform the conditions of accreditation.</p>
Appendix 2 Water Quality Parameters P 44	Layout	Table 2b – recirculating water systems – water quality requirements	<p>Accepted</p> <p>Clarification/re wording required</p> <p>This is referring to the SOP's provided with the application to be included or in addition to FSMS</p>
Appendix 3 Validation (Disinfection) Study Protocol P 45	Definitions	Recirculation tanks - Water sources Wet storage v depuration	<p>Accepted</p> <p>Clarification/re wording required to remove ambiguity.</p>
P 45	Process	Validation frequency – as specified by the Authority	<p>Response</p> <p>Validation is a process that forms part of the FSMS of the accredited producer.</p> <p>Frequency TBD by PPSP as part of the assessment of the FSMS.</p>
P 46	Definitions	36 hours – wet storage and depuration ?	<p>Accepted</p> <p>Clarification/re wording required to improve clarity to reflect wet storage being a temporary storage to improve quality whereas depuration is a process to reduce contamination of at least 36 hours</p>
P 46	Layout	Separate columns for wet storage and depuration to improve readability	<p>Accepted</p> <p>Re-organisation of tables is required to improve clarity and readability</p>
P 46	Definitions	Critical limits – wet storage v depuration	<p>Accepted</p> <p>Clarification/re wording required to remove ambiguity between processes</p>
<b>Oysters Tasmania submission</b>			
<b>Reference</b>	<b>Type</b>	<b>Details</b>	<b>Assessment</b>
Regulation as a minimum	Purpose	Guide to make clear that it represents 'minimum requirements'	<p>Response</p> <p>A 'Purpose' section will be added to the Guide</p>

Limiting accreditation to the PPSA 2011	Legislative foundation	Request for evidence of statutory approvals from other agencies exceeds scope of Chief Inspector, breach of PIP Act and other privacy legislation.  Legal Challenges  Privacy	Response S 12 PPSA Application for Accreditation and information requirements  S 22 (a) PPSA appeal provisions to Administrative Appeals Division relating to an application for accreditation.  S 84 PPSA Disclosure of Information provisions  S 9 (7) State Service Act 2000 – confidentiality provision
NCC  2022 Volume 1 Schedule 9 Tasmania	Legislative foundation	Special Use Buildings and Chief Inspector not required to make assessments against NCC	Response  Function Control Authority's (Chief Inspector's) role is to assess the design and performance of building work on any Special Use building to ensure it satisfies the objective of the NCC to facilitate safe manufacture, preparation, storage and packaging of food for sale for human consumption for premises regulated under the PPSA.  This applies to all primary production and processing sectors regulated under the PPSA – not just the BM sector.
Advice on other agencies' Acts	Legislative foundation	'plumbing installation'	Response  Guide is advising potential applicants to seek advice from Council in relation to any approvals that <i>may</i> be required, from Council.  Council is the permit authority and regulator of plumbing installations and works in Tasmania.
Limiting FSP's to significant food safety hazards	Legislative foundation	'significant hazard' v 'hazard'	Response  Std 4.2.1 clause 16 – Food Safety Management Systems for Bivalve Molluscs requires primary producers to have in place a

			<p>system to effectively control <b><u>the hazards</u></b> (biological, chemical or physical), not only 'significant hazards'.</p> <p>Std 4.2.1 and the PPSA regulate food safety risk.</p> <p>Business risk and biosecurity risk are outside the scope of the PPSA or this Guide.</p> <p>Note: – ASQAP 8.2.9 now includes requirements for SCA to consider animal and human health risks of disinfection by-products (ie biosecurity risk)</p>
Seeking and approving only relevant details	Legislative foundation	Information requirements in consideration of an application for accreditation or variation to accreditation	<p>Response</p> <p>S 12 PPSA Application for Accreditation and information requirements</p> <p>S 84 PPSA Disclosure of Information provisions</p> <p>S 9 (7) State Service Act 2000 – confidentiality provision</p> <p>Note – an application must conform to the requirements of the Chief Inspector about its form, contents and the manner in which it is made (s 12 (1)(b))</p>
Specific criteria to maximise guidance and accountability	Process	Lack of detail on specific design criteria and what PPSP considers to be food safe.	<p>Response</p> <p>Prescription has been provided where it is available and relevant.</p> <p>The Form 10 referral process and desk top review of FSMS documentation as part of the application process has been put in place to avoid business constructing/fitting out premises with non-compliant materials that are only observed at 'inspection' and then subject to costly retro-fitting/replacement/refurbishment.</p>

			<p>FSC and PPSA are outcomes focused legislation that have minimal prescription. Historically, prescriptive legislation has impinged industry's ability to be responsive to new technology and processes.</p> <p>Businesses are required to demonstrate to the regulator (PPSP) that they are able to achieve the outcomes of the PPPSA and FSC and how they will achieve this.</p> <p>'Food safe' is defined across a range of legislation to encompass materials that come in contact with foods, are suitable for use in food production and processing and are not a contamination risk to food through their use. 'Food grade' is another commonly used term.</p>
No requirements unrelated to significant food safety hazards	Legislative foundation	Requirements of Guide have no basis in the FSC	<p>Response</p> <p>All items listed relate to hygienic and safe food production and processing and the performance outcomes of the FSC.</p>
No requirement to update, and no case for certificate expiry	Legislative foundation	<p>Annual review of FSMS</p> <p>Annual return process and Certificate of Accreditation</p> <p>Variation application fees</p>	<p>Response</p> <p>It is a requirement of HACCP based FSMS's for an annual review of the system.</p> <p>Fee waivers are available for application fees and are at the discretion of the Chief Inspector.</p> <p>The annual return process is the completion of an Annual Return form then payment of fees once an assessment of the information provided has been made.</p>
FSP exemption	Legislative foundation	Exemption from requirement for FSP	<p>Response</p> <p>All producers supplying into the human consumption market are required to prepare and implement a FSMS.</p>

			<p>Some producers have operations that cover both human supply and nursery operations and as such the nursery component is exempt from inclusion in the FSMS and the requirement for audit.</p> <p>Those producers that are engaged in 'growing on' only are not required to prepare and implement a FSMS or undergo an annual food safety audit.</p>
Audit frequency	Legislative foundation	Extension of audit frequency	<p>Response</p> <p>Requests for a deviation from the specified audit frequency under s 15 of the PPSA may be made to the Chief Inspector and will be considered on a case by case basis.</p> <p>Note - Bivalve production is considered a high risk food safety process and commodity, due to its ready-to-eat status (ie no further kill step applied such as cooking).</p>
Distinct regulation of distinct risks			<p>Accepted</p> <p>In line with the previous feedback discussed from the ShellMAP submission, re-organisation and re-wording of some sections of the Guide is occurring to more clearly distinguish between wet storage and depuration information to remove ambiguity and improve readability.</p>
Source of shellfish	Definition		<p>Accepted</p> <p>Please see previous comment.</p>
Culling	Definition		<p>Accepted</p> <p>ASQAP definition to be adopted and the use of 'unhealthy' replaced by 'dying' ie dead, dying or damaged</p>
Tray loading and tank loading and filling	Process		<p>Accepted</p> <p>In line with the previous feedback discussed from the ShellMAP</p>



			<p>submission, re-organisation and re-wording of some sections of the Guide is occurring to more clearly distinguish between wet storage and depuration information to remove ambiguity and improve readability.</p>
The period of wet storage or depuration	Process		<p>Accepted</p> <p>A re-write of the text may resolve this and emphasise the differences between the two processes clearer.</p>
Drain down	Process	Wet storage and depuration differences	<p>Accepted</p> <p>In line with the previous feedback discussed from the ShellMAP submission, re-organisation and re-wording of some sections of the Guide is occurring to more clearly distinguish between wet storage and depuration information to remove ambiguity and improve readability.</p>
Equipment cleaning and maintenance	Process	Cleaning chemicals Example cleaning and maintenance schedules	<p>Response</p> <p>All chemicals used need to be food grade or mixed and used at concentrations that will not pose a contamination risk (chemical residue) to food.</p> <p>The requirement for chemicals from an approved supplier related to the approved supplier section of the FSMS for accredited producers (ie use of food grade lubricants and cleaning compounds on food contact items, etc).</p> <p>The examples provided are examples only and the obligation is on the applicant to prepare and determine the frequency and manner of cleaning and maintenance for inclusion in their FSMS or operating manual appended to their FSMS.</p> <p>This is a standard feature of HACCP based FSMS.</p>

			<p>The Guide is not intended to prescribe the frequency and type of maintenance to be undertaken in relation to these processes. The applicant needs to tell us what they're doing and how this will be managed and monitored through their FSMS.</p>
Duration	Process	36 hours	<p>Accepted Clarification/re wording required to improve clarity to reflect wet storage being a temporary storage to improve quality whereas depuration is a process to reduce contamination of at least 36 hours</p>
Study of recirculation	Process	Validation (disinfection) study	<p>Response</p> <p>The purpose of a validation (disinfection) study is to demonstrate that the proposed process will achieve the outcome required. In the case of depuration, the contamination load in the shellfish meat is reduced to a level that complies with the FSC and in the case of wet storage, conditions in the tank do not increase the microbial load on bivalves added to a wet storage tank.</p> <p>Results of the validation study are then supported by verification testing of product ready for supply to the market.</p> <p>Daily sampling and testing is not practical given lab locations in Tasmania and may result in delays in product reaching market if samples do not arrive at the lab or days are missed off the sampling schedule.</p> <p>A validation study demonstrates that your proposed system and operating procedures will achieve the outcome and not re-contaminate the product during the process.</p>

			<p>Note: the Guide states if the protocol in Appendix 3 is not followed then an alternative approach may be approved.</p> <p>This can be re-written to the following:</p> <p>The validation study must follow the validation study protocol in Appendix 3 or an alternative protocol, as approved by the PPSP.</p>
Foundations of wet storage and depuration prescriptions	Process	Terminology and limits	<p>Response</p> <p>The information provided in the specifications section of the checklist is in the process of being reviewed in light of your feedback however this work has not been completed in time for this workshop.</p>
Water testing	Legislative foundation	Frequency of water testing	<p>Response</p> <p>The Chief Inspector is the equivalent to the 'Authority' in NSW and as such can stipulate the frequency in relation to monitoring.</p>
Commitments by the regulator	Legislative foundation	Timelines, roles and responsibilities, review and traceability	<p>Response</p> <p>PPSP respond to applications by considering the information provided and requesting further and additional information, if it is deemed necessary (s 12 Application requirements)</p> <p>This can be process, commodity and site specific and includes a combination of desk top review of supporting information and site visits.</p> <p>There is no statutory timeline for the consideration of an application under the PPSA.</p> <p>Applicant checklist provided in Appendix 1 to assist applicants.</p>

			<p>All Guidance material is subject to review either at either a stipulated timeframe or as changes occur to related legislation.</p> <p>Non-compliance identified in an audit report is managed in line with the PPSA and Auditor Code of Conduct.</p> <p>Traceability is only required to be 1 step forward and 1 step backward under the current national food regulation framework and is covered in a producers FSMS and verified at audit.</p> <p>With rapidly evolving traceability technology, producers are now able to explore implementing enhanced traceability measures that go beyond the current regulatory requirements.</p> <p>Loss of traceability at wholesaler/retailer/broker points in the supply chain becomes a regulatory food safety matter for each state's respective Food Act regulators and falls outside the scope of the PPSA at this point.</p>
<p>Delegations from the Chief Inspector of Primary Produce Safety</p>	<p>Legislative foundation</p>	<p>Roles and responsibilities</p>	<p>Response</p> <p>The current separation of pre-harvest functions to ShellMAP and post-harvest functions to the PPSP is based on two different skillsets required in both areas.</p> <p>The ShellMAP team hold expertise in the evaluation and analysis of environmental data to undertake the functions of classification and management of the harvest areas for accredited producers under the PPSA.</p> <p>The ShellMAP functions related to industry development and collaboration such as supporting innovation in production methods</p>

			<p>and environmental management and monitoring, sit outside the scope of the PPSA and its objectives and are aligned with the functions of MRD.</p> <p>The PPSP team, like ShellMAP hold science qualifications that also enable them to evaluate and analyse environmental data, however in addition to these foundation qualifications, hold specialised and additional qualifications in food safety disciplines such as food safety auditing, food science and technology and regulation.</p> <p>Delegations are provided by the Chief Inspector to NRE Tas staff across a range of areas such as BOB, PPSP and ShellMAP and are issued on the basis that an Authorised Officer only operates within their scope of expertise.</p>
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Mark Boulter submission – Shellfish QA Specialist - IMAS

Reference	Type	Details	Assessment
P 18	Typo	Liquid waste or process water is directed into drainage and an approved oswm system/Taswater	Accepted  This has been changed to ‘which is an approved...’
P 20	Definition	cultivation	Response Definition from PPS Seafood Regs
P 22	Definition	Live shellfish	Accepted  ‘fit for human consumption’ has been included in the text of the Guide
P 23	Process	Optimal temperature        Contamination	Accepted Temperature range of 8-18°C to be added here based on previous version of the ShellMAP policy.  Text around minimises drastic temperature variation to be added.  Text to be re-worked to better reflect the potential differences in

			system design between the two processes
P 25	Process	Differentiation between two systems	Accepted  Covered in previous ShellMAP comments
P 26	Layout	Operational requirements	Accepted  Re-working of text to point to Appendix 2
P 26	Process	Alternatives to tray systems	Accepted  Will review the text to consider broadening the types of racking/placement as we had not considered bags.  Would an option to include 'Other' on the checklist suffice and a point to acknowledge that there may be other alternatives to tray systems in the text of the Guide?
P 27	Process	Tank filling	Accepted  Well spotted and will be edited in the subsequent draft of the Guide
P 27	Process	36 hours?	Accepted  On the issue of 36 hours, the Guide requires editing to reflect a minimum of 36 hours or other approved and validated process time.
P 27	Process	Treatment process	Accepted Edit to clarify the process and requirements for each ie wet storage or depuration
P 27	Terminology	Harvest/removal	Accepted  Edit of text to replace 'harvest' with 'removal'
P 30	Process	Terminology Example cleaning schedule	Accepted  Edit to replace 'reused' with 'used'  Cleaning schedule is an example and will be dependent on the type and manufacturers specifications for filter maintenance

			Re-working of the text to emphasise the table is an example only and is to be customised to each producer's producer and conditions of accreditation.
P 31	Process	Salinity monitoring	Response  Clarification to be provided and consideration of re-wording to 'in accordance with manufactures requirements' or the like  Note – this is an example calibration schedule
P 32	Process	Repeat points around validation/verification	Accepted  Will re-write to address in subsequent draft of the Guide
P 32	Training	HACCP training applicability	Accepted  Will review as additional text may be required here to clarify in the absence of depuration training that HACCP is a starting point to understanding hazards, monitoring, verification and validation. Depuration training is the preference, however in the absence of training, HACCP would be considered as a good starting point.
P 39	Definition	Pool/tray	Accepted Currently reviewing to determine if clarification required in 'Definitions' or in Appendix 1
P 40 & 41	Process	Layout	Response  Further review to consider best location for this information – I am not sure it belongs in the body of the text and feel it is better suited to the checklist.
P 41	Process	Turbidity	Response Will add in 'if applicable' here as this is relevant to UV disinfection
P 43 & 44	Process	'After wet storage/depuration'	Accepted  Yes after water treatment

			The text will be reviewed with the aim to improve ambiguity and use more descriptive terms.
P 44	Process	Source water	Accepted  Yes after water treatment  The text will be reviewed with the aim to improve ambiguity and use more descriptive terms.
P 44	Process	DO limit	Accepted  Re-write of text to clarify and include the limit from the spec section of Appendix 1
P 45	Process	Water Source/s	Accepted Re-write of text here to separate out wet storage v depuration parameters.  This reflects earlier feedback from ShellMAP
P 46	Process	Limits Sampling schedule and frequency	Accepted  These comments are under review against ASQAP and the previous ShellMAP draft policy.
<b>Michel Bermudes - submission</b>			
<b>Reference</b>	<b>Type</b>	<b>Details</b>	<b>Assessment</b>
	General	Overarching	Accepted Helpful for new growers
	Content	Training	Accepted Inclusion of a 'training resources' section
	Process	Inclusion of a timeline for application processes	Response No statutory timeline in the PPSA for assessment and consideration of applications
	FSMS	Updated FSMS required	Response FSMS template is an industry template that is currently under review by Oysters Tasmania
	General	New grower information package	Response NRE Tasmania is willing to provide content to industry grower information package