

**3 November 2023**

**268-23**

## **Supporting document 2 – Costs and benefits**

Harmonisation of marine biotoxin standards for bivalve shellfish  
– Application A1243

---

### **Executive summary**

Food Standards Australia New Zealand (FSANZ) has assessed an application made by SafeFish, on behalf of the Australian Shellfish Quality Assurance Advisory Committee (ASQAAC), seeking to amend the Australia New Zealand Food Standards Code (the Code) to change the current maximum levels in Schedule 19 of the Code for two marine biotoxins in bivalve shellfish (molluscs).

The amendments will align the shellfish biotoxins diarrhetic shellfish toxins (DST) and paralytic shellfish toxins (PST) maximum levels for bivalve molluscs in Schedule 19 of the Code with the levels stated in both:

- Codex Standard CAC 292-2008 Standard for Live and Raw Bivalve Molluscs, and the
- New Zealand Regulated Control Scheme - Bivalve Molluscan Shellfish for Human Consumption.

In assessing the application, FSANZ must have regard to whether costs that arise from a food regulatory measure varied as a result of the application outweigh the benefits. This Supporting Document analyses the costs and benefits of the application.

FSANZ has concluded there is likely to be a net benefit to accepting the application, that is the benefits of increased harmonisation and other potential benefits would outweigh the cost associated with the potential for slightly more frequent fishery closures. Information received during the consultation process did not change that assessment.

# Table of contents

- EXECUTIVE SUMMARY..... I**
- TABLE OF CONTENTS..... 1
- 1 INTRODUCTION ..... 2**
- 1.1 FSANZ ACT REQUIREMENTS..... 2
- 1.2 EXEMPTION FROM DEVELOPING OIA IMPACT ANALYSIS..... 2
- 2 DESCRIPTION OF THE PROBLEM..... 2**
- 3 OBJECTIVES ..... 3**
- 4 OPTIONS CONSIDERED ..... 3**
- 4.1 OPTION 1 – MAINTAIN THE STATUS QUO ..... 3
- 4.2 OPTION 2 – HARMONISE THE ML FOR DST AND PST TO CODEX ..... 3
- 5 CONSIDERATION OF COSTS AND BENEFITS ..... 3**
- 5.1 NET BENEFIT EXPECTED FROM ACCEPTING THE APPLICATION ..... 3
- 5.2 RESPONSES FROM STAKEHOLDERS..... 4
- 5.3 IMPACTS ON CONSUMERS ..... 5
- 5.3.1 *Impact on food safety for consumers* ..... 5
- 5.3.2 *Impact on prices for impacted products* ..... 5
- 5.4 IMPACTS ON INDUSTRY ..... 5
- 5.4.1 *About the industry*..... 5
- 5.4.2 *Industry expected to benefit from harmonisation of standards*..... 6
- 5.4.3 *Potential benefits for industry as a result of improved food safety*..... 7
- 5.4.4 *Costs for industry*..... 7
- 5.4.5 *Impacts on government*..... 10
- 5.5 CONCLUSION ..... 11
- ATTACHMENT A – LIST OF QUESTIONS FOR STAKEHOLDERS ..... 12**
- ATTACHMENT B – STAKEHOLDER RESPONSES REGARDING CONSIDERATION OF COSTS AND BENEFITS..... 13**

# 1 Introduction

## 1.1 FSANZ Act requirements

Food Standards Australia New Zealand (FSANZ) has assessed an application made by SafeFish, on behalf of the Australian Shellfish Quality Assurance Advisory Committee (ASQAAC), seeking to amend the Australia New Zealand Food Standards Code (the Code) to change the current maximum level (ML) in Schedule 19 of the Code for two marine biotoxins in bivalve shellfish (molluscs).

In assessing the application, the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) requires FSANZ to have regard to whether costs that would arise from a proposed food regulatory measure outweigh the direct and indirect benefits to the community, government or industry that would arise from that proposed measure.

This Supporting Document analyses the potential costs and benefits arising out of the draft variation.

FSANZ's assessment at the Call for Submissions stage was that the direct and indirect benefits that would arise from increased harmonisation would outweigh the cost associated with the potential for more frequent fishery closures. Information received during the consultation process did not change that assessment.

In considering the costs and benefits and in reaching that conclusion, FSANZ relied on the best available information at that time. FSANZ also had regard to all submissions received.

## 1.2 Exemption from developing OIA impact analysis

The Office of Impact Analysis<sup>1</sup> (OIA) has stated that the change is unlikely to have a more than minor regulatory impact on businesses and individuals.

As such, the preparation of a Regulation Impact Statement (RIS) was not required (OIA ID – OBPR22-03706).

# 2 Description of the problem

The current biotoxin MLs for bivalve molluscs are listed in Schedule 19 of the Code and referenced in Standard 1.4.1.

The MLs in the Code were determined in 1999 and have not been reviewed since then.<sup>2</sup>

The MLs for Codex (a set of internationally agreed food standards) were updated for marine biotoxins in 2008. As a result, there is a difference between the MLs established by Codex and the Code. The Codex MLs under review in this application, established after Proposal P158 and using more recent data, are lower than those set by FSANZ.

The Codex MLs are based on a Food and Agriculture Organization (FAO) and World Health Organization (WHO) risk assessment which reviewed several significant epidemiological studies undertaken after 1999.

---

<sup>1</sup> Formerly the Office of Best Practice Regulation (OBPR)

<sup>2</sup> The current MLs were determined under Proposal P158 – Review of the Maximum Permitted Concentrations of Non-metals in Food

## 3 Objectives

It is important to set objectives when evaluating a proposed change to regulation.

The objectives of the changes are to:

- Increase alignment with international standards
- Ensure food standards remain contemporary, based on the latest data
- Reduce the risk of adverse health events

## 4 Options considered

This consideration of costs and benefits has considered the following options below. The first would maintain the status quo and the second would amend the Code to change the MLs requested in the application.

### 4.1 Option 1 – Maintain the status quo

Maintaining the status quo would be to reject the application. The following costs and benefits are assessed relative to this option.

### 4.2 Option 2 – Harmonise the ML for DST and PST to Codex

This option would amend the Code to change the MLs requested in the application.

This option would align diarrhetic shellfish toxins (DST) and paralytic shellfish toxins (PST) MLs for bivalve molluscs in Schedule 19 of the Code with the levels stated in both:

- Codex Standard CAC 292-2008 Standard for Live and Raw Bivalve Molluscs, and the
- New Zealand Regulated Control Scheme - Bivalve Molluscan Shellfish for Human Consumption.

## 5 Consideration of costs and benefits

### 5.1 Net benefit expected from accepting the application

The purpose of this consideration was to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where status quo is Option 1: rejecting the application). This analysis considered costs and benefits to the community, industry, and government.

FSANZ has concluded there is likely to be a net benefit of the proposal because the benefits of increased harmonisation with international standards would outweigh the costs associated with the potential for more frequent closures.

MLs are necessary in order to protect public health and safety. Lower MLs based on more recent risk assessments would further reduce the amount of biotoxins allowed in bivalve molluscs. Overall, this would be a health protective measure.

The main benefits and costs of the application are summarised in the table below.

**Table 1 – Major impacts by social group**

<b>Social group</b>	<b>Impact</b>	<b>Notes on impact</b>
Consumers	Benefits	Greater margin of safety providing a reduced risk of food poisoning
	Costs	Potential for higher prices of impacted seafood, due to potential for increased closures (less supply) and higher testing costs
Seafood industry	Benefits	Improved harmonisation with international standards, potentially lowering costs for exporting businesses  Potential increased demand, resulting from increased trust from consumers in the safety of seafood products  Potential positive financial (and other) short term and long-term benefits, resulting from reduced risk of food safety incidents due to greater protection of public health and safety
	Costs	Potential for more frequent closures, resulting in lost sales and potential stock losses
Government	Benefits	Potential reduced health expenditure due to a greater margin of safety  Simplified enforcement

It is important to note that some cost and/or benefits identified in Table 1 may flow from one impacted group to another. The increased cost of testing may be passed on by the seafood industry, reducing the impact on the industry and increasing costs for consumers (to the extent that the industry is able to pass on costs).

The impacts would only occur in Australia. New Zealand has already adopted the lower thresholds to manage the harvest of bivalve molluscs, through the Regulated Control Scheme – Bivalve Molluscan Shellfish for Human Consumption. Therefore, in New Zealand, there would effectively be no change to the status quo.

## **5.2 Responses from stakeholders**

FSANZ has relied on the best available information (primarily from the application) to inform the consideration of costs and benefits.

FSANZ has been unable to quantify the impacts in dollar terms.

FSANZ sought additional information from stakeholders through the Call for Submissions to test our assumptions and improve the analysis of this Approval Report. Refer to Attachment A – List of questions for stakeholders Attachment A – List of questions for stakeholders for the full list of questions.

Stakeholder responses to these questions are summarised in Attachment B – Stakeholder responses Table 5, along with other responses received relating to the consideration of costs and benefits found in Table 6.

## **5.3 Impacts on consumers**

### **5.3.1 Impact on food safety for consumers**

Updating the MLs referenced in the Code is a health protective measure.

The high toxicity of DST and PST, as well as a low margin of safety, means that consumption of the toxins can have severe health impacts where toxins are consumed.

The MLs in the Code have been in place since 1999. Since that time, Codex adopted a standard in 2008, which includes MLs for biotoxins based on more recent risk assessments published by the FAO and WHO, and EFSA.

Accepting the application recognises the new information (that Codex is based on). It follows that the level of risk to public health and safety would at least be maintained, and may be reduced, by increasing the margin of safety.

Therefore, consumers may benefit from reduced adverse health impacts due to food poisoning.

### **5.3.2 Impact on prices for impacted products**

There is a potential for the prices of impacted seafood to increase. This is due to the potential for decreased supply of impacted seafood products as a result of the potential for increased closures. Industry may pass on the costs of increased testing to consumers.

## **5.4 Impacts on industry**

Industry are expected to:

- Benefit from the harmonisation of standards
- Benefit from increased consumer trust
- Experience costs if there are more frequent closures
  - This cost may be partially offset through a potential reduction in costs that would result from food safety incidents, in potential situations where food safety incidents are prevented by the greater margin of safety

The impacts are discussed in more detail in the following section.

### **5.4.1 About the industry**

#### **5.4.1.1 Value of the industry**

The total value of impacted products was approximately \$150m in 2020. This is according to ABARES data on the value of the combined wild harvest and aquaculture commercial Australian bivalve industry production.

A breakdown of this figure by state and by commodity is presented in Table 2, below.

**Table 2 – Value of industry by commodity and state (2020)**

	NSW (\$'000)	SA (\$'000)	Tas (\$'000)	WA (\$'000)	Vic (\$'000)	QLD (\$'000)	Total (\$'000)
Oysters	58,242	24,948	30,758	-	-	500	114,448
Scallops	-	-	..	9,199	-	3,662	12,861
Mussels	282	3,472	2,289	-	5,189 <sup>a</sup>	-	11,232
Pipis	2,117	4,798	-	-	-	-	6,915
Other molluscs	106	1,537	1,619	-	1,555	-	4,817
<b>Total</b>	<b>60,747</b>	<b>34,755</b>	<b>34,666</b>	<b>9,199</b>	<b>6,744</b>	<b>4,162</b>	<b>150,273</b>

<sup>a</sup>2017-18 figure as 2019-20 data not available

'-' no data recorded by ABARES

'..' rounded to zero

Note that scallop producers in Western Australia, the Northern Territory and Queensland do not conduct routine biotoxin analyses and are therefore not impacted by this application.

#### **5.4.1.2 Number of impacted businesses**

There is no single source of data for the number of impacted businesses. According to data provided by the Applicant;

- in NSW there are:
  - 244 oyster businesses
  - 41 pipi licences
  - two mussel producing businesses
- In SA there are:
  - 92 aquaculture growers
  - 15 licences for pipis and cockles
  - one company producing mussels
- In Tasmania there are:
  - 65 marine oyster farming businesses
  - 6 businesses harvesting wild oysters, pipis, and clams

For more information on the number of impacted businesses, refer to the application (page 14).

#### **5.4.2 Industry expected to benefit from harmonisation of standards**

Currently in Australia, there are two tiers of regulatory standards, each stating different biotoxin MLs – one for domestic products and one for exported products. Export standards are set by the regulator in the region the product is exported to.

This could cause confusion for industry and could create additional work for exporting companies to ensure they comply with both sets of standards.

Adopting Codex MLs would mean compliance with the Code would equate to compliance with international standards. For PST; the USA, China, Canada and the European Union (EU) align with Codex. For DST; the USA, the EU and Singapore align with Codex (see section 1.4.2 in the Approval Report for further details). This would have the potential to reduce costs such as administrative burden for exporting businesses.

### **5.4.3 Potential benefits for industry as a result of improved food safety**

Increased safety of impacted seafood may lead to more consumer confidence, which then could result in more demand.

The cost of increased closures (discussed below in section 5.4.4.1) may be partially offset by potential savings in costs associated with food safety incidents as a result of a greater margin of safety. This may include reduced costs from the direct impacts of recalls, and longer term avoided costs like the impact of reduced consumer confidence.

### **5.4.4 Costs for industry**

The amendments would lower the threshold for closing fisheries during a toxic algal bloom, resulting in a greater number of days closed during these events, as well as an increase in the total number of closures.

#### ***5.4.4.1 Small increase in the frequency and duration of closures***

According to the data available, a decrease in the ML could result in shellfish aquaculture zones being closed for harvest for a slightly higher proportion of the year as a result of toxic algal blooms.

The potential scale of this impact has been calculated by investigating the test results of Australian shellfish data provided by the applicant.

The data was collected as part of the state Shellfish Quality Assurance Programs' biotoxin risk management. Biotoxin risk management requirements are detailed in the Australian Shellfish Quality Assurance Program Manual of Operations. These requirements are set by the ASQAAC: a government-industry cooperative program that assures food safety of shellfish when grown, harvested and handled in accordance with its operational guidelines.

The application contains a summary of the results of 8156 tests for DST and 7044 tests for PST in Australian bivalve shellfish from 2012 to 2017. For a more detailed breakdown by state and species, refer to:

- Attachment 2a to the application for DST
- Attachment 2b to the application for PST

FSANZ subsequently requested more current data from the applicant. The applicant was able to provide additional data for the period 2018 to 2022 for:

- Tasmania (4482 DST tests, 5503 PST tests)
- NSW (3330 DST, 3388 PST)
- WA (254 DST, 252 PST)

To review the additional data provided in full, refer to the updated information provided for the application.

The only major shellfish producing state which did not provide updated data is South Australia, as it was not expected that updated data would change the analysis for them.

The analysis of the cost impacts of this application uses data from 2012 to 2022 for NSW, Tasmania, and Western Australia and for all other jurisdictions the 2012 to 2017 data is used.

The data provided was analysed to determine how often DST and PST would be detected at the lower thresholds.



Analysis of this data indicates that the number of detections would increase in Australia by:

- 2.2 for DST per year on average
- 5.5 for PST per year on average.

This analysis is explained below.

*Potential for increased number of closures due to increased detection of DST*

The below table shows the expected number of additional detections per year. It is estimated that there would be on average 2.2 additional detections per year due to DST.

This has been calculated based on data provided by the applicant. It is based on the number of detections under the amended standard, less detections under current standard, divided by the number of years that the data covers.

Data from 2012 to 2022 is used for NSW, Tasmania, and Western Australia (11 years of data) and for all other jurisdictions the 2012 to 2017 data is used (6 years of data).

**Table 3 – Estimated number of additional detections per year of DST by state**

	NSW (2012 to 2022)	SA (2012 to 2017)	Tas (2012 to 2022)	WA (2012 to 2022)	Vic (2012 to 2017)	Total
Total number of samples tested over time period	6,172	426	8,939	394	268	16,199
Total number of samples exceeding existing limit	13	16	8	1	8	40
Proportion of samples exceeding existing limit (%)	0.21%	3.76%	0.09%	0.25%	2.99%	0.49%
Total number of samples exceeding amended limit	20	22	9	2	10	53
Proportion of samples exceeding amended limit (%)	0.32%	5.16%	0.10%	0.51%	3.73%	0.65%
<b>Number of additional detections per year</b>	<b>+0.6</b>	<b>+1.0</b>	<b>+0.1</b>	<b>+0.1</b>	<b>+0.3</b>	<b>+2.2</b>

*Note: few samples were tested in QLD and NT with no toxins detected, therefore data from these jurisdictions has been excluded from the table and the estimate*

The number of additional closures has not been estimated.

Where DST or PST is detected, a number of subsequent tests are performed until there are two consecutive tests where DST or PST is not detected. Therefore, one closure will be associated with more than one detection. The ratio of closures to detections is not known. The number of additional closures would be less than the increase in detections. No additional data was provided during the Call for Submissions to establish the relationship between closures and detections.

*Potential for increased number of closures due to increased detection of PST*

The below table shows the expected number of additional detections per year. It is estimated that there would be on average 5.5 additional test failures per year in Australia due to PST. This figure has been corrected following the Call for Submissions. This has been calculated based on data provided by the applicant. It is based on the number of detections under the amended standard, less detections under current standard, divided by the number of years that the data covers.

**Table 4 - Estimated number of additional detections per year of PST by state**

	NSW (2012 to 2022)	SA (2012 to 2017)	Tas (2012 to 2022)	WA (2012 to 2022)	Vic (2012 to 2017)	Total
Total number of samples tested over time period	5,004	292	10,242	378	257	16,173
Total number of samples exceeding existing limit	19	7	319	1	2	348
Samples exceeding existing limit (%)	0.38%	2.40%	3.11%	0.26%	0.78%	2.15%
Total number of samples exceeding amended limit	25	7	373	1	2	408
Samples exceeding amended limit (%)	0.50%	2.40%	3.64%	0.26%	0.78%	2.52%
<b>Number of additional detections per year</b>	<b>+0.5</b>	<b>-</b>	<b>+4.9</b>	<b>-</b>	<b>-</b>	<b>+5.5</b>

*Note: data from QLD, NT, and ACT excluded from estimate due to low number of samples*

The number of additional closures has not been estimated.

As discussed above, the ratio of closures to failed tests is not known. The number of additional closures would be less than the increase in detections. No additional data was provided during the Call for Submissions to establish the relationship between closures and detections.

#### **5.4.4.2 Consequences of closures**

Costs associated with growing area closures are dependent on the fishery.

For all shellfish species there would be costs as a result of the fishery being closed.

For scallops, pipis, and mussels there would also be some costs of lost stock.

A submission received from Oysters Tasmania indicated the potential cost that would impact the Tasmanian oyster industry. As noted in section 5.4.4.1, errors were made in Table 4 that FSANZ was made aware of through the Call for Submissions. As a result, the submission from Oysters Tasmania refers to figures that now differ to the information found in Table 4.

Oysters Tasmania valued their industry at \$40 million, and estimated the changes would generate \$350,000 in losses. This estimated loss would now be less when using the corrected figures. The submission also explained it was reasonable to assume an additional detection would give rise to an additional week of closure in one growing area, consistent with the information provided by the applicant, which states the maximum impact of an additional detection will affect one oyster growing area for one week. As discussed, the ratio of closure to failed tests is not known, as one closure is expected to be associated with more than one detection.

No other additional data was provided during the Call for Submissions to quantify this impact.

Large companies would be able to minimise the cost impact. For these companies, a closure in one area would result in a shift in harvesting activity to another area that is not impacted by the closure.

However, for wild fisheries such as pipis, there would be limited options for moving to

alternative areas. There is only one pipi harvest ground in SA, although this is a large harvest area and on occasion this area may be sub-divided to allow harvest to continue in one part of the area whilst another section is closed. In NSW there are several fishing grounds that effort might be reallocated to.

For aquaculture species, growers would be limited to harvesting from their specific leases. Mid to large companies and co-operatives would have access to leases in multiple growing areas and would have the ability to shift harvest effort to growing areas that are not impacted by closures.

For smaller companies that only exist in one growing area, the cost of the closure will depend on:

- the season (commercial demand and prices tend to be higher prior to Christmas and Easter)
- the condition of the shellfish (affecting whether they are selling at all and the price),
- the volume of shellfish and the length of the closure

In most cases, the impact would be to delay sales of the shellfish until the toxins are depurated. In most cases marine biotoxin events are short lived. Weekly sampling ensures areas are re-opened as soon as possible.

The actual closures themselves may be between two weeks and several months, although the majority of closures would be shorter than one month. The impact of the change would in most cases be a maximum of one extra week closure – the period when toxins are rising and might fall between the current and the amended ML.

When toxin levels are rising, particularly for PSTs, they rapidly exceed the current ML to levels up to two orders of magnitude above the ML. In many cases, the biotoxin rise would exceed the amended ML so fast that there will be no impact from this change.

*Impacts on importers expected to be minimal*

The amendments in the approved draft variation would also apply to seafood imported into Australia.

Based on data for the decade 2010 to 2020<sup>3</sup>, there has only been one instance where imported products would not meet the lower threshold. The detected amount of biotoxin in this instance was also above the current standard.

Based on this data, FSANZ concludes there is unlikely to be any significant impact on imported seafood.

#### **5.4.5 Impacts on government**

Government agencies would benefit from having a single set of standards, simplifying monitoring and enforcement of regulation.

Governments would also benefit from reduced healthcare costs, as the lower threshold has the potential to reduce the number of consumers requiring medical treatment.

The value of this benefit has not been quantified but is expected to be small.

---

<sup>3</sup> Department of Agriculture Water and the Environment. Failing food reports. 2021 [Available from: <https://www.agriculture.gov.au/import/goods/food/inspection-compliance/failing-food-reports>]

## **5.5 Conclusion**

FSANZ concludes that the benefits of the amended change (international harmonisation) would likely outweigh the costs (increased closures).

Additional data that was provided during the Call for Submissions stage did not change this conclusion.

## Attachment A – List of questions for stakeholders

FSANZ has relied on the best available information (primarily from the application) to inform the consideration of costs and benefits.

At the Call for Submissions stage, FSANZ sought additional information from stakeholders to test our assumptions and improve the analysis for the Approval Report. To elicit this information, we posed a number of questions that are listed below.

Question 1: Are there any significant impacts missing from table 1?

Question 2: Do you have any data that can be used to quantify the potential reduction in foodborne illnesses?

Question 3: Do you agree with the value of the industry and the number of impacted businesses? If not, do you have any alternative data that you would like us to consider?

Question 4: Do you agree with the estimated number of additional detections per year? Do you have any additional data that could be used to improve the estimate or estimate the potential number of additional closures?

Question 5: Do you have any evidence that can be used to calculate the potential cost impact of the proposal?

Question 6: Do you agree that there is unlikely to be any impact on international trade? If not, do you have evidence that can be used to demonstrate an impact?

Question 7: Do you agree that there is a benefit to government? Do you have any evidence that can be used to quantify any of the potential impacts?

Question 8: Do you agree that benefits outweigh costs?

## Attachment B – Stakeholder responses regarding consideration of costs and benefits

Table 5: Responses to questions in Supporting Document 2

Response	Submitter	FSANZ response
<b>Question 1: Are there any significant impacts missing from table 1?</b>		
No	Department of Health, Western Australia	Noted.
<b>Question 2: Do you have any data that can be used to quantify the potential reduction in foodborne illnesses?</b>		
No responses.		
<b>Question 3: Do you agree with the value of the industry and the number of impacted businesses? If not, do you have any alternative data that you would like us to consider?</b>		
No response in regard to the monetary value for the industry by commodity and State. In regard to the number of impacted businesses this would be accurate as bivalve molluscs businesses have to register with the Department of Health in WA under the Food Act 2008. Similar arrangements apply to the other states and therefore the number of impacted businesses would be reflected accurately.	Department of Health, Western Australia	Noted.
<b>Question 4: Do you agree with the estimated number of additional detections per year? Do you have any additional data that could be used to improve the estimate or estimate the potential number of additional closures?</b>		
Yes, the additional DST and PST detections per year is provided in Table 3 and Table 4 respectively and the calculation is based on the number of detections under the proposed standard, less detections under the current standard, divided by the number of years that the data covers. Has previously provided the most recent data available for the period 2012 to 2017 and then provided additional data as requested for the period 2018 to 2022.	Department of Health, Western Australia	Noted.
<b>Question 5: Do you have any evidence that can be used to calculate the potential cost impact of the proposal?</b>		
No responses.		
<b>Question 6: Do you agree that there is unlikely to be any impact on international trade? If not, do you have evidence that can be used to demonstrate an impact?</b>		

Response	Submitter	FSANZ response
Yes, agree given the stats for 2010 to 2020 (there has only been one instance where imported products would not meet the lower threshold).	Department of Health, Western Australia	Noted.
<b>Question 7: Do you agree that there is a benefit to government? Do you have any evidence that can be used to quantify any of the potential impacts?</b>		
<p>Yes, there may be a situation where product meets the MLs prescribed in the Code Schedule 19 but does not meet export standards. This causes confusion to industry and regulators. Adopting Codex MLs will reduce inconsistency as it would mean the compliance with the Code would equate to compliance with all international standards.</p> <p>Agrees that Government agencies would therefore benefit from having a single set of standards, simplifying monitoring and enforcement of legislation, and the lowering of MLs in providing a health protective measure.</p> <p>Notes the alignment with FSANZ principle of keeping the levels of contamination from toxins in the food chain as low as reasonably achievable (ALARA).</p> <p>Welcomes a review of the MLs using recent scientific evidence.</p>	Department of Health, Western Australia	Noted.
<b>Question 8: Do you agree that benefits outweigh costs?</b>		
Yes, agree there is likely to be a net benefit in harmonisation that would outweigh the cost associated with the potential for more frequent closures.	Department of Health, Western Australia	Noted.

**Table 6: Summary of issues regarding consideration of costs and benefits**

Response	Submitter	FSANZ response
<p><b>Corrections to supporting document 2 – costs and benefits</b></p> <p>Section 5.4.4.1 lists the average number of additional detections per year on page 8. The data presented is derived from Tables 3 and 4, notes errors in these tables.</p> <p>The periods of concern are 11 years for data collected from 2012-2022 (as opposed to the 9 years stated), and 7 years for data collected from 2012-2017 (as opposed to the 5 years listed).</p> <p>Table 4 contains errors for Victoria and Tasmania. Victorian exceedances were 2 only for both the current and proposed ML (rather than the 8 stated). The total number of samples exceeding the proposed limit for PST in Tasmania should be 373, not 420. This is made up of 309 from 2012-2017 and 64 from 2018-2022. The correct total number of additional closures in Tasmania is 4.5 per year, bringing the national total to 5 per year.</p>	<p>SafeFish</p>	<p>Noted. The correct periods of data collection, 11 years and 6 years, respectively, were applied to the calculations in Tables 3 and 4 in the Call for Submissions documents. These were inaccurate in the wording of the report and have now been corrected.</p> <p>The errors in Table 4 have also been corrected. The updated table can be seen in SD 2 (Table 4Table 4).</p> <p>These corrections did not change the conclusions drawn from the consideration of costs and benefits.</p> <p>The suggested total number of additional detections differs to FSANZ's final estimate and is due to a different period of data collection used.</p>



**Costs**

The costs of accepting the application outweigh the benefits. Accepting the application would cost the Tasmanian industry and Australian community an estimated \$350,000 per year, and generate negligible benefits for the community, Government, or industry.

The frequency of tests in Tasmania has been less than one per week per growing area from 2012-2022, a detection could correspond to more than a week of closure for a growing area. However, the receipt of a result in the range between the current and proposed MLs between 2012-2022 would tend to be associated with an above-average frequency of testing. So, an assumption that an additional detection corresponds to an additional week of closure in one growing area is reasonable, accepting the application would generate 9.3 additional weeks of closures in a Tasmanian growing area each year.

There are around 20 growing areas in Tasmania for biotoxin management purposes. Tasmania produces around \$40 million of oysters each year, translating to \$2 million worth of oysters on average per Tasmanian growing area. 9.3 additional weeks represents 18% of the year. Assuming additional closures would reduce the value of oyster sales by 18%, this will cost Tasmanian growing areas \$350,000 (conservative cost estimate). The 'additional detections' would tend to occur in Tasmanian growing areas with annual production above the \$2 million average. \$350,000 of oysters at farm gate prices amounts to a considerably greater value for consumers at retail prices. Additional closures can lead to a larger-than-estimated reduction in production, consumption, employment, and incomes.

Assuming a one-to-one relationship between closures and sales revenue is reasonable. Once oysters reach maturity they are sold, and the vacated space is filled with spat. A closure means the grower has to renege on a promise to sell, reducing the reliability of the grower and the price the grower

**Oysters Tasmania**

Errors in the Call for Submissions (SD 2) document (Table 4) have been corrected. These corrections affected the calculations reported for additional detections of PST per year in Tasmania, along with Victoria. These errors mean the estimated cost by Oysters Tasmania would now be less.

FSANZ clarified with the submitter that the \$350,000 estimated cost per year was intended to represent one growing area, as it was unclear whether this was instead an estimate per growing area. FSANZ also clarified that the figure related to the Tasmanian oyster industry, not all Tasmanian shellfish.

Response	Submitter	FSANZ response
<p>can attract over the long term. It also means that the buyer, who wants oysters now, either decides to not buy oysters, or to obtain oysters from elsewhere. Wrong to assume that the buyer will simply agree to purchase the stock on the same terms once the farm is reopened. Another buyer may agree to buy the stock once the farm is reopened, at a lower price, and receiving money later than planned is costly. Moreover, the stock may have spawned in the interim, or become unsuitable for sale, so no sale may arise. Closure also means that the grower cannot restock, as the unsold mature oysters continue to take up finite space and nutrients. This delays future sales, possibly by more than the duration of the closure given that spat and juvenile stock are not always available and the growth conditions are not even throughout the year.</p> <p>Some of the additional 9.3 weeks of closures in a Tasmanian growing area per year will represent extensions of existing closures. The remainder of the additional weeks of closures will be stand-alone closures, and such instances are a significant proportion of all instances. Additional closures bring the fixed costs associated with renegeing on promises to customers and suppliers of spat and juvenile stock.</p> <p>Understands there may be some dispute about FSANZ's calculations of 'additional detections'. If additional Tasmanian PST detections were half of what FSANZ has calculated, then conservatively estimate that accepting the application would reduce annual Tasmanian oyster sales by \$175,000.</p>	<p>Oysters Tasmania</p>	<p>The application is likely to benefit exporting businesses who currently have to comply with two sets of standards. The current situation has been noted by one submitter to be confusing for industry and regulators and that changing the MLs would be beneficial in the enforcement of legislation and continue to be a health protective measure.</p>
<p><b>Benefits</b> Accepting the application would generate negligible benefits for the community, Government, or industry.</p>		

**Public health and safety**

FSANZ's work indicates that accepting the application would not further their objective of protection of public health and safety.

Based on FSANZ risk analysis there is no evidence that Australia moving to the New Zealand approach would protect public health and safety. There is evidence that such a move would not protect public health and safety and limited evidence that such a move could undermine public health and safety.

Note a suspected case of illness in New Zealand after consumption of a commercially purchased oyster, and possible failure of risk management. New Zealand's adherence to the MLs proposed in the application may have contributed to this food safety incident, which may have created a false confidence that gave rise to a laxity in other aspects of food safety management, such as testing frequency, testing methodology, sample sizes, growing area sizes, grower cooperation, and grower risk aversion.

Accepting the application should not be thought of as generating a consumer or industry benefit of reduced risk of food poisoning, or generating a resulting increase in trust and demand, or as generating a government benefit from a reduced risk of food poisoning or a resulting reduction in health expenditure.

Accepting the application would reduce oyster consumption and hence reduce this public health benefit.

In determining what is best for public health and safety, the evidence from Australian experience is more direct, data-rich, and up-to-date than the position of Codex. As shown FSANZ's estimates of 'additional detections', there were dozens of instances where bivalves from a Tasmanian growing area, with PST between the proposed and current MLs, could have been, and probably were, legally harvested

**Oysters Tasmania**

FSANZ received no additional information during the Call for Submissions to quantify the potential reduction in foodborne illness. The amendments will continue to protect public health and safety, and risk may be reduced. Increased safety of impacted seafood may lead to more consumer confidence, which could result in greater demand.

Response	Submitter	FSANZ response
<p>and sold, and in each instance tens of thousands of oysters would have been consumed by thousands of Australians. The evidence from Australian experience is more up-to-date because, while the Australian position was struck in 1999 and the Codex position was struck in 2008.</p> <p>In the request to reject the application, notes that FSANZ should recommend Codex investigation of the Australian experience with a view to potential updating of the Codex position. Were this investigation of such rich and important data not to occur, it would be a travesty of science and human health.</p>		
<p><b>Trade</b>  Accepting the application would generate no trade benefit. No current nor prospective export destination, nor exporter or importer, for any seafood product, has indicated that the status quo in Australia generates barriers or costs.</p> <p>In assessing whether accepting the application would generate a trade benefit, FSANZ should place considerable weight on submissions from industry, who would be the beneficiaries. Contends that accepting the application would generate no trade benefit, and it is expected that no industry submission will contain a conflicting contention. If this is the case, there would be no basis for FSANZ to hold a view that accepting the application would generate a trade benefit.</p> <p>The application does not argue that accepting the application would generate a trade benefit, and does not argue that any industry participant is of such a view.</p>	<p>Oysters Tasmania</p>	<p>The amendments are not likely to generate negative impacts on international trade. There is potential to reduce costs such as administrative burden for exporting businesses.</p>

Response	Submitter	FSANZ response
<p><b>Simplified enforcement</b> Accepting the application would generate negligible benefit for government via simplified enforcement. The federal government lists oyster growing areas from which exports are approved, and notes that such areas must be 'open'. Any routine work arising from differences in MLs between countries would be negligible. It is a matter for exporters to ensure that their product meets standards in the importing country.</p>	Oysters Tasmania	FSANZ has received a submission indicating that the amendments will simplify the monitoring of MLs and enforcement of legislation.