FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

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Supporting document 2

Harmonisation of marine biotoxins 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 to change the current maximum levels in Schedule 19 of the Code for two marine biotoxins in bivalve shellfish (molluscs).

If approved, the proposed amendments would 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 the benefits of increased harmonisation would outweigh the cost associated with the potential for more frequent fishery closures.

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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 to Standard 1.4.1 of the Code for two marine biotoxins in bivalve shellfish (molluscs).

In assessing the Application, FSANZ must have regard to whether costs that would arise from a food regulatory measure varied as a result of the application outweigh the potential benefits.

This Supporting Document analyses the potential costs and benefits of the application; and addresses the other matters to which FSANZ has had regard in accordance with section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

In undertaking its analysis and having regard to the abovementioned matters, FSANZ has relied on the best available information at the time.

However, information received from the Call for Submissions may result in FSANZ arriving at a different conclusions to those set out below.

1.2 Exemption from developing OIA impact analysis

The Office of Impact Analysis[1] (OIA) has stated that the proposed change is unlikely to have a more than minor regulatory impact.

As such, the preparation of a Regulation Impact Statement (RIS) is 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.[2]

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.

[1] Formerly the Office of Best Practice Regulation (OBPR)
[2] 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 proposed 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 cost benefit analysis has considered the following options, 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 Cost benefit analysis

5.1 Net benefit expected from accepting the application

The purpose of this consideration is 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 considers costs and benefits to the community, government, and industry.

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

Social group	Impact	Notes on impact
Consumers	Benefits	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
	Costs	Potential for more frequent closures, resulting in opportunity costs and potential stock losses
Government	Benefits	Potential reduced health expenditure
		Simplified enforcement

It is important to note that some cost and/or benefits identified in Table 1 would 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 Questions for 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.

We are seeking additional information from stakeholders to test our assumptions and improve the analysis for the Approval Report. To elicit this information, we have posed a number of questions throughout this document.

Refer to Attachment A for the full list of questions.

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

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 safety margin, 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.

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

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

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 lower thresholds

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[b]	-	11,232
Pipis	2,117	4,798	-	-	-	-	6,915
Other molluscs	106	1,537	1,619	-	1,555	-	4,817
Total	**60,747**	**34,755**	**34,666**	**9,199**	**6,744**	**4,162**	**150,273**

[b]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).

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?

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. This would have the potential to reduce costs 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. 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

Proposed 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 by:

- 2.2 for DST per year on average
- 9.7 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 proposed 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 (9 years of data) and for all other jurisdictions the 2012 to 2017 data is used (5 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 proposed limit	20	22	9	2	10	53
Proportion of samples exceeding proposed limit (%)	0.32%	5.16%	0.10%	0.51%	3.73%	0.65%
Number of additional detections per year	**+0.6**	**+1.0**	**+0.1**	**+0.1**	**+0.3**	**+2.2**

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 in not known. The number of additional closures would be less than the increase in detections. Data is welcomed that may enable this relationship to be established.

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 9.7 additional test failures per year due to PST.

This has been calculated based on data provided by the applicant. It is based on the number of detections under the proposed 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	8	354
Samples exceeding existing limit (%)	0.38%	2.40%	3.11%	0.26%	3.11%	4.20%
Total number of samples exceeding proposed limit	25	7	420	1	8	461
Samples exceeding proposed limit (%)	0.50%	2.40%	4.10%	0.26%	3.11%	2.85%
Number of additional detections per year	**+0.5**	**-**	**+9.2**	**-**	**-**	**+9.7**

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 in not known. The number of additional closures would be less than the increase in detections. Data is welcomed that may enable this relationship to be established.

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?

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 an opportunity cost as a result of the fishery being closed.

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

The cost impact of the additional closures are not known. FSANZ welcomes data that may assist 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 proposed 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 proposed 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 proposed ML so fast that there will be no impact from this change.

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

Impacts on importers expected to be minimal

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

Based on data for the decade 2010 to 2020[3], 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 impact on imported seafood.

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?

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.

[3] 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]

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?

5.5 Conclusion

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

FSANZ welcomes any data that stakeholders can provide that will improve the certainty of the cost benefit analysis.

Question 8: Do you agree that benefits outweigh costs?

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.

We are seeking additional information from stakeholders to test our assumptions and improve the analysis for the Approval Report. To elicit this information, we have posed a number of questions throughout this document.

Answers to the following questions should be included with submissions.

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?