

6 July 2023
250-23

Call for submissions – Application A1243

Harmonisation of marine biotoxins standards for bivalve shellfish

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 molluscs. FSANZ has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [current calls for public comment and how to make a submission](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

For information on how FSANZ manages personal information when you make a submission, see FSANZ's [Privacy Policy](#).

Submissions should be made in writing; be marked clearly with the word 'Submission'. You also need to include the correct application or proposal number and name. Electronic submissions can be made by emailing your submission to submissions@foodstandards.gov.au. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 17 August 2023

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
WELLINGTON 6140
NEW ZEALAND
Tel +64 4 978 5630

Table of contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION	3
1.1 THE APPLICANT	3
1.2 THE APPLICATION.....	3
1.3 THE CURRENT STANDARD	4
1.3.1 <i>Maximum levels for marine biotoxins</i>	4
1.3.2 <i>Other standards for marine biotoxin maximum levels in bivalve molluscs</i>	5
1.3.3 <i>Other standards for marine biotoxin maximum levels recognised in New Zealand</i>	5
1.4 INTERNATIONAL STANDARDS.....	6
1.4.1 <i>Codex Alimentarius</i>	6
1.4.2 <i>National standards or other regulations</i>	6
1.5 REASONS FOR ACCEPTING APPLICATION	6
1.6 PROCEDURE FOR ASSESSMENT	6
2 SUMMARY OF ASSESSMENT	6
2.1 RISK ASSESSMENT	6
2.2 DST AND PST DETECTION DATA	7
2.2.1 <i>DST</i>	7
2.2.2 <i>PST</i>	7
2.3 RISK MANAGEMENT	7
2.3.1 <i>Regulatory request</i>	7
2.3.2 <i>Other control measures</i>	8
2.3.3 <i>Proposed risk management approach</i>	8
2.4 RISK COMMUNICATION.....	9
2.4.1 <i>Consultation</i>	9
2.4.2 <i>World Trade Organization (WTO)</i>	9
2.5 FSANZ ACT ASSESSMENT REQUIREMENTS	10
2.5.1 <i>FSANZ Act Section 29</i>	10
2.5.2 <i>Subsection 18(1)</i>	10
2.5.3 <i>Subsection 18(2) considerations</i>	11
3 DRAFT VARIATION	12
3.1 TRANSITIONAL ARRANGEMENTS.....	12
4 REFERENCES	12
ATTACHMENT A – DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE	13
ATTACHMENT B – DRAFT EXPLANATORY STATEMENT	15

Supporting documents

The following documents which informed the assessment of this application are available on the FSANZ [website](#):

- SD1 Paralytic Shellfish Poisoning and Diarrhetic Shellfish Poisoning - Cases in Australia and New Zealand
- SD2 Harmonisation of marine biotoxin standards for bivalve shellfish - Costs and Benefits

Executive summary

SafeFish on behalf of the Australian Shellfish Quality Assurance Advisory Committee (ASQAAC) applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to change the current maximum level (ML) in Schedule 19 for two marine biotoxins in bivalve molluscs.

The reason for the requested amendment is to align the MLs in the Code for the two marine biotoxins with the MLs set by the Codex Alimentarius Commission (Codex) and those under the New Zealand Regulated Control Scheme - Bivalve Molluscan Shellfish for Human Consumption. The two biotoxins are diarrhetic shellfish poisons and paralytic shellfish poisons (hereafter referred to as diarrhetic shellfish toxins and paralytic shellfish toxins).

MLs for marine biotoxins are necessary in order to protect public health and safety, as marine biotoxins cause serious and sometimes long term toxicity in humans.

FSANZ undertook an assessment to determine if the applicant's request should be accepted.

The proposed amendments will lower the existing MLs for diarrhetic shellfish toxins and paralytic shellfish toxins in the Code and therefore pose no health and safety concerns.

A cost benefit analysis concluded the benefit of increased harmonisation would outweigh the cost associated with the potential for more frequent fishery closures.

FSANZ has concluded that the Code should be amended to align the MLs for diarrhetic shellfish toxins and paralytic shellfish toxins in bivalve molluscs with the MLs established by Codex.

FSANZ has therefore prepared a draft variation to the Code, which if approved would:

- lower the ML for diarrhetic shellfish toxins, and
- change the reporting unit for paralytic shellfish toxins, which has a net effect of lowering the ML.

If approved, the draft variation would come into force at gazettal but with a one year transition period to permit industry to clear current stock and to assist producers to ready themselves to comply with the new requirements for diarrhetic shellfish toxins and paralytic shellfish toxins in bivalve molluscs. During the transition period (a 12 month period of time commencing on the date of commencement of the draft variation), a food product may be sold if the product complies with either the Code containing the existing requirements in Schedule 19, or with the Code as amended by the draft variation. After the transition period, all bivalve molluscs for sale in the Australian and New Zealand markets would have to comply with the new requirements set out in the proposed draft variation.

FSANZ seeks submissions on the draft variation.

1 Introduction

1.1 The Applicant

The application is from SafeFish¹, on behalf of the Australian Shellfish Quality Assurance Advisory Committee (ASQAAC).

SafeFish provides technical advice to both industry and regulators, to support Australia's seafood trade and market access negotiations. SafeFish also supports both industry and regulators with technical advice during seafood food safety related incidents.

ASQAAC is a SafeFish partner. ASQAAC has an industry and regulator representative from each of the shellfish growing states and a representative from the Department of Agriculture, Fisheries and Forestry. Food Standards Australia New Zealand (FSANZ) has representation on both SafeFish and ASQAAC. SafeFish is a permanent observer on ASQAAC.

1.2 The Application

The application sought to amend the Australia New Zealand Food Standards Code (the Code) to change the current maximum level (ML) in Schedule 19 for two marine biotoxins in bivalve molluscs. The two marine biotoxins are diarrhetic shellfish toxins and paralytic shellfish toxins.

The purpose of the application is to align the MLs in the Code for the two marine biotoxins with the MLs set by the Codex Alimentarius Commission (Codex) and those under the New Zealand Regulated Control Scheme - Bivalve Molluscan Shellfish for Human Consumption.

Bivalve molluscs are shellfish with a two part hinged shell, such as oysters, mussels, pipis, clams, cockles and scallops. Marine biotoxins, also known as shellfish toxins or poisons, can sometimes be present in the plankton consumed by bivalve molluscs.

MLs for marine biotoxins are necessary in order to protect public health and safety, as marine biotoxins cause serious and sometimes long term toxicity in humans.

The specific requests as stated in the application were as follows:

- Lower the ML for **diarrhetic shellfish toxins** expressed as okadaic acid equivalent (OA equivalent) from 0.20 to 0.16 mg/kg in bivalve molluscs.
- Defining **paralytic shellfish toxins** in mg saxitoxin dihydrochloride equivalents/kg rather than mg saxitoxin equivalents/kg. While the ML would remain at 0.8 mg/kg, the change in definition results in a more conservative ML for paralytic shellfish toxins. The net effect is to lower the ML for paralytic shellfish toxins from 0.8 to approximately 0.6 mg/kg.²

While the application refers to diarrhetic shellfish toxins and paralytic shellfish toxins, the terminology for shellfish toxins/marine biotoxins in Schedule 19 of the Code is diarrhetic shellfish poisons and paralytic shellfish poisons.

In order to distinguish between the toxin itself and the poisoning in humans that arises, this

¹ <https://www.safefish.com.au/>

² The application and this CFS report generally refer to a change to the ML for paralytic shellfish toxins, as this is the net effect of a change in definition.

report and its supporting documents (SD1 and SD2) will hereafter use the following terminology and abbreviations³:

- DST – diarrhetic shellfish toxin (synonymous with diarrhetic shellfish poison)
- PST - paralytic shellfish toxin (synonymous with paralytic shellfish poison).
- DSP – diarrhetic shellfish poisoning
- PSP – paralytic shellfish poisoning.

1.2.1.1 Codex standard

The application sought to align the Code with Codex Standard CODEX STAN 292-2008 – Standard for Live and Raw Bivalve Molluscs (Codex 2008). This standard includes the following MLs (per kilogram of mollusc flesh) relevant to the changes requested in the application:

Okadaic acid (OA) group	≤0.16 milligrams of okadaic equivalent
Saxitoxin (STX) group	≤0.8 milligrams (2HCL) of saxitoxin equivalent ⁴

New Zealand has adopted the Codex MLs (see 1.3.3 below).

1.3 The current standard

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Code. The requirements relevant to this application are summarised below.

1.3.1 Maximum levels for marine biotoxins

Subsection 1.1.1—10(3) of the Code provides that a food for sale must comply with any provisions relating to the composition of, or presence of specified substances in, food of that kind. Standard 1.4.1 Contaminants and natural toxicants contains the provisions relating to the levels of contaminants or natural toxicants in food. The limits prescribed by Standard 1.4.1 apply to the portion of the food that is ordinarily consumed.

Section S19—5 prescribes MLs for marine biotoxins, amongst other things. Food products with marine biotoxins exceeding the MLs listed in the Code are non-compliant and cannot legally be sold in Australia or New Zealand. This approach ensures that levels of marine biotoxins are kept as low as possible and are at levels that have been assessed as safe for human consumption. Specifically, Section S19—5 of the Code sets MLs in mg/kg in column three, for the contaminants listed in column one (with any relevant definitions/conditions), for the foods listed in column 2.

1.3.1.1 FSANZ Proposal P158 - background to current levels

The current MLs for bivalve molluscs in Schedule 19 of the Code were established in 1999 under Proposal P158 – Review of the Maximum Permitted Concentrations of Non-metals in Food (FSANZ 1999). The MLs have not been reviewed since that time.

³ The Draft Variation and accompanying text will continue to state diarrhetic shellfish poisons and paralytic shellfish poisons.

⁴ ‘milligrams (2HCL) of saxitoxin equivalent’ is equivalent to ‘mg saxitoxin dihydrochloride equivalents’ requested by the applicant.

Microscopic unicellular algae (mostly 20 to 200 µm size) form an important component of the plankton diet of shellfish such as mussels, oysters and scallops. Of the estimated 2000 living dinoflagellate species, about 30 species produce biotoxins that can cause human illness. Shellfish and other species present in a local aquatic ecosystem can accumulate biotoxins when biotoxin-producing algae are present, which can pose a food safety risk to consumers when eating shellfish.

The symptoms of toxic shellfish poisoning depend on the type and quantity of toxin consumed, and can vary from mild gastrointestinal discomfort through to complete respiratory paralysis. Affected seafood neither looks nor tastes different from uncontaminated seafood, and common methods of cooking or preparation will not make seafood containing biotoxins safe to consume.

Given the risk from marine biotoxins, MLs in bivalve molluscs for four biotoxins (PST, DST, amnesic shellfish poison and neurotoxic shellfish poison) were established in Schedule 19 under Proposal P158 (FSANZ 1999).

1.3.2 Other standards for marine biotoxin maximum levels in bivalve molluscs

There are no other standards for marine biotoxin levels recognised in Australia. However exporters of bivalve molluscs from Australia will need to comply with the MLs applying in the importing country, potentially including Codex MLs. Therefore under the current arrangements exporters may need to comply with one domestic ML and an international ML.

1.3.3 Other standards for marine biotoxin maximum levels recognised in New Zealand

Standard 1.4.1 and Schedule 19 apply in both Australia and New Zealand. In addition, New Zealand has already adopted the Codex MLs in a Notice made under the *Animal Products (Regulated Control Scheme - Bivalve Molluscan Shellfish) Regulations 2006*, under the *Animal Products Act 1999*.

The Notice is the Animal Products Notice Regulated Control Scheme – Bivalve Molluscan Shellfish for Human Consumption. The Notice specifies the requirements that must be met in relation to bivalve molluscan shellfish harvested for human consumption. The Notice supplements and gives effect to the general standards for bivalve molluscan shellfish in the Regulations.

The Notice sets the following maximum permitted levels for marine biotoxins⁵ in the edible portion of bivalve molluscan shellfish to manage their harvest, for example growing area closures if levels are exceeded:

- Paralytic shellfish poison – 0.8 mg saxitoxin dihydrochloride equivalent per kg
- Diarrhetic shellfish poison – 0.16 mg of okadaic acid equivalent per kg

Once bivalve molluscs become a food for sale, the Food Act 2014 and the levels in the Code apply. Therefore, the changes to the MLs in the Code requested by the applicant are consistent with those already in place under the *New Zealand Animal Products Act 1999*. More details of the New Zealand requirements are on the Ministry for Primary Industries website.⁶

⁵ Relevant to the changes to MLs requested in the application

⁶ [Introduction to bivalve molluscan shellfish growing, harvesting, processing, and operating | NZ Government \(mpi.govt.nz\)](https://www.mpi.govt.nz/introduction-to-bivalve-molluscan-shellfish-growing-harvesting-processing-and-operating/)

1.4 International standards

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex).

1.4.1 Codex Alimentarius

Codex Alimentarius is a compilation of harmonised international food standards, guidelines and codes of practice. Collectively, Codex texts aim to protect consumer health and promote fair practices in food trade. As stated in section 1.2 above, the relevant Codex Standard is CODEX STAN 292-2008 – Standard for Live and Raw Bivalve Molluscs.

1.4.2 National standards or other regulations

Table 11 of the application provides information on MLs in place outside of Australia and New Zealand. Since submitting the application, this table has been updated by the applicant, and provided as additional information. 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. Some countries report the values using different reporting units, so for these countries direct comparisons cannot be made.

1.5 Reasons for accepting Application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), and
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The application is being assessed under the General Procedure in the FSANZ Act.

2 Summary of assessment

2.1 Risk assessment

The application sought to reduce the MLs for DST and PST, which is a health protective measure, therefore an updated toxicological assessment was not required. However, FSANZ has reviewed the relevant biotoxin case report and food recall data for Australia and New Zealand. The case report data and food recall data show that there have been few cases of either PSP or DSP in either country and no known confirmed cases of PSP or DSP in commercially produced bivalves where routine biotoxin monitoring has been conducted (SD1).

FSANZ is of the view that further risk assessment in this case is not warranted because the current risk management strategies for commercially produced bivalve molluscs appear to be effective in protecting public health and safety from PST and DST. Further, harmonising the Code MLs with the lower MLs in Codex STAN 292-2008 (and as enforced in New Zealand) will further reduce the permitted levels of PST and DST in bivalve molluscs, and overall be a health protective measure.

2.2 DST and PST detection data

In order to estimate the potential scale of the impact of the changes to the MLs, the applicant provided analytical data for DST and PST detections for two time periods; 2012 – 2017 and 2018 – 2022.⁷ From 2012-2017, there were 8156 tests for DST and 7044 tests for PST; and from 2018-2022 data there were 8066 tests for DST and 9143 tests for PST.

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 (ASQAP) 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.

Based on that data, the percentages of samples impacted by the proposed changes were calculated, and provided as state by state and species by species information. A summary is provided below.

2.2.1 DST

From the 2012-2017 DST data, it was determined that changing the ML would result in a 0.16% average increase in the number of regular monitoring results that report above the ML (ranging from 0 – 3.9% impact per species per state). Analysis of the 2018-2022 DST data showed a similar impact at an average 0.05% increase in exceedances (ranging from 0 – 2.4% impact per species per state).

2.2.2 PST

A 0.58% average increase in exceedances was estimated from the 2012-2017 data (ranging from 0 – 5.1% impact per species per state), whereas the average increase in exceedances from the 2018-2022 data was 0.21% (ranging from 0 – 0.53% impact per species per state). The lower figures for the 2018-2022 data represent a lower frequency of toxic blooms during this period.

For an analysis of the impact on the number of detections due to a change in the MLs for DST and PST, see SD2 – Costs and Benefits.

2.3 Risk management

2.3.1 Regulatory request

The applicant has requested a change to the MLs in Schedule 19 for two marine biotoxins, DST and PST, as described below.

2.3.1.1 *Diarrhetic shellfish toxins*

The applicant has requested a reduction in the ML, from 0.20 mg/kg to 0.16 mg/kg, expressed as okadaic acid equivalents. There is no change to the unit of measurement.

2.3.1.2 *Paralytic shellfish toxins*

The applicant has requested a change in the unit of measurement, from saxitoxin equivalents

⁷ The latter was provided as additional information, during the assessment period.

to saxitoxin dihydrochloride equivalents.⁸ No change to the numerical ML was requested. By including the mass of the dihydrochloride salt when calculating the ML, the practical effect is to reduce the maximum amount of the shellfish toxin. When calculating the ML under the current Code requirement using saxitoxin equivalents, 0.8 mg/kg is effectively a 24% higher limit compared to using saxitoxin dihydrochloride equivalents (Turnbull et al. 2020). Put another way, the limit is reduced from 0.8 mg/kg to approximately 0.6 mg/kg under the change requested in the application.

Changing the Code to specify the ML as saxitoxin dihydrochloride equivalents will provide regulatory certainty, with no confusion as to which unit of measurement should be used. Section 3.1.1 D (3rd paragraph) of the application describes the poor stability of the saxitoxin hydrate (free base), the evolution of testing methods from mouse bioassay to chemical analytical methods, and the problems caused by the inconsistent use of reporting units (i.e. saxitoxin equivalents vs saxitoxin dihydrochloride equivalents).

2.3.2 Other control measures

In addition to the MLs for marine biotoxins set in Schedule 19 of the Code, Australia and New Zealand have other control measures in place.

In Australia, Standard 4.2.1 – Primary production and processing standard for seafood applies to primary producers and processors of bivalve molluscs. They are required to have a documented food safety management system that incorporates, among other requirements, conditions on harvesting (including for depuration or relaying) that effectively controls the hazards in bivalve molluscs. The standard requires the business to comply with either conditions in the ASQAP Manual which are specified in the Schedule to this Standard, including to have a marine biotoxin management plan; or conditions recognised by the Authority.⁹

Biotoxin risk management is usually a combination of analysis of shellfish for biotoxins and an analysis of water in which the shellfish are grown for toxin producing phytoplankton. The minimum frequency of biotoxin monitoring stipulated in the ASQAP Operations Manual is monthly for low risk growing areas. Growing areas with a higher biotoxin risk will have an increased frequency of monitoring and monitoring also increases during times of heightened risk (as indicated by either biotoxin results or elevated counts of toxin producing phytoplankton species).

As noted in SD1, case report data and food recall data for Australia and New Zealand shows there have been few suspected or confirmed cases of either PSP or DSP, and no confirmed cases of PSP or DSP in commercially produced bivalves where routine biotoxin monitoring has been conducted.

New Zealand requirements for growing, harvesting and processing of bivalve molluscan shellfish are contained in separate legislation, as described in Section 1.3.3 above.

2.3.3 Proposed risk management approach

The risk management options available to FSANZ after assessment, were to either:

⁸ The regulatory limit is expressed in terms of saxitoxin *equivalents* as the PSTs include more than just saxitoxins, and other derivatives may simultaneously be present in the shellfish ingested by humans.

⁹ Authority is defined in Chapter 4 of the Code as the State, Territory or Commonwealth agency or agencies having the legal authority to implement and enforce primary production and processing Standards.

- reject the application, or
- prepare a draft variation of the Code.

FSANZ has concluded that, for reasons set out in this report, Schedule 19 of the Code should be amended as requested. FSANZ's assessment is that amendment of the Code is the only option that can achieve alignment with the Codex standard, and that there are no non-regulatory options that can appropriately address the regulatory request. In making its assessment, FSANZ had regard to the criteria prescribed in the FSANZ Act (see section 2.5).

FSANZ therefore prepared a proposed draft variation which is described below.

2.3.3.1 Schedule 19 amendment

Schedule 19 of the Code contains the MLs for the contaminants under consideration, i.e. DST and PST.

If approved, the draft variation would amend Schedule 19 by amending the MLs for DST and PST in bivalve molluscs as follows:

- Lower the ML for **diarrhetic shellfish toxins** (poisons) expressed as okadaic acid equivalent (OA equivalent) from 0.20 mg/kg to 0.16 mg/kg
- Define **paralytic shellfish toxins** (poisons) in mg saxitoxin dihydrochloride equivalents/kg rather than mg saxitoxin equivalents/kg.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media channels and Food Standards News.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation.

The draft variation will be considered for approval by the FSANZ Board taking into account all comments received from this call for submissions.

2.4.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

Notifications to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade and Application of Sanitary and Phytosanitary Measures Agreement have been made to enable other WTO members to comment on the proposed amendments.

2.5 FSANZ Act assessment requirements

2.5.1 FSANZ Act Section 29

In assessing the application, FSANZ must have regard to section 29 of the FSANZ Act. FSANZ must consider:

- whether costs that arise from a food regulatory measure varied as a result of the application outweigh the benefits
- whether other measures would be more cost effective than a food regulatory measure varied as a result of- the application.

Supporting Document 2 (SD 2) sets out a cost benefit analysis; 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 of its assessment and decision to prepare a draft variation.

However, information received from the Call for Submissions may result in FSANZ arriving at a different conclusion to those set out in SD 2.

2.5.1.1 Net benefit expected

For reasons set out in SD 2, FSANZ has concluded there is likely to be a net benefit to accepting the application, that the benefit of increased harmonisation would outweigh the cost associated with the potential for more frequent fishery closures.

2.5.1.2 No other more cost-effective measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

For more information refer to SD 2.

2.5.1.3 Any relevant New Zealand standards

The relevant standards in the Code apply in both Australia and New Zealand. There are also relevant New Zealand only standards – see Section 1.3.3 of this report above.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.5.2.1 Protection of public health and safety

MLs are set to protect public health and safety. 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.¹⁰ The application is requesting that the Code is amended to reflect the Codex MLs. As the MLs are lower than those currently in the Code, the measure is health protective.

2.5.2.2 *The provision of adequate information relating to food to enable consumers to make informed choices*

FSANZ is not aware of any issues relevant to this objective.

2.5.2.3 *The prevention of misleading or deceptive conduct*

FSANZ is not aware of any issues relevant to this objective.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ used the best available scientific evidence to conduct the risk analysis. The applicant submitted a dossier of information and scientific literature as part of its application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application.

FSANZ's analysis of case report and food recall data for Australia and New Zealand is provided in the SD1.

- **the promotion of consistency between domestic and international food standards**

If approved, the changes to the MLs would mean they are consistent with Codex (CODEX STAN 292-2008), and therefore will support international trade. For PST (see section 2.3.1.2 above), there will no confusion regarding the ML, due to a more specific unit of measurement (saxitoxin dihydrochloride equivalents rather than saxitoxin equivalents) being specified in the Code.

- **the desirability of an efficient and internationally competitive food industry**

Amendment of the MLs in the Code would bring Australia into line with domestic standards in New Zealand, as well as a number of other international standards including the European Union and the USA.

In this way, Australia and New Zealand would remain competitive with other international markets.

- **the promotion of fair trading in food**

The revised MLs will promote trade and commerce in the food industry by having lower MLs as requested by the Australian shellfish industry, on the basis that they provide consistency between Australia and New Zealand and globally.

¹⁰ Refer to Section D, pages 10 - 12, of the application.

- **any written policy guidelines formulated by the Forum on Food Regulation**

There are no written policy guidelines relevant to this application.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

3.1 Transitional arrangements

FSANZ and the applicant discussed the need for a transition period, and propose a 12 month transition period from gazettal. FSANZ supports this transition period to allow sufficient time for the industry to put in place administrative processes in relation to the new MLs. These processes include notifications to laboratories, changes to testing regimes i.e. the way laboratories calculate the results, changes to internal documents that list the MLs, and notifications to importing business partners.

FSANZ proposes a transitional arrangement where, during a transition period commencing on the date of gazettal of the draft variation (if approved) and ending 12 months after that date, bivalve molluscs may be sold if they comply with either the Code as in force without the amendments made by the draft variation, or the Code as amended by the draft variation. The intent would be to provide a 12 month transitional arrangement that covers both stock-in-trade existing at the time of the commencement of draft variation (if approved), as well as bivalve molluscs that are packaged, labelled and made available for sale during the transition period.

After the one year transition period, all bivalve molluscs in the Australian and New Zealand market would have to comply with the proposed draft variation (if approved).

4 References

Codex CXS 292-2008 – Standard for Live and Raw Bivalve Molluscs - Adopted in 2008, amended in 2013, revision in 2014 and 2015. [Standards | CODEXALIMENTARIUS FAO-WHO](#)

FSANZ (1999) Proposal P158 [Proposal P158 - Review of the maximum permitted concentrations of non-metals in food \(foodstandards.gov.au\)](#). Food Standards Australia New Zealand, Canberra.

Turnbull AR, Harwood DT, Boundy MJ, Holland PT, Hallegraeff G, Malhi N, et al. Paralytic shellfish toxins—call for uniform reporting units. *Toxicon*. 2020;178:59-60.

Attachments

- A. Draft variation to the Australia New Zealand Food Standards Code
- B. Draft Explanatory Statement

Attachment A – Draft variation to the Australia New Zealand Food Standards Code



Food Standards (Application A1243 – Harmonisation of marine biotoxin standards for bivalve shellfish) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert Delegate's name and position title]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1243 – Harmonisation of marine biotoxin standards for bivalve shellfish) Variation*.

2 Variation to a Standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

4. Effect of the variations made by this instrument

- (1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.
- (2) During the transition period, a food product may be sold if the product complies with one of the following:
 - (a) the Code as in force without the variations made by this instrument; or
 - (b) the Code as amended by the variations made by this instrument.
- (3) For the purposes of this clause, ***transition period*** means the period commencing on the instrument’s date of commencement and ending 12 months after the date of commencement.

Schedule

Schedule 19—Maximum levels of contaminants and natural toxicants

- [1] **Section S19—5 (cell at table item dealing with “Diarrhetic shellfish poisons (Okadaic acid equivalent)”, column headed “Maximum level”)**

Repeal the cell, substitute:

0.16

- [2] **Section S19—5 (cell at table item dealing with “Paralytic shellfish poisons (Saxitoxin equivalent)”, column headed “Contaminant”)**

Repeal the cell, substitute:

Paralytic shellfish poisons (Saxitoxin dihydrochloride equivalent)

Attachment B – Draft Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1243 – Harmonisation of marine biotoxin standards for bivalve shellfish) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted application A1243 which seeks to change the maximum level (ML) for two marine biotoxins (diarrhetic shellfish poisons and paralytic shellfish poisons) in bivalve molluscs. The Authority considered the application in accordance with Division 1 of Part 3 and has prepared a draft variation – the *Food Standards (Application A1243 – Harmonisation of marine biotoxin standards for bivalve shellfish) Variation*.

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be subject to the disallowance or sunset provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunset if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunset legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the

FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has prepared a draft variation that amends the table to section S19—5 of the Code, to amend the MLs for two marine biotoxins, diarrhetic shellfish poisons and paralytic shellfish poisons, in bivalve molluscs.

The reason for making these amendments is to align the MLs for diarrhetic shellfish poisons and paralytic shellfish poisons in the Code, with the equivalent MLs set by the Codex Alimentarius Commission (Codex) and with those set in New Zealand under the New Zealand Regulated Control Scheme - Bivalve Molluscan Shellfish for Human Consumption. As such, these amendments would ensure consistency of domestic MLs for diarrhetic shellfish poisons and paralytic shellfish poisons in bivalve molluscs.

4. Documents incorporated by reference

The draft variation prepared by the Authority does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1243 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary.

The Office of Impact Analysis (OIA) granted FSANZ an exemption from the requirement to develop a Regulation Impact Statement (RIS) for this application (correspondence dated 22 December 2022 and 17 February 2023, OIA ID OBPR22-03706). This exemption was provided as the OIA assessed the proposed change was unlikely to have a more than minor regulatory impact on consumers, businesses and government.

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

Clause 1 provides that the name of the variation is the *Food Standards (Application A1243 – Harmonisation of marine biotoxin standards for bivalve shellfish) Variation*.

Clause 2 provides that the Code is amended by the Schedule to the variation.

Clause 3 provides that the variation will commence on the date of gazettal of the instrument.

Clause 4 provides a transitional arrangement. The stock-in-trade exemption provided by section 1.1.1--9 of Standard 1.1.1 will not apply to the amendments made by the draft variation (see subclause 4(1)). Instead, subclauses 4(2) and (3) provide a transitional arrangement where, during a 12 month transition period commencing on the date of gazettal,

bivalve molluscs may be sold if they comply with either: the Code as in force without the amendments made by the draft variation; or the Code as amended by the draft variation. The intention is to provide a 12 month transitional arrangement that covers both stock-in-trade at the time of the commencement of the draft variation (if approved), as well as bivalve molluscs that are packaged, labelled and made available for sale before the end of the transition period.

Item [1] of the Schedule to the draft variation would amend the table to section S19—5 by repealing the cell in the column headed “Maximum level” for the table item dealing with “Diarrhetic shellfish poisons (Okadaic acid equivalent)”; and substituting that cell with “0.16”.

If approved, the effect of this amendment would be that the ML for the marine biotoxin diarrhetic shellfish poisons in bivalve molluscs will be lowered from 0.2 mg/kg to 0.16 mg/kg.

Item [2] of the Schedule to the draft variation would amend the table to section S19—5 by repealing the cell in the column headed “Contaminant” for the table item dealing with “Paralytic shellfish poisons (Saxitoxin equivalent)”; and substituting that cell with “Paralytic shellfish poisons (Saxitoxin dihydrochloride equivalent).

If approved, the effect of this amendment would be that the reporting unit for the marine biotoxin paralytic shellfish poisons in bivalve molluscs would be changed from a saxitoxin equivalent to a saxitoxin dihydrochloride equivalent. This amendment would effectively lower the ML for marine biotoxin paralytic shellfish poisons in bivalve molluscs from 0.8 mg/kg to approximately 0.6 mg/kg.