3 November 2023
268-23

Approval report – Application A1243

Harmonisation of marine biotoxin 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.

On 6 July 2023, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received seven submissions.

FSANZ approved the draft variation on 25 October 2023. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 3 November 2023.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

[1] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

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Supporting documents

The following documents, which informed the assessment of this application are available on the FSANZ website:

SD 1 Risk assessment
SD 2 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 requested amendment is as follows:

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

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 requested amendments would lower the existing ML for diarrhetic shellfish toxins and paralytic shellfish toxins in the Code and therefore increase the margin of safety associated with poisoning from the two toxins. The amendment to the reporting unit for paralytic shellfish toxins would also provide regulatory certainty, with no confusion as to which unit of measurement should be used.

In considering the costs and benefits, FSANZ concluded the benefit of increased harmonisation outweighs the cost associated with the potential for more frequent fishery closures.

FSANZ 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.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation. FSANZ received seven submissions. Six submitters supported the draft variation. One submitter, from the Tasmanian oyster industry, did not support the draft variation, mainly because they considered it would generate costs in excess of benefits.

After consideration of all submissions and for the reasons set out in this report, FSANZ has approved a draft variation to the Code which will 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.

The approved draft variation will come into force at gazettal but with a one-year transition period to permit industry to clear current stock-in-trade 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 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 variation. After the transition period, all bivalve molluscs for sale in the Australian and New Zealand markets will have to comply with the

new requirements arising from this application.

1 Introduction

1.1 The applicant

The application is from SafeFish[2], 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.[3] 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.[4]

While the application refers to diarrhetic shellfish toxins and paralytic shellfish toxins, the

[2] https://www.safefish.com.au/

[3] FSANZ is represented on SafeFish and the Australian Shellfish Quality Assurance Advisory Committee (ASQAAC), providing technical advice to ensure the safety of seafood. FSANZ considered and assessed any potential for conflict of interest in accepting this application.

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

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 report and its supporting documents (SD 1 and SD 2) will hereafter use the following terminology and abbreviations[5]:

- 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 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[6]

New Zealand has adopted the Codex MLs (see Section 1.3.4 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.

1.3.2 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

[5] The approved draft variation and accompanying explanatory statement continue to state diarrhetic shellfish poisons and paralytic shellfish poisons.

[6] 'milligrams (2HCL) of saxitoxin equivalent' is equivalent to 'mg saxitoxin dihydrochloride equivalents' requested by the applicant.

Food (FSANZ 1999). The MLs have not been reviewed by FSANZ since that time.

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).

1.3.3 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.

1.3.4 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 biotoxins[7] 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

[7] Relevant to the changes to MLs requested in the application

website.[8]

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. China, Hong Kong and Japan still report DST in 'mouse units', therefore for these countries direct comparisons with Codex cannot be made. As noted in the application, the mouse assay method of detection is being phased out internationally.

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.

1.7 Decision

For reasons set out in this report, FSANZ decided to approve a draft variation amending the Code to:

- 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.

The draft variation as proposed following assessment was approved without change after FSANZ had regard to all submissions. The approved draft variation is at Attachment A.

The related 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.

[8] Introduction to bivalve molluscan shellfish growing, harvesting, processing, and operating | NZ Government (mpi.govt.nz)

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a draft variation to the Code from 6 July 2023 to 17 August 2023.

FSANZ received seven submissions, six of which supported the draft variation. Oysters Tasmania requested that FSANZ reject the application for a number of reasons.

Submitter comments and the response from FSANZ are detailed in Table 1 below.

Table 1: Summary of issues

Issue	Raised by	FSANZ response
Support for draft variation Department of Health, Western Australia noted alignment with both Codex and the New Zealand Regulated Control Scheme - Bivalve Molluscan Shellfish for Human Consumption. Department of Natural Resources and Environment Tasmania considers the application provides alignment with international standards, ensures the currency of food standards by utilising the most recently available data to inform decision making and further reduces the risk of adverse health events for the community. DAFF noted alignment with Codex. As DST is not currently tested under the Imported Food Inspection Scheme (IFIS), this will not impact on importers of shellfish. The NSW Food Authority noted that internationally aligned MLs will ensure an internationally consistent approach to consideration of DSTs and PSTs in bivalve molluscs. NZ Food Safety noted the amendments to align do not pose any health and safety concerns. They also noted the 12 month transition period.	Department of Health, Western Australia Department of Natural Resources and Environment Tasmania Department of Agriculture, Fisheries and Forestry (DAFF) NSW Food Authority NZ Food Safety	Noted.

Issue	Raised by	FSANZ response
As an ASQAAC member, the Department of Natural Resources and Environment Tasmania participated in and contributed to the preparation of the SafeFish application. Tasmania, in comparison to other jurisdictions, has a high biotoxin risk rating and can therefore be considered at an elevated risk of biotoxin detections, regardless of a change in the biotoxin MLs. From the additional data supplied to update the SafeFish application to encompass the monitoring period from 2018-2022, a change to the MLs would equate to a potential additional 3.5 PST closures in shellfish growing areas per year in Tasmania, with each closure affecting one oyster growing area for one week per year. Although there would be potential for an increase in shellfish growing area closures, the progressive weekly biotoxin monitoring arrangements in Tasmania facilitate shellfish growing areas re-opening as soon as possible. Supports the unanimous ASQAAC view that whilst there will be an impact across the Australian shellfish industry, it is minimal in comparison to the overall health protection measure provided by harmonisation of the MLs.	Department of Natural Resources and Environment Tasmania	Noted.
Review of NSW data from routine biotoxin testing over the last 5 years revealed existing PST and DST limits in the Code were not exceeded, however 4 samples would have exceeded the stricter Codex values. These were mostly sourced from pipi's (known to accumulate DST) and one event where mussels were sampled following a harvest area closure. Is an active member of ASQAAC. In accordance with the Australian Shellfish Quality Assurance Program, the NSW Shellfish Program, includes routine biotoxin monitoring under the NSW Marine Biotoxin Management Plan.	NSW Food Authority	Noted.

Issue	Raised by	FSANZ response
Under the Imported Food Inspection Scheme (IFIS), bivalve molluscs and bivalve mollusc products are classified as risk food. They are referred to the IFIS for biotoxin testing for PSP at 0.8 mg/kg and domoic acid at 20 mg/kg, consistent with current limits in the Code. From July 2021 to present, there has been 100% compliance for these tests. As results are reported as less than 0.8 mg/kg, it is uncertain how many consignments tested would have failed with a lower limit of 0.6 mg/kg. Currently the department is not testing imported bivalve molluscs for the presence of DST under the IFIS. Risk advice published by FSANZ in January 2021, states that DST do not present a potential medium to high risk to public health.	DAFF	Noted. FSANZ notes that the risk advice published in 2021 concluded that the risk to public health associated with OA group toxins (which cause DSP) in Australia is currently considered low on the basis of historically low reported incidence of DSP associated with OA group toxins in Australia and available international prevalence data. See Imported foods (foodstandards.gov.au).
Clarification regarding reporting units used historically in Australia, with potential to impact the interpretation of Supporting Document 1 Known Cases. In relation to Australian marine biotoxin standards for PST, SafeFish is aware there is some confusion around the reporting units used in Australia in the past. Prior to 2012, Australia was using methods of analysis that gave results in mg STX.2HCl equiv./kg, i.e. in alignment with Codex. At the time these would have been reported as mg/kg or ug/100g. It was only in 2012 when a specialist national marine biotoxin facility was set up that the reporting unit was changed to mg STX equiv./kg, as a literal interpretation of what is specified in the Code.	SafeFish	Noted. FSANZ assessment is that this information does not require revision or change the conclusion in SD 1.

Issue	Raised by	FSANZ response
Corrections to Supporting Document 2 – costs and benefits 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. 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). 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.	SafeFish	Noted. The correct periods for data collection, 11 years and 6 years, respectively, were applied to the calculations in Tables 3 and 4 in the Call for Submissions SD 2. These were incorrectly stated in the wording of the report and have now been corrected. The errors in Table 4 have also been corrected. The updated table can be seen in SD 2. These corrections did not change the conclusions drawn from the consideration of costs and benefits. The suggested total number of additional detections differs to FSANZ's final estimate and is due to a different period of data collection used.
Consideration of costs and benefits Provided responses to questions asked in the SD 2 – Costs and benefits.	Department of Health, Western Australia	Noted. Refer to Table 5 in SD 2 – Costs and benefits.

Issue	Raised by	FSANZ response
Represents Tasmania's oyster farmers, who employ around 350 Tasmanians and produce around $40 million worth of oysters each year. Request FSANZ reject the application, on the grounds that accepting the application would: • generate costs in excess of benefits; and • not further the objectives of FSANZ's consideration of applications, including the protection of public health and safety; and • run counter to: – the need for standards to be based on risk analysis using the best available scientific evidence; and – the desirability of an efficient and internationally competitive food industry. If FSANZ approve the application, Oysters Tasmania will request Food Ministers require a review on grounds that approval would not be consistent with objectives of the legislation, would not protect public health and safety and would place an unreasonable cost burden on industry.	Oysters Tasmania	Noted. FSANZ gave careful consideration to the submission from Oysters Tasmania. A response to each issue raised in the submission is provided below and in Table 6 in SD 2. FSANZ notes that Oysters Tasmania's concerns relate to PST only.
The costs of accepting the application outweigh the benefits. Accepting the application would cost Tasmanian industry — together with the Australian community who consume what the Tasmanian industry produces — an estimated $350,000 per year. Accepting the application would generate negligible benefits for the community, Government, or industry. Accepting the application would generate no trade benefit. Accepting the application would generate negligible benefit for government via simplified enforcement. Accepting the application would reduce the efficiency of the Australian food industry, as less would be produced, with no offsetting public health and safety benefit and reduce the international competitiveness of the	Oysters Tasmania	Noted. FSANZ does not agree. Errors in the Call for Submissions 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.

Issue	Raised by	FSANZ response
Australian food industry.		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. 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. 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. FSANZ has received a submission indicating that the amendments will simplify the monitoring of MLs and enforcement of legislation. FSANZ's assessment is that the proposed changes are likely to result in a net benefit, where benefits from international harmonisation outweigh the cost of potential additional closures. See Table 6 in SD 2 for more detail.

Issue	Raised by	FSANZ response
Consistency between domestic and international food standards If the application would generate significant costs and no benefits begs the question of why the application was lodged. Two reasons seem likely. Firstly, excessive weight put on academic studies underpinning Codex, despite their age and small sample sizes, relative to the empirics of a 25-year ongoing experiment on the Australian population, due to familiarity regulators and researchers have with academic studies. Secondly, regulators and researchers value the neatness of international and domestic rules being aligned. However, in this instance, the trade benefit that often comes with rule harmonisation does not apply. FSANZ should not consider that moving a domestic standard to align with an international standard would be a benefit. FSANZ should defend a proven domestic rule and pursue its interest in harmonisation by encouraging Codex to investigate and possibly adopt the Australian rule.	Oysters Tasmania	Noted. See responses above regarding the consideration of costs and benefits. For the reasons summarised in this report, and after careful consideration of the Oysters Tasmania submission, FSANZ decided to approve the draft variation. FSANZ did not identify any sound reason to reject the application or the draft variation. FSANZ notes submissions from other stakeholders, including the Tasmanian Government, supporting the application and the draft variation. FSANZ is not aware of any other concern from the shellfish industry regarding the proposed MLs. FSANZ has updated SD 1 to examine the currently available information on the risk to public health and safety from PST and DST and noted the current MLs provide only a low margin of safety.
FSANZ Objectives Accepting the application will not provide information to enable consumers to make informed choices. May reduce availability of bivalves and hence choices. Will not prevent misleading or deceptive conduct. Approval would imply current arrangements were inappropriate which would be misleading.	Oysters Tasmania	Noted. In its assessment, FSANZ had regard to the objective *of provision of adequate information relating to food to enable consumers to make informed choices* in subsection 18(1) of the FSANZ Act. FSANZ did not identify any issues relevant to this objective, The application, for example, does not impact on provision of information to consumers. Similarly, FSANZ has not identified any issues regarding conduct that could be misleading or deceptive that could arise from approval of the proposed draft variation.

Issue	Raised by	FSANZ response
In reviewing applications FSANZ must have regard to the need for standards to be based on risk analysis using the best available scientific evidence. It would be nonsensical for FSANZ to reject risk management strategies that FSANZ itself considers to be effective. FSANZ has not undertaken a quantitative analysis of the costs from increased closures that would arise if the application were accepted. However the quantitative advice in this submission indicates those costs would be significant. This reinforces that the scientific, evidence-based approach should be to reject the application.	Oysters Tasmania	Noted. FSANZ based its assessment on the best available scientific evidence. See section 2.5.3, SD 1, and SD 2. FSANZ acknowledges that the case report data and food recall data show there have been few cases of PSP or DSP and no known confirmed cases in commercially produced bivalves where routine biotoxin monitoring has been conducted. However, conclusions from the risk assessment were that harmonising levels with Codex would clarify the units for expressing PST (and effectively reduce the ML for PST), thereby increasing the margin of safety associated with PSP. The ratio of closures to detections is not known, as one closure is expected to be associated with more than one detection. Potential costs associated with growing area closures will be dependent on the fishery, their size, the season, the condition of the shellfish, and the length of closure, and is therefore difficult to estimate.
Desirability of an efficient and internationally competitive food industry Accepting the application would reduce the efficiency of the Australian food industry, as less would be produced, with no offsetting public health and safety benefit, reduce the international competitiveness of the Australian food industry, reduce the volume of Australian bivalves available to the Australian market, which is the overwhelming destination for Australian bivalves. It would also reduce the reliability, and increase the cost, of Australian supply. New Zealand exports more than A$4 million worth of oysters and more than A$18 million worth of mussels to Australia each year, but neither of these amounts represent a majority of New Zealand exports, let alone New Zealand production. Therefore, this is considerable capacity for New Zealand to fill gaps in the Australian market created by any	Oysters Tasmania	Noted. It is difficult to determine whether less shellfish would be produced as a result of this amendment. The ratio of closures to additional detections due to the amended MLs is not known. For some businesses, the impacts of additional time spent in closure may be delayed sales, for others there may be stock losses. FSANZ notes that exports from Australia are already required to meet importing country requirements, which for PST and DST are generally aligned with the Codex Standard. As noted in section 2.5.3 below, amendment of the MLs in the Code will bring Australia into line with domestic standards in New Zealand, as

Issue	Raised by	FSANZ response
acceptance of the application. Accepting an application that would provide a market advantage to New Zealand at the expense of Australia would call into question trans-Tasman cooperation in food safety regulation.		well as a number of other standards including in the European Union and the USA. Changing the Code to specify the PST ML as saxitoxin dihydrochloride equivalents will provide regulatory certainty and consistency with respect to the unit of measurement used internationally, with no confusion as to which unit of measurement should be used. This avoids any mismatch between the PST measurement results between two countries.
Note that the stated purpose of the application is for FSANZ to review the MLs. Understand it is on this basis that the four industry representatives on the fifteen person ASQAAC agreed to the application being lodged. As such, the dot point on page 12 of the application stating “Application endorsed by Australian Shellfish Industry” is misleading. (This comment was made in the context of trade as reported in SD 2)	Oysters Tasmania	Noted. FSANZ notes that all other submissions were supportive of the draft variation. No other representatives from the Australian shellfish industry have advised FSANZ of their lack of support for the application.

2.2 Risk assessment and Detection data

2.2.1 Risk assessment

FSANZ has undertaken a risk assessment (Supporting Document 1 – SD 1) that examines currently available information on the risk to public health and safety and the incidence of PSP and DSP in Australia and New Zealand. After reviewing the best available evidence, FSANZ concludes that there is a low margin of safety associated with current regulatory levels for shellfish for PST and DST.

For example, FSANZ notes that the acute reference dose (ARfD) for PST could be exceeded by the consumption of ~ 53 g of shellfish at the current regulatory limit in the Code (0.8 mg/kg STX). The lowest observed adverse effect level (mild cases of illness) could be exceeded by consumption of 150 g of shellfish at the current regulatory limit. However since 2012, there have been no reported cases of PSP or DSP associated with commercial bivalve production in Australia.

The Joint FAO/IOC/WHO ad hoc Expert Consultation has clarified that analytical data for PST for all methods should be expressed as mg STX.2HCl equivalents per kg of whole flesh. For DST analytical data for all methods should be expressed as mg OA equivalents per kg of whole flesh.

Harmonising levels with Codex would clarify the units for expressing PST and effectively reduce the MLs for PST and DST thereby increasing the margin of safety associated with PSP and DSP in Australia.

2.2.2 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.[9] 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.

2.2.2.1 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 –

[9] The latter was provided as additional information, during the assessment period.

2.4% impact per species per state).

2.2.2.2 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 SD 2 – Costs and benefits.

2.3 Risk management

2.3.1 Regulatory request

The applicant 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 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 requested a change in the unit of measurement, from saxitoxin equivalents to saxitoxin dihydrochloride equivalents.[10] 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 and consistency with the unit of measurement used internationally, 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

[10] 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.

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.[11]

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 SD 1, 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 1.3.4 above.

2.3.3 Risk management conclusion

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

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

Based on its assessment, and for the reasons set out in the A1243 call for submissions, FSANZ considered it appropriate to prepare a draft variation to the Code to amend Schedule 19 of the Code to

- 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; and
- define paralytic shellfish toxins (poisons) in mg saxitoxin dihydrochloride equivalents/kg rather than mg saxitoxin equivalents/kg.

FSANZ called for submissions on the draft variation.

After having regard to all submissions received, and for the reasons set out in this report, FSANZ decided to approve the draft variation proposed following assessment without amendment.

Amendment of the Code is the only option that can achieve alignment with the Codex standard. There are no non-regulatory options that can appropriately address the regulatory request.

The new MLs will be consistent with those in Codex, the MLs enforced in New Zealand and the MLs used in a number of other countries, (refer to section 1.4.2 above), hence reducing administrative burden or confusion caused by different standards for different situations. The amendment to the ML for PST will provide clarity and regulatory certainty as to the units to

[11] 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.

be used and greater consistency with international standards. The new MLs are supported by the assessment of risk to public health and safety which was based on the best available evidence.

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. The call for submissions was notified via the Food Standards Notification Circular, media release, FSANZ's social media channels, and Food Standards News.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions were called to assist consideration of the draft variation to the Code. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application/proposal.

The draft variation was considered for approval by the FSANZ Board having regard to all submissions made during the call for submissions period.

2.4.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

FSANZ however made notifications to the WTO for this application for transparency in accordance with both the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT). The notifications were published on 7 July 2023, and were as follows:

- Australia SPS: Notifications G/SPS/N/AUS/56, closing date for comments 5 September 2023
- New Zealand SPS: Notifiation G/SPS/N/NZL/727, closing date for comemnts 16 August 2023
- Australia TBT: Notification G/SPS/N/NZL/727, closing date for comments 5 September 2023

No comments were received.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

Supporting Document 2 (SD 2) sets out a consideration of costs and benefits.

For reasons set out in SD 2, FSANZ's assessment is that there is likely to be a net benefit to

approval of the draft variation, that the benefit of increased harmonisation with international standards outweighs the cost associated with the potential for more frequent fishery closures. In undertaking the consideration of 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.

The Office of Impact Analysis (OIA) has stated that the proposed 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).

2.5.1.2 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. Amendment of the Code is the only option that can align the relevant MLs with the Codex standard. 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 1.3.4 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 DST and PST 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.[12]

The draft variation will lower the MLs to align them with Codex. Lower MLs will provide better protection of public health and safety, noting that the current MLs offer only a small margin of safety for consumers. At present, only a small amount of contaminated shellfish needs to be consumed to reach intake levels at which symptoms of toxicity can occur (see SD 1).

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.

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

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 risk assessment is provided in the SD 1.

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

The changes to the MLs will 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 be 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 will bring Australia into line with domestic standards in New Zealand, as well as a number of other standards including in the European Union and the USA.

- **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.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

There are no written policy guidelines relevant to this application.

3 Transitional arrangements

FSANZ and the applicant discussed the need for a transition period, and proposed 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. The transition period will permit industry to clear current stock-in-trade and assist producers to ready themselves to comply with the new requirements for DST and PST in bivalve molluscs.

FSANZ has set a transitional arrangement where, during a transition period commencing on the date of gazettal of the approved draft variation 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 approved draft variation, or the Code as amended by the

approved draft variation. The intent is to provide a 12 month transitional arrangement that covers both stock-in-trade existing at the time of the commencement of the variation, 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 will have to comply with the new requirements as set out in the approved draft variation.

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. Approved draft variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement

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

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

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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 –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 sought 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 approved a draft variation – the *Food Standards (Application A1243 – Harmonisation of marine biotoxin standards for bivalve shellfish) Variation*.

Following consideration by the Food Ministers' Meeting, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislation Act 2003*.

2. Variation will be a legislative instrument

The approved draft variation is 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).

The instrument is not subject to the disallowance or sunsetting 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 sunsetting 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 sunsetting 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 approved a draft variation amending the table to section S19—5 of the Code, to change the MLs for two marine biotoxins, diarrhetic shellfish poisons and paralytic shellfish poisons, in bivalve molluscs. The amendments will align these MLs 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.

4. Documents incorporated by reference

The approved draft variation 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 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 6 July 2022 for a six week period.

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

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is 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 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 variation; or the Code as amended by the 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 variation, 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 variation amends 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”.

The effect of this amendment is that the ML for the marine biotoxin diarrhetic shellfish poisons in bivalve molluscs is lowered from 0.2 mg/kg to 0.16 mg/kg.

Item [2] of the Schedule to the variation amends 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).

The effect of this amendment is that the reporting unit for the marine biotoxin paralytic shellfish poisons in bivalve molluscs is changed from a saxitoxin equivalent to a saxitoxin dihydrochloride equivalent. This amendment effectively lowers the ML for marine biotoxin paralytic shellfish poisons in bivalve molluscs from 0.8 mg/kg to approximately 0.6 mg/kg.