UPDATED INFORMATION FOR A1243

Changes to text and tables in Application 1243 as a result of additional biotoxin data for the period 2018-2022.

Disadvantages:
(changes to this section on pages 12 and 13 of the Application 1243)

- Marginal increase in shellfish zone closures

  A decrease in the ML could result in shellfish aquaculture zones being closed for harvest for a slightly higher proportion of the year as a result of toxic algal blooms. The potential scale of this impact has calculated by investigating the test results of Australian shellfish data from 2012-2017 (8156 DST tests and 7044 PST tests; Attachments 2a/b) and from 2018-2022 data (8066 tests for DST and 9143 tests for PST; Attachment 2c). From the 2012-2017 DST data, it has been determined that changing reporting units 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).

  For 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.

  Correspondingly, there will be a minor increase in the number of days shellfish growing areas are closed for harvest. We estimate the maximum number of additional closures for any bivalve species in any state associated with this change would be 1 per annum in South Australia for DST in pipis and an additional three and a half PST closures per year in Tasmania (2012-2017 data), each affecting one oyster growing area for one week. Estimates of closure events from the 2018-2022 data are the same or lower in accordance with the lower rate of exceedances found during these years. These results indicate that if the regulations were harmonised, there would be a very low impact to the Australian shellfish industry based on the substantial data to date. ASQAAC are aware of this minimal impact and are unanimously in support of progressing this application for harmonisation.

Potential impact of change of DST and PST MLs to domestic production

(changes to page 15 of the Application 1243, ending under Table 7)

The results of 8156 tests for DST and 7044 tests for PST in Australian bivalve shellfish from 2012-2017[a] and 8066 tests for DST and 9143 tests for PST from 2018-2022 are shown below in Tables 4a,b and Tables 5a,b. Analysis of the 2012-2017 PST data shows that the average impact of changing reporting units for PST would be a 0.58% increase in the number of monitoring results that report above the ML (ranging from 0 – 5.1% impact per species per state; Attachment 2b), whereas the estimated impact using the 2018-2022 data is similar but less, at an average 0.21% in the number of monitoring results that report above the ML (ranging from 0 – 0.53% impact per species per state; Attachment 2c).

The impact of changing the ML for DST estimated from the 2012-2017 data is a 0.16% average increase (ranging from 0 – 3.9% impact per species per state; Attachment 2a), whereas the estimate from the 2018-2022 data is an average increase of 0.05% (with the only species per state impacted being mussels from NSW (0.53% increase in exceedance) and cockles/pipis from NSW (2.42% increase; Attachment 2c).

Table 4a. Detections of Diarrhetic Shellfish Toxin in commercial Australian bivalve mollusc species between 2012-2017 tested as part of ASQAP biotoxin monitoring programs. Data is presented by state. Source: ASQAP confidential data.

Bivalve samples tested by State	**Number of samples analysed for DST in 2012-2017**	**Samples >0.16 mg OA equiv/kg**	**Samples >0.20 mg OA equiv./kg**	**Samples 0.16-0.20 mg OA equiv./kg**	**% of samples 0.16- 0.20 mg OA equiv./kg**
NSW	2843	10	7	3	0.11
SA	426	22	16	6	1.41
WA	140	2	1	1	0.71
TAS	4457	9	8	1	0.02
VIC	268	10	8	2	0.75
QLD	18	0	0	0	0
NT	4	0	0	0	0
All States	*8156*	*53*	*40*	*13*	*0.16*

[a] Most Australian States have a low risk of biotoxin contamination, and therefore conduct biotoxin sampling on aquaculture leases on a minimum monthly frequency, changing to weekly testing during periods of elevated phytoplankton counts or biotoxin levels. Tasmania, having a high risk of biotoxin contamination in many growing areas, conducted weekly biotoxin monitoring in most growing areas for much of the 2012-2017 dataset, but is currently sampling at increased frequency (2 or more times a week) in sites where biotoxin blooms are in development, skewing risk estimates. The scallop industry only samples prior to and during the fishing period on a frequency determined by the current risk (informed by results of testing).

Table 4b. Detections of Diarrhetic Shellfish Toxin in commercial Australian bivalve mollusc species between 2018-2022 tested as part of ASQAP biotoxin monitoring programs. Data is presented by state. Source: ASQAP confidential data.

Bivalve samples tested by State	Number of samples analysed for DST in 2018-2022	Samples >0.16 mg OA equiv/kg	Samples >0.20 mg OA equiv./kg	Samples 0.16-0.20 mg OA equiv./kg	% of samples 0.16- 0.20 mg OA equiv./kg
NSW	3330	10	6	4	0.12
WA	254	0	0	0	0
TAS	4482	0	0	0	0
All combined	*8066*	*10*	*6*	*4*	*0.05*

Table 5a. Detections of Paralytic Shellfish Toxin in commercial Australian bivalve mollusc species between 2012-2017 tested as part of ASQAP biotoxin monitoring programs. Data is presented by state. Source: ASQAP confidential data.

Bivalve samples tested by State	Number of samples analysed for PST in 2012-2017	Samples >0.8 mg STX equiv./kg	Samples impacted if reporting units change to STX.2HCL equiv./kg	% of samples impacted if reporting units change
NSW	1616	7	4	0.2
ACT	6	5	0	0
SA	292	7	0	0
WA	126	1	0	0
TAS	4739	272	37	0.8
VIC	257	2	0	0
NT	4	0	0	0
QLD	4	0	0	0
All States	*7044*	*294*	*41*	*0.58*

Table 5b. Detections of Paralytic Shellfish Toxin in commercial Australian bivalve mollusc species between 2018-2022 tested as part of ASQAP biotoxin monitoring programs. Data is presented by state. Source: ASQAP confidential data.

Bivalve samples tested by State	Number of samples analysed for PST in 2018-2022	Samples >0.8 mg STX equiv./kg	Samples >0.8 mg STX.2HCl equiv./kg	Samples impacted if reporting units change to STX.2HCL equiv./kg	% of samples impacted if reporting units change
NSW	3388	12	14	2	0.06
WA	252	0	0	0	0.00
TAS	5503	47	64	17	0.31
All States	*9143*	*59*	*78*	*19*	0.21

To estimate the potential increase in closure days associated with the proposed change to MLs we assumed weekly testing during the impacted period. Most states (Tasmania excepted) only sample biotoxins on a minimum monthly basis and increase sampling when phytoplankton or biotoxin data indicates biotoxins may be present. Thus, the results from all states except Tasmania are representative of the impact during rare high-risk periods, rather than the impact during normal conditions. During 2022 Tasmania implemented increased sampling frequency during bloom development to two, occasionally three, samples per week, potentially skewing results from this period.

In most cases marine biotoxin events are short lived. Weekly sampling ensures areas are re-opened as soon as possible. Costs associated with growing area closures are dependent on the fishery. For all shellfish species this includes lost opportunity in the impacted harvest area. For scallops, pipis and mussels, costs also include lost stock and costs associated with harvesting the stock, as shellfish cannot be returned to the water after harvest. For the rarer, longer-term closures as might occur in some of the harvest areas on the east coast of Tasmania, costs include lost markets. However, for longer term closures, the loss of market would occur regardless of this proposed change to ML.

When considering in 2017 whether to apply to FSANZ to harmonise biotoxin standards with Codex, ASQAAC (representing oysters, mussels, pipis and clams) considered the impact detailed in Tables 6a and 7a. Industry and regulator representatives discussed the issue over several years, allowing enough time for consultation within each state. ASQAAC determined that the advantages of the proposed changes outweigh the disadvantages. ASQAAC's view is that the shellfish industry would benefit from harmonisation of biotoxin standards because it would mean that they would have consistent regulations for domestic and international trade, a reputation for supplying safe shellfish in accordance with all international standards, and greater protection from potential illness. Impact estimates from the 2018-2022 are presented in Tables 6b and 7b below.

Table 6a. The annual impact of the proposed change to the DST ML for each bivalve species in each state, estimated from 2012-2017 data. Species that are not listed for each state are not impacted. Source: ASQAP confidential data.

Impacted species/state	Estimated additional DST failed samples per year[a]	No. harvest areas	Estimated additional DST failed sample per growing area per year
Pipis in NSW	0.5	10	0.05
Pipis in SA	1.0	1	1.00
Mussels in WA	0.2	4	0.05
Oysters in Tas	0.2	23	0.01
Mussels in Vic	0.2	6	0.03
Pipis in Vic	0.2	3	0.07

[a] Calculated using the following: total number of samples analysed between 2012-2017 multiplied by the percentage of samples for that species detected above 0.16 and below 0.20 mg OA equivalent/kg divided by 100 then divided by the number of years testing occurred (N=6).

Table 6b. The annual impact of the proposed change to the DST ML for each bivalve species in each state, estimated from 2018-2022 data. Species that are not listed for NSW, WA or TAS are not impacted. Source: ASQAP confidential data.

Impacted species/state	Estimated additional DST failed samples per year[a]	No. harvest areas	Estimated additional DST failed sample per growing area per year
Cockles/Pipis in NSW	0.6	10	0.06
Mussels in NSW	0.2	4	0.05

[a] Calculated using the following: total number of samples analysed between 2018-2022 multiplied by the percentage of samples for that species detected above 0.16 and below 0.20 mg OA equivalent/kg divided by 100 then divided by the number of years testing occurred (N=5).

Table 7a. The annual impact of the proposed change to the PST ML for each bivalve species in each state, estimated from 2012-2017 data. Species that are not listed for each state are not impacted. Source: ASQAP confidential data.

Impacted species/state	Estimated additional PST failed samples per year[b]	No. harvest areas	Additional PST failed sample per growing area per year
Oysters in NSW	0.2	74	0.003
Mussels in NSW	0.5	2	0.25
Pacific oysters in Tas	3.5	23	0.15
Mussels in Tas	1.8	3	0.60
Clams in Tas	0.3	2	0.15
Scallops in Tas	0.5	Variable (1 - 4)	0.5 – 0.12

[b] Calculated using the following: total number of samples analysed between 2012-2017 multiplied by the percentage of samples for that species that is over the ML if the reporting unit is changed divided by 100 then divided by the number of years testing occurred (N=6).

Table 7b. The annual impact of the proposed change to the PST ML for each bivalve species in each state, estimated from 2018-2022 data. Species that are not listed for each state are not impacted. Source: ASQAP confidential data.

Impacted species/state	Estimated additional PST failed samples per year[a]	No. harvest areas	Additional PST failed sample per growing area per year
Oysters in NSW	0.2	74	0.003
Mussels in NSW	0.2	2	0.10
Pacific oysters in Tas	3.2	23	0.14
Mussels in Tas	0.2	3	0.07

[a] Calculated using the following: total number of samples analysed between 2018-2022 multiplied by the percentage of samples for that species that is over the ML if the reporting unit is changed divided by 100 then divided by the number of years testing occurred (N=5).

J. International Standards

(changes to page 21 of the Application 1243, ending under Table 11)

J.1 International Standards

Codex standards relevant to this application are:

Codex Alimentarius Commission Standard 292-2008 (CXS 292-2008[3]). 2008 Standard for live and raw bivalve molluscs. In Codex Alimentarius International Food Standards. Rome: Codex Alimentarius Commission. MLs for PST (saxitoxin group) and DST (okadaic acid group) can be found on page 2. A range of importing country standards for PST (including Codex) are provided in Table 11.

For PST it appears that most countries with a ML stated in mg STX equiv. /kg are referring to the need to include toxicity equivalents of PST analogues in the calculation of total PST, i.e. the amount of each analogue needs to be converted into the toxic equivalent amount of saxitoxin. Australia is the only country so far identified that reports in STX equivalents rather than STX.2HCl equivalents (Table 11).

Table 11. Comparison of levels for biotoxins between the FSANZ Food Standards Code and other International Standards (differences highlighted in red). Note that Australia currently does not import from or export bivalve shellfish to the European Union or Canada, although some growing areas are approved for EU export and have exported in the past. In-country reporting units have not been confirmed for Singapore or Japan.

Country Regulation	**Paralytic Shellfish Toxin (PST)**		**Diarrhetic Shellfish Toxin (DST)**
	Official Rule	**In-country reporting Unit**	
FSANZ FS Code[1]	0.8 mg/kg (STX equivalents)	0.8 mg/kg (STX equivalents)	0.2 mg/kg (OA equivalents)
Codex Standard[3]	0.8 mg/kg (STX.2HCl equivalents)	0.8 mg/kg (STX.2HCl equivalents)	0.16 mg/kg (OA equivalents)
United States of America[27]	0.8 mg/kg (0.8 ppm) (STX equivalents)	0.8 mg/kg (0.8 ppm) (STX.2HCL equivalents)	0.16 mg/kg (0.16 ppm) (total OA equivalents)
China & Hong Kong[28]	4 MU/g	0.8 mg/kg (STX.2HCl equivalents)	0.05 MU/g
Canada[29*]	0.8 mg/kg (STX equivalents) (bivalve shellfish edible tissue)	0.8 mg/kg (STX.2HCl equivalents)	1 mg/kg (bivalve shellfish digestive tissue)[6] 0.2 mg/kg (bivalve shellfish edible tissue)[6] (Sum of OA and dinophysis toxins)
European Union[30]	0.8 mg/kg (STX.2HCl equivalents)	0.8 mg/kg (STX.2HCl equivalents)	0.16 mg/kg (160 µg/kg) (OA equivalents)
New Zealand[31]	0.8 mg/kg (STX.2HCl equivalents/kg)	0.8 mg/kg (STX.2HCl equivalents)	0.16 mg/kg (OA equivalents)
Singapore[32]	0.8 mg/kg (STX equivalents/kg)		0.16 mg/kg (OA equivalents)
Japan[33]	4 MU/g		0.05 MU/g

Key: mg = milligrams, kg = kilograms, µg = micrograms, STX = Saxitoxins, OA = Ocadaic acids, ppm = parts per million, MU = mouse unit: 1MU (Mouse Unit) represents the amount of toxin that causes death in a mouse of 20g body weight in 15 minutes in case of paralytic shellfish poisoning toxin, while in case of diarrrheal shellfish poisoning toxin 1MU represents the amount of poison that causes death in a mouse of 16-20g body weight in 24 hours.

*currently under review by Health Canada.

C.2 Surveys on the levels of the DST in foods

(changes start at paragraph 2 in this section (page 33 of the Application 1243) and end after table 15)

As described in Section 'A.1.5 Current controls and their effectiveness', biotoxin monitoring in bivalve shellfish pre-harvest occurs regularly as part of the state shellfish quality assurance programs. Results from the monitoring of DST pre-harvest are given in Tables 14a,b and Tables 15a,b (by state and species for 2012 -2017 and 2018-2022).

Table 14a. Detections of Diarrhetic Shellfish Toxin in commercial Australian bivalve mollusc species between 2012-2017 tested as part of ASQAP biotoxin monitoring programs. Data is presented by species monitored. Source: ASQAP confidential data.

Bivalve samples tested for DST by Species	**Number of samples analysed for DST in 2012-2017**	**Samples >0.20 mg OA equiv./kg**	**% of samples > 0.20 mg OA equiv./kg**
Oysters	6484	2	0.03
Clams	93	1	1.08
Cockles/Pipi	568	28	4.93
Mussels	799	9	1.13
Scallops	212	0	0.00
Total	8156	40	0.49

Table 14b. Detections of Diarrhetic Shellfish Toxin in commercial Australian bivalve mollusc species between 2018-2022 tested as part of ASQAP biotoxin monitoring programs. Data is presented by species monitored. Source: ASQAP confidential data.

Bivalve samples tested for DST by Species	**Number of samples analysed for DST in 2018-2022**	**Samples >0.20 mg OA equiv./kg**	**% of samples > 0.20 mg OA equiv./kg**
Oysters	7346	0	0.00
Clams	50	0	0.00
Cockles/Pipi	172	3	1.74
Mussels	498	1	0.20
Total	*8066*	*4*	*0.05*

Table 15a. Detections of Diarrhetic Shellfish Toxin in commercial Australian bivalve mollusc species between 2012-2017 tested as part of ASQAP biotoxin monitoring programs. Data is presented by state. Source: ASQAP confidential data.

Bivalve samples tested for DST by State	Number of samples analysed for DST in 2012-2017	Samples >0.20 mg OA equiv./kg	% of samples > 0.20 mg OA equiv./kg
NSW	2843	7	0.25
SA	426	16	3.76
WA	140	1	0.72
TAS	4457	8	0.02
VIC	268	8	2.99
QLD	18	0	0.00
NT	4	0	0.00
All States	8156	40	0.49

Table 15b. Detections of Diarrhetic Shellfish Toxin in commercial Australian bivalve mollusc species between 2018-2022 tested as part of ASQAP biotoxin monitoring programs. Data is presented by state. Source: ASQAP confidential data.

Bivalve samples tested for DST by State	Number of samples analysed for DST in 2018-2022	Samples >0.20 mg OA equiv./kg	% of samples > 0.20 mg OA equiv./kg
NSW	3330	6	0.18
WA	254	0	0.00
TAS	4482	0	0.00
All States	*8066*	*6*	*0.07*

C.2 Surveys on the levels of PST in seafood

(changes to page 45 of Application 1243, ending after Table 23)

Biotoxin monitoring in Australian bivalve species at risk of contamination with marine biotoxins is regularly conducted in commercial harvest areas following ASQAP requirements[22]. The rate of occurrence of PST contamination in various bivalve species (pre-market; Tables 22a,b and Tables 23a,b) validates the requirement for this type of monitoring. Note that biotoxin monitoring in NSW, Vic, SA and WA is conducted on a minimum monthly basis and increases during rare times of heightened risk (as indicated by elevated levels of toxin or counts of toxin producing phytoplankton species). Tasmania is the only state with weekly, ongoing monitoring, which of recent times has increased to a greater frequency during the development phase of algal blooms (i.e. PST detected below 0.8 mg STX equiv./kg). As biotoxin contamination levels are monitored before product enters the market, few end-product surveys on the prevalence of PST in Australian bivalves are available.

Table 22a. Detections of Paralytic Shellfish Toxin in commercial Australian bivalve mollusc species between 2012-2017 tested as part of ASQAP biotoxin monitoring programs. Data is presented by species monitored. Source: ASQAP confidential data.

Bivalve samples testing for PST nationally by species	Number of samples analysed for PST in 2012-2017	Samples > 0.8 mg STX equiv./kg	% of samples > 0.8 mg STX equiv./kg
Oysters	5356	106	1.98
Clams	107	6	5.61
Pipis/Cockles	422	0	0.00
Mussels	936	170	18.16
Scallops	223	12	5.38
Total	**7044**	**294**	**4.17**

Table 22b. Detections of Paralytic Shellfish Toxin in commercial Australian bivalve mollusc species between 2018-2022 tested as part of ASQAP biotoxin monitoring programs. Data is presented by species monitored. Source: ASQAP confidential data.

Bivalve samples testing for PST nationally by species	Number of samples analysed for PST in 2018-2022	Samples > 0.8 mg STX equiv./kg	% of samples > 0.8 mg STX equiv./kg
Oysters	8343	30	0.36
Clams	52	0	0.00
Pipis/Cockles	180	0	0.00
Mussels	568	26	4.58
Total	**9143**	**55**	**0.61**

Table 23a. Detections of Paralytic Shellfish Toxin in commercial Australian bivalve mollusc species between 2012-2017 tested as part of ASQAP biotoxin monitoring programs. Data is presented by state. Source: ASQAP confidential data.

Bivalve samples tested for PST by State	Number of samples analysed for PST in 2012-2017	Samples > 0.8 mg STX equiv./kg	% of samples > 0.8 mg STX equiv./kg
NSW	1616	7	0.43
ACT	6	5	83.33
SA	292	7	2.40
WA	126	1	0.79
TAS	4739	272	5.74
VIC	257	2	0.78
NT	4	0	0.00
QLD	4	0	0.00
All States	**7044**	**294**	**4.17**

Table 23b. Detections of Paralytic Shellfish Toxin in commercial Australian bivalve mollusc species between 2018-2022 tested as part of ASQAP biotoxin monitoring programs. Data is presented by state. Source: ASQAP confidential data.

Bivalve samples tested for PST by State	Number of samples analysed for PST in 2012-2017	Samples > 0.8 mg STX equiv./kg	% of samples > 0.8 mg STX equiv./kg
NSW	3388	12	0.35
WA	252	0	0.00
TAS	5503	47	0.85
Combined data	**9143**	**59**	**0.65**