

Executive Summary

This application is made on behalf of the Australian Shellfish Quality Assurance Advisory Committee: a committee consisting of one regulator and one industry representative from each shellfish producing state; a representative from the Department of Agriculture Water and the Environment; and observers from the Seafood Importers Association and SafeFish. The application requests that Food Standards Australia New Zealand (FSANZ) conducts a review on the current biotoxin maximum levels (ML) for bivalve molluscs in Schedule 19 of the Food Standards Code¹ (hereafter called the FSANZ Code) referenced in Standard 1.4.1², with a view to harmonising the Maximum Level (ML) for diarrhetic (DST) and paralytic shellfish toxins (PST) with those in the Codex Standard CAC 292-2008 Standard for Live and Raw Bivalve Molluscs³ and the New Zealand Regulated Control Scheme - Bivalve Molluscan Shellfish for Human Consumption⁴. The proposed changes will harmonise Australia with the international Codex food standard (CAC 292-2008³), which is supported by the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO). This application aligns with the objectives specified in Section 18(1) of the FSANZ Act⁵ to “a) ensure the protection of public health and safety” and Section 18(2) to “have regard to a) the best available scientific evidence b) promotion of consistency between domestic and international food standards and c) the desirability for an efficient and internationally competitive food industry”.

The MLs for marine biotoxins in seafood currently listed in the FSANZ Code were last reviewed between 1997 and 1999 (Proposal P158 ‘Review of the maximum permitted concentrations of non-metals in food’⁶). The assessment at the time stated:

“There are four major groups of shellfish toxins, namely, paralytic shellfish poisons, diarrhetic shellfish poisons, amnesic shellfish poisons and neurotoxic shellfish poisons, which can be found in bivalve molluscs and cause serious and, in some cases, long term toxicity in humans. There is, however, a poor understanding of the dose response relationship associated with this toxicity and the current regulatory levels are pragmatically derived on the basis of the limited information available on the dose levels which do not appear to cause toxic symptom in humans.”

Since 1999, several significant studies have emerged that would inform a new risk assessment. These studies were considered in risk assessments by working groups from the FAO and WHO in 2004⁷ and the European Food Safety Authority (EFSA) in 2008⁸ and 2009^{9, 10}. As a result, both working groups determined lowest observed adverse effect levels (LOAEL) and acute reference doses (ARfD) for DST and PST. Both working groups acknowledged the toxicity of these compounds and the low safety margin employed to set the regulatory levels. The FAO publication⁷ was used to inform the Codex Committee of Fish and Fishery Products, which developed MLs for marine biotoxins in 2008³. The Codex MLs for DST and PST are lower than those listed in the FSANZ Code¹. New Zealand has since adopted the Codex MLs through the Regulated Control Scheme - Bivalve Molluscan Shellfish for Human Consumption⁴. In addition, quantitative modelling of the dose response to PST by Arnich and Thebault¹¹ determined a significantly lower threshold of harm from PST than determined by both the FAO/WHO and EFSA working groups, highlighting the narrow safety margin associated with the ML of this toxin group.

The 1999 FSANZ risk assessment (Proposal P158⁶) reviewed industry data on marine biotoxins in a limited number of Australian shellfish samples because biotoxin testing was not readily available at that period and was only conducted in response to the presence of toxic algae. A commercial biotoxin analytical service started in Australia in 2012 and all states with commercial bivalve production have

been monitoring for marine biotoxins since that date. Data from the monitoring programs have demonstrated that commercial farms can meet the lower Codex and NZ MLs for both DST and PST with minimal disruption to commercial production (maximum impact was one additional DST closure for pipis in South Australia every year and an additional 3.5 PST closures per year in Tasmania, each affecting one oyster growing area for one week).

Adopting Codex MLs would involve:

- Lowering the DST ML from 0.20 mg Okadaic Acid equivalents/kg (OA equiv./kg) to 0.16 mg OA equiv./kg.
- Defining the PST ML in mg saxitoxin dihydrochloride equivalents/kg (mg STX.2HCl equiv./kg), rather than mg saxitoxin equivalents/kg (mg STX equiv./kg). As the STX dihydrochloride salt is 24% heavier than its free base, this results in a 24% difference between the standards, with the Codex standard being more conservative (0.8 mg STX.2HCl equiv./kg = 0.60 mg STX equiv./kg).

We recommend adoption of the Codex ML for DST and PST in bivalve shellfish based on:

- High toxicity of DST and PST and low safety margin associated with current MLs
- Harmonisation with Codex CAC 292-2008 Standard for Live and Raw Bivalve Molluscs
- Harmonisation with NZ Regulated Control Scheme - Bivalve Molluscan Shellfish for Human Consumption
- Consistent testing parameters for domestic and export production, with the ability to meet all market requirements
- Alignment with the FSANZ principle from Proposal P158 of keeping the levels of contamination from toxins in the food chain as low as reasonably achievable (ALARA)
- The proposed change would result in minimal economic disruption
- Support from Australian industry and regulators

This application has been written in accordance with the Food Standards Australia New Zealand Application Handbook, 1 July 2019. Each section of the Application is headed up with the corresponding Handbook reference. Information contained in this application is focused on new information since the last FSANZ review in 1999 (Proposal P158⁶).

References

1. FSANZ. Australia New Zealand Food Standards Code, Schedule 19 : Maximum levels of contaminants and natural toxicants. Australia: Food Standards Australia New Zealand; 2015. p. 1-7.
2. FSANZ. Australia New Zealand Food Standards Code – Standard 1.4.1 – Contaminants and natural toxicants. 2016. p. 3.
3. Codex Alimentarius Commission. Codex Standard 292-2008 (CXS 292-2008). Standard for live and raw bivalve molluscs. Rome: Codex Alimentarius Commission; 2008.
4. Government NZ. Animal Products Notice: regulated control scheme - bivalve molluscan shellfish for human consumption. Ministry for Primary Industries. Wellington, New Zealand 2018.
5. FSANZ. Food Standards Australia New Zealand Act No. 188, 1991. Compilation No 28, 2018.
6. FSANZ. Review of the maximum permitted concentrations of non-metals in food. Full assessment report. Proposal P158. 1999.
7. FAO/WHO/IOC. Joint ad hoc expert consultation on biotoxins in bivalve molluscs. Oslo, Norway; 2004 September 26–30.
8. EFSA. Scientific opinion of the Panel on Contaminants in the Food Chain: marine biotoxins in shellfish – okadaic acid and analogues. . The EFSA Journal. 2008;589:1-62.
9. EFSA. Scientific opinion of the panel on contaminants in the food chain: marine biotoxins in shellfish - saxitoxin group. The EFSA Journal. 2009;1019:1-76.
10. EFSA. Scientific Opinion of the Panel on Contaminants in the Food Chain: marine biotoxins in shellfish - summary on regulated marine biotoxins. The EFSA Journal. 2009;1306:1-23.