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 will 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.