2 March 2026
383–26

Call for submissions – Application A1329

Exclusion of Blacklip Rock oysters farmed in the Northern Territory from the ML for cadmium in molluscs

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by the Department of Agriculture and Fisheries, Northern Territory Government of Australia, seeking to amend the Australia New Zealand Food Standards Code (the Code) to exempt Blacklip Rock oysters *(Saccostrea spathulata)* from the cadmium maximum level (ML) of 2 mg/kg for molluscs and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

Submissions on this application need to be made through the Consultation Hub.

All submissions on applications and proposals will be published on the Consultation Hub. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published following consultation and before the next stage in the statutory assessment process.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at Making a submission.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices. There is no need to send an email or hard copy of your submission if you have submitted it through the FSANZ Consultation Hub.

DEADLINE FOR SUBMISSIONS: 11:59pm (Canberra time) 13 April 2026

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

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

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

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

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Table of contents

Supporting document

The following document which informed the assessment of this application are available on the A1329 page on the FSANZ website[1]:

SD1 Risk Assessment

[1] https://www.foodstandards.gov.au/food-standards-code/applications/a1329-exclusion-blacklip-rock-oysters-farmed-northern-territory-ml

Executive summary

The Department of Agriculture and Fisheries, Northern Territory (NT) Government of Australia, has applied to amend Schedule 19 of the Australia New Zealand Food Standards Code (the Code) to exempt Blacklip Rock oysters (*Saccostrea spathulata*) from the maximum level (ML) of 2 mg/kg for cadmium in molluscs.

Concentrations of cadmium in Blacklip Rock oysters vary across aquaculture sites in the NT. Approximately half of the samples tested exceed the current ML of 2 mg/kg.

FSANZ conducted a risk assessment to evaluate any risks to public health and safety that could arise from 2 scenarios:

- The exclusion of Blacklip Rock oysters farmed in the NT from the ML of 2 mg/kg for cadmium in molluscs.
- The introduction of an alternative ML of 3 mg/kg for cadmium in Blacklip Rock oysters farmed in the NT, considered to be the level as low as reasonably achievable in the catchment area.

FSANZ has concluded that the public health and safety risk associated with the consumption of Blacklip Rock oysters farmed in the NT is low for Australian consumers. The estimated long-term dietary exposure to cadmium is 85% of the health-based guidance value (HBGV) for high consumers in the Australian population.

Higher cadmium concentrations may occur in Blacklip Rock oysters than those evaluated in the risk assessment. FSANZ has determined it is not appropriate to exclude Blacklip Rock oysters farmed in the NT from the ML for cadmium in molluscs. Instead, an alternative ML of 3 mg/kg for cadmium in Blacklip Rock oysters farmed in the NT was assessed to be a safe and appropriate risk management measure.

Following assessment, for the reasons set out in this report, FSANZ has prepared a draft variation to amend section S19—4 of the Code to:

- exclude Blacklip Rock oysters farmed in the NT from the ML for cadmium in molluscs of 2 mg/kg, to commence on the date of gazettal
- insert a new ML of 3 mg/kg for cadmium in Blacklip Rock oysters farmed in the NT, to commence the day after a period of 24 months from the date of gazettal.

The effect of the draft variation, if approved, would be to exclude Blacklip Rock oysters farmed in the NT from a ML for cadmium for a period of 24 months commencing from the date of gazettal. This would enable the sale of oyster stocks currently being farmed in the NT. At the end of the 24-month period, a new ML of 3 mg/kg for cadmium in Blacklip Rock oysters farmed in the NT would commence.

FSANZ seeks submissions on the draft variation of the Code.

1 Introduction

1.1 The applicant

The application is from the Department of Agriculture and Fisheries, Northern Territory (NT) Government of Australia (DAF NT).

1.2 The application

DAF NT has applied to amend Schedule 19 of the Australia New Zealand Food Standards Code (the Code) to exempt Blacklip Rock oysters (*Saccostrea spathulata*) from the maximum level (ML) of 2 mg/kg for cadmium in molluscs.

FSANZ has revised the name of the application following its acceptance for assessment to *A1329 – Exclusion of Blacklip Rock oysters farmed in the Northern Territory from the ML for cadmium in molluscs*, aligning the application name with the scope of the assessment and proposed draft variation to the Code.

DAF NT has assessed sources of pollution within the catchment area of shellfish harvest sites across the NT and determined cadmium uptake in Blacklip Rock oysters to be naturally occurring and not derived from anthropogenic sources.

Schedule 19 of the Code sets out the MLs of specified metal and non-metal contaminants and natural toxicants in nominated foods. A ML in the Code is set at a level consistent with public health and safety and as low as reasonably achievable based on Good Manufacturing Practice (GMP) and/or Good Agricultural Practice (GAP).

The applicant requested to exempt Blacklip Rock oysters from the ML for cadmium in molluscs in the Code on the basis that no public health and safety issues are expected from the consumption of Blacklip Rock oysters that contain cadmium at levels greater than 2 mg/kg. The application provided the following rationale:

- Cadmium from oysters is poorly absorbed in the body, due to the high content of essential minerals (e.g. zinc, iron and calcium) in oysters which compete with cadmium uptake in the body.
- No adverse health effects have been identified in populations consuming large amounts of oysters containing cadmium at similar levels to those in Blacklip Rock oysters.
- Adverse health effects due to cadmium dietary exposure have only been confirmed in a population consuming a predominantly rice-based diet (i.e. low in essential minerals) for which the rice was contaminated with cadmium from a neighbouring mine.
- Previous risk assessments of dietary cadmium by FSANZ raised no public health and safety concerns (e.g. the 2019 Australian Total Diet Study).

Traditional Owners in the NT have driven the development of a Blacklip Rock oyster aquaculture industry in the region to support the demand for a market of locally sourced oysters. Tropical oyster farming is a priority area for research and development in the NT.

The application is limited to farmed oysters permitted for sale under aquaculture licence arrangements. The application made to FSANZ in April 2025 included data for Blacklip Rock oysters both farmed and wild-caught in the NT. Following discussions with the applicant regarding the scope of the assessment and the permissions sought in the Code, new site-

specific data for Blacklip Rock oysters farmed in the NT was submitted to FSANZ in November 2025.

FSANZ assessed cadmium concentrations of 398 Blacklip Rock oysters farmed at 4 aquaculture sites (approximately 100 per site) in the NT sampled by DAF NT to derive the mean cadmium concentrations of market size oysters (≥70 mm length). The 4 aquaculture sites currently operate as research sites and are expected to transition to commercial farms under NT licensing and regulatory frameworks. Samples of Blacklip Rock oysters included in the risk assessment were grown under research trial conditions.

According to the application, excluding Blacklip Rock oysters farmed in the NT from the ML for cadmium in molluscs would likely result in the establishment of new aquaculture sites due to considerable interest from remote communities in Northern Australia.

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 in section **Error! Reference source not found.**.

1.3.1 ML for cadmium in molluscs

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—4 prescribes MLs for cadmium in molluscs (excluding Dredge (Bluff) oysters and Queen scallops), amongst other foods. Food products with cadmium 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 cadmium are kept as low as possible and are at levels that have been assessed as safe for human consumption. Specifically, section S19—4 of the Code sets MLs in mg/kg in column 3, for the contaminants listed in column one (with any relevant definitions and conditions), for the foods listed in column 2.

Standard 1.4.1 and Schedule 19 apply in both Australia and New Zealand.

The ML for cadmium in molluscs was established in 1997 under Proposal P144 – Review of the Maximum Permitted Concentrations for Cadmium in Food. The ML for cadmium in molluscs has not been reviewed since that time.

1.3.1.1 Exemptions

The reference to molluscs in the Code specifically excludes Dredge (Bluff) oysters and Queen scallops from the ML. These species have naturally occurring cadmium levels above 2 mg/kg and were determined to not require a ML on the basis that the species are not grown in areas where contamination from anthropogenic sources could occur, and the consumption of molluscs contributes only a minor amount of cadmium to the total dietary exposure in Australia and New Zealand.

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

The Codex General Standard for Contaminants and Toxins in Food and Feed specifies the ML of a substance. The Codex ML for cadmium in marine bivalve molluscs is 2 mg/kg, excluding oysters and scallops.

The ML for cadmium in marine bivalve molluscs was adopted in 2006 at the 38th session of the Codex Committee on Food Additives and Contaminants (CCFAC). The exclusion of oysters and scallops was supported by Australia in the development of the Codex ML on the basis that the Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) estimates for the percent contribution of oysters to cadmium dietary exposures for all Global Environment Monitoring System – Food (GEMS) regional diets of less than 5% did not meet the CCFAC criteria for setting a ML.

In 2024, the Codex Committee on Contaminants in Foods (CCCF) agreed to prepare a Code of Practice for the prevention and reduction of cadmium contamination in foods. The Code of Practice aims to provide guidance on practices to prevent and reduce cadmium contamination, including for farmed and wild-harvested seafood.

1.4.2 National standards or other regulations

The European Union (EU) and jurisdictions in Southeast Asia have established a ML for cadmium in marine bivalve molluscs. MLs for cadmium in oysters have not been established in the USA or Canada (Table 1).

Table 1. National standards for the ML for cadmium in marine bivalve molluscs.

Location	ML for cadmium in marine bivalve molluscs	Year
EU	1.0 mg/kg	2023
United States of America (US)	No ML for cadmium in fish or fishery products, including oysters	NA
Canada	No ML for cadmium in food	NA
China	2.0 mg/kg (with viscera removed)	2018
Hong Kong	2.0 mg/kg	2023
Singapore	1 mg/kg	NR

NA: Not applicable; NR: Not reported.

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)
- 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.

2 Summary of the assessment

FSANZ conducted a risk assessment to evaluate any risks to public health and safety that could arise from 2 scenarios:

- The exclusion of Blacklip Rock oysters farmed in the NT from the ML for cadmium in molluscs of 2 mg/kg.

- The introduction of an alternative ML for cadmium in Blacklip Rock oysters farmed in the NT of 3 mg/kg, considered to be the level as low as reasonably achievable in the catchment area.

FSANZ undertook a risk assessment of the alternative ML of 3 mg/kg for cadmium in Blacklip Rock oysters farmed in the NT based on the outcomes of an initial risk assessment of the exclusion of the species from the ML and subsequent discussions with the applicant.

Evaluations of cadmium by JECFA were available. FSANZ has used these safety assessments as the basis of its evaluation and conducted a literature review to determine whether there is any new information that would require a revision of the JECFA conclusions.

The risk assessment is provided in Supporting Document 1 (SD1). A summary of the risk assessment is included below in section 2.1.

2.1 Risk assessment

JECFA identified renal tubular dysfunction as the critical effect of cadmium in humans. The Committee established a Provisional Tolerable Monthly Intake (PTMI) of 25 µg/kg bw for cadmium, based on a meta-analysis of urinary β2-microglobulin concentrations in 30,000 individuals exposed to cadmium across 35 epidemiological studies. The health-based guidance value (HBGV) was expressed on a monthly basis due to the long half-life of cadmium in humans of 10–33 years.

Based on the evaluated epidemiological and toxicological evidence, FSANZ has determined that a Tolerable Monthly Intake (TMI) of 25 µg/kg bw remains appropriate for cadmium.

A dietary exposure assessment was conducted to estimate exposures to cadmium for the Australian population as the intended market for Blacklip Rock oysters is primarily domestic Australian markets. Overall, the public health and safety risk associated with the consumption of Blacklip Rock oysters farmed in the NT is low for Australian consumers.

For the worst-case scenario assessed, approximately 194 g of Blacklip Rock oyster meat could be consumed per month (equivalent to approximately 38 Blacklip Rock oysters per month) before exceeding the TMI for cadmium of 25 µg/kg bw/month. This estimate is representative of a consumption pattern of eating approximately one dozen oysters (12) per day, 3 times per month. For the worst-case exposure assessment based on longer term oyster consumption amounts (mean of 33 g/day and 90th percentile (P90) of 45 g/day) and the frequency of oyster consumption (3 times per month), the estimated mean and P90 total dietary exposures to cadmium are 65% and 85% of the TMI respectively, for the Australian population aged 2 years and above.

FSANZ considers the worst-case exposure assessment based on longer term oyster consumption to be conservative and likely an overestimate of the mean and P90 total dietary exposures to cadmium. The longer-term consumption scenario assumes Blacklip Rock oysters would be consumed throughout the year. However, the harvesting season for

Blacklip Rock oysters would be restricted to the dry season in the NT (from May to October). Furthermore, the mean cadmium concentration included in the calculations for the worst-case dietary exposure assessment was the highest mean concentration across the 4 sampled aquaculture sites.

Higher cadmium concentrations may occur in Blacklip Rock oysters than those evaluated in the risk assessment. Thus, FSANZ assessed the public health and safety risks of an alternative ML of 3 mg/kg for cadmium in Blacklip Rock oysters farmed in the NT, considered to be the lowest level reasonably achievable in the catchment area.

For the scenario of a ML of 3 mg/kg, the amount of oyster meat that could be consumed before exceeding the TMI is more than double that estimated using the worst-case scenario dietary exposure estimate based on concentration data of oysters sampled from 4 aquaculture sites in the NT. The estimated long-term P90 total dietary exposure to cadmium would be reduced to 55% of the TMI for the Australian population aged 2 years and above.

FSANZ concludes that setting an alternative ML of 3 mg/kg for cadmium in Blacklip Rock oysters would present a lower public health and safety risk than an exclusion from the ML for the species.

2.2 Risk management

Cadmium is a known contaminant in food. Dietary cadmium accumulates in the body over time and can lead to adverse effects on human health. MLs for contaminants are provided in the Code for circumstances where it has been determined that there is a potential risk to public health and safety if the prescribed limits of a certain substance are exceeded, and that the risk should be managed by regulation. To determine whether it is appropriate to exclude a food that can contain cadmium from an established ML, there must be evidence that the change would not pose a risk to the health and safety of consumers.

2.2.1 Proposed risk management approach

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

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

After assessing the application, and for the reasons listed in this report, FSANZ decided to prepare a draft variation to the Code.

For the reasons set out in the sections below, FSANZ has determined it is not appropriate to simply exclude Blacklip Rock oysters from a ML for cadmium. Instead, FSANZ is proposing to amend Schedule 19 of the Code to both exclude Blacklip Rock oysters farmed in the NT from the cadmium ML of 2 mg/kg for molluscs, and insert a new ML of 3 mg/kg for cadmium specifically for Blacklip Rock oysters farmed in the NT.

In addition, to enable the sale of oyster stocks currently being farmed in the NT, FSANZ is proposing to delay the commencement of the cadmium ML for Blacklip Rock oysters farmed in the NT for a period of 24 months commencing from the date of gazettal.

Further details on the proposed amendments are provided below in sections 2.2.2 to 2.2.5.

2.2.2 Exclusion from the ML for cadmium for Blacklip Rock oysters

The applicant requested an exclusion to the Code ML for cadmium for Blacklip Rock oysters sold in Australia and New Zealand.

When considering an amendment to the Code, FSANZ's primary objective under the FSANZ Act is to determine whether the proposed change would pose a risk to public health and safety.

Oysters are excluded from the Codex ML for cadmium in molluscs (section 1.3.1.1). Harmonisation with Codex is preferred where possible. However, harmonisation with Codex is secondary to measures put in place to protect the public health and safety of Australians and New Zealanders.

FSANZ also notes global efforts to reduce overall dietary exposure to cadmium, such as the Codex CCCF development of a Code of Practice for the prevention and reduction of cadmium contamination in foods (see section 1.4.1).

To understand the possible health impact of an exclusion, FSANZ considered the following:

- Whether there were factors, based on the risk assessment and evidence provided by the applicant, that would reduce or increase the overall exposure of dietary cadmium to consumers.

- Considering these factors, whether an exclusion from the ML would increase dietary cadmium exposure beyond the HBGV for oyster consumers.

FSANZ's risk assessment concluded the following.

- The current Code ML of 2 mg/kg for cadmium for molluscs remains suitable to ensure health protection for the Australian and New Zealand population (SD1, section 3.1).

- Of the market size Blacklip Rock oysters sampled, the mean cadmium concentrations of approximately half of the samples tested exceeded the current ML of 2 mg/kg.

- Based on the safety and dietary exposure assessments, the public health and safety risk associated with the consumption of Blacklip Rock oysters farmed in the NT is low for Australian consumers. The estimated long-term dietary exposure to cadmium is 85% of the HBGV for high consumers in the Australian population aged 2 years and above[2]. However, higher cadmium concentrations may occur in Blacklip Rock oysters than those evaluated in the risk assessment.

- The presence of dietary minerals (iron and zinc) in oysters may lower cadmium absorption. The FSANZ risk assessment identified that there is insufficient evidence to quantify the extent to which this effect occurs, including in potentially sensitive subpopulations such as iron deficient individuals (SD1, section 2.6.2).

While Blacklip Rock oysters are predicted to comprise a small market share (section 2.2.3.2), the applicant states that the Blacklip Rock oyster industry is growing, with significant

[2] A separate dietary exposure assessment for the New Zealand population was not considered for this assessment as the intended market for Blacklip Rock oysters is primarily domestic Australian markets (SD1, section 3). The New Zealand population was considered for the alternative ML scenario only as the ML will also apply to New Zealand if included in the Code.

investment and more sites planned. FSANZ understands some sites in the NT may be more vulnerable to higher levels of cadmium in Blacklip Rock oysters due to environmental factors, specifically episodic algal blooms (SD1, section 1). It is not known whether new or existing NT aquaculture sites may have higher cadmium concentrations in Blacklip Rock oysters in the future.

Based on the above, FSANZ considered an outright exclusion for all Blacklip Rock oysters, as per the applicant's request, unsuitable on the grounds of public health and safety.

2.2.3 New ML of 3 mg/kg for cadmium in Blacklip Rock oysters farmed in the NT

For the reasons stated in section 2.2.2, FSANZ did not consider the requested exclusion appropriate and instead considered whether, based on the risk assessment and discussions with the applicant, an alternative ML was a safe and appropriate risk management measure.

2.2.3.1 ML of 3 mg/kg for cadmium in Blacklip Rock oysters

The FSANZ risk assessment concluded for the scenario of an ML of 3 mg/kg, the meat weight of Blacklip Rock oysters that could be consumed before exceeding the TMI was estimated to be approximately 429 g per month. This amount is more than double the worst-case scenario estimate of consumption. Based on longer term oyster consumption amounts, frequency of oyster consumption and an ML of 3 mg/kg, the estimated long-term dietary exposure to cadmium would be reduced to ≤55% of the HBGV for the Australian population aged 2 years and above. For the same cadmium concentration (ML of 3 mg/kg) and considering longer term consumption, the estimated mean and P90 total dietary exposures to cadmium are 45% and 90% of the HBGV, respectively, for the New Zealand adult population (aged 15 years and above)[3]. Additional information provided by the applicant indicated that the intended market for NT Blacklip Rock oysters is primarily domestic Australian markets. Given the domestic market share is predicted to be small and targeted at domestic consumption, FSANZ considers exportation to New Zealand unlikely.

2.2.3.2 Other considerations

The FSANZ risk assessment also evaluated whether there were other factors that would reduce the overall consumer exposure to cadmium from Blacklip Rock oysters farmed in the NT.

Other control measures

In addition to the MLs for cadmium 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 sets out food safety and suitability requirements for seafood. Primary producers and processors of bivalve molluscs are required to have a food safety management system that documents the conditions on the areas from which the product may be harvested (including harvested

[3] The higher P90 dietary exposure estimate for the New Zealand adult population (90%) than the Australian population (55%) is because only one day of food consumption data are used to estimate dietary exposures for the New Zealand adult population. Where dietary exposures are able to be averaged using 2 days of food consumption data or more, the tails of the exposure distribution are narrowed resulting in lower P90 dietary exposure values, as demonstrated with the results for Australia.There are an insufficient number of oyster consumers in the 2002 New Zealand National Children's Nutrition Survey to calculate reliable exposure estimates for New Zealand children (aged 5-14 years). Information on the 2002 New Zealand National Children's Nutrition Survey is available online at: https://www.health.govt.nz/statistics-research/surveys/past-surveys/nutrition

for depuration or relaying), along with conditions on the water used for wet storage. A seafood business must comply with the conditions of the Australian Shellfish Quality Assurance Program (ASQAP) Operations Manual or conditions recognised by the Authority. The ASQAP Operations Manual specifies the requirements for chemical assessment in catchment areas where potential risks are identified, including heavy metal contamination.

Harvesting season

The harvesting season for Blacklip Rock oysters in the NT would be restricted to the dry season, limiting the availability of farmed Blacklip Rock oysters to a 6-month period annually (from May to October). The longer-term consumption scenario in the FSANZ risk assessment assumes Blacklip Rock oysters would be consumed throughout the year. Thus, FSANZ considers the worst-case exposure assessment based on longer term oyster consumption amounts to be conservative and likely an overestimate of dietary exposures to cadmium.

Market share

Further, the new ML would apply to Blacklip Rock oysters farmed in the NT only. As noted in the SD1, the expected market product for Blacklip Rock oysters farmed in the NT is whole, fresh oysters from hatchery-produced stock grown and harvested in the NT. The intended market is primarily domestic Australian markets, with a production target of 1 million Blacklip Rock oysters per aquaculture site each year. This is a comparatively small share of the Australian oyster market, equivalent to approximately 2% of national production. Any Blacklip Rock oysters farmed outside of the NT would still be required to meet the current Code ML of 2 mg/kg.

For the reasons outlined above, FSANZ determined that a new ML of 3 mg/kg for cadmium in Blacklip Rock oysters farmed in the NT does not pose a risk to public health and safety. Discussions with the applicant confirmed that this ML was reasonably achievable.

2.2.4 Delayed commencement of new ML for Blacklip Rock oysters farmed in the NT

In recognition of the cost to oyster growers if current stocks that contain cadmium over the ML of 3 mg/kg cannot be sold, FSANZ considered whether there was a risk to public health and safety if these oysters were consumed over a short period.

Current stocks of Blacklip Rock oysters farmed in the NT are a small proportion (less than 15%) of the production target post transition of aquaculture sites to commercial farms.

FSANZ's risk assessment found that cadmium exposure from all food sources would remain below the HBGV for Australian consumers under the exclusion of the species from the ML. Minor and transient exceedances in the HBGV for cadmium would not be associated with an increased risk of adverse health outcomes.

FSANZ considers it appropriate to delay the commencement of the new ML for cadmium in Blacklip Rock oysters farmed in the NT for a period of 24 months. A delayed commencement would enable current stocks of oysters to be sold without a risk to public health and safetyand provide time for the applicant to adjust growing practices and/or location to meet the new ML.

2.2.5 Schedule 19 amendment

In making its assessment, FSANZ had regard to the criteria prescribed in the FSANZ Act (see section 2.5) and is proposing 2 amendments to the Code.

Schedule 19 of the Code contains the ML for cadmium. If approved, the draft variation would amend Schedule 19 by amending the ML for cadmium to:

- exclude Blacklip Rock oysters (*Saccostrea spathulata*) farmed in the NT from the ML for cadmium in molluscs

- insert a new ML of 3 mg/kg for cadmium in Blacklip Rock oysters (*Saccostrea spathulata*) farmed in the NT, to commence after a period of 24 months from the date of gazettal.

2.3 Risk communication

2.3.1 Consultation

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

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

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

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade. There are not any relevant international standards and amending the Code to both exclude Blacklip Rock oysters farmed in the NT from the cadmium ML of 2 mg/kg for molluscs, and insert a new ML of 3 mg/kg for cadmium specifically for Blacklip Rock oysters farmed in the NT is unlikely to affect international trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

FSANZ had 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 (as per paragraph 29(2)(a) of the FSANZ Act).

FSANZ has assessed that a Regulation Impact Statement is not required for this application. This is because the proposed regulatory option of excluding Blacklip Rock oysters farmed in the NT from the cadmium ML of 2 mg/kg for molluscs, and inserting a new ML of 3 mg/kg for cadmium specifically for Blacklip Rock oysters farmed in the NT with a delayed

commencement has been assessed as safe and is considered to be minor in impact and deregulatory in nature.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the potential positives and negatives of moving away from the status quo by amending the Code.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. However, information received from the call for submissions may result in FSANZ arriving at a different outcome.

2.4.1.2 Costs and benefits of the proposed measure

Industry

The Australian oyster market in 2022/23 was 176 million oysters, predominantly Sydney Rock oysters and Pacific oysters, with New South Wales, South Australia and Tasmania accounting for 99% of production[4].

The applicant has noted that commercialisation of the NT Blacklip Rock oyster industry will take 5 to 10 years to reach estimated production targets of approximately 1 million oysters sold per farm per year. Across the 4 existing sites, NT production of 4 million oysters annually at current national production levels would account for around 2% of national production.

The proposed delayed commencement of the new ML for cadmium for Blacklip Rock oysters farmed in the NT would allow the NT oyster aquaculture industry to sell current stock and adjust their growing practices and/or location to meet the proposed new ML.

A small volume of Blacklip Rock oysters are produced from a single operator in Bowen, Queensland. The applicant notes growing interest in farming Blacklip Rock oysters in North Queensland, with production in Queensland expected to grow. The scope of this application does not extend to oysters farmed outside of the NT.

Blacklip Rock oyster production in other regions of Australia may be at a disadvantage, given the existing and lower cadmium ML (2 mg/kg) for molluscs will continue to apply to producers of Blacklip Rock oysters outside the NT. This disadvantage is expected to be minor, given the small volume of Blacklip Rock oysters understood to be sold outside the NT.

Consumers

FSANZ's risk assessment determined a delayed commencement of the new ML of 24 months does not present a risk to public health and safety.

The intended market for NT Blacklip Rock oysters is primarily domestic Australian markets. Consumers might benefit from additional choice in oyster variety.

Government

The NT government may encounter costs related to monitoring and enforcement. Given this

[4] https://www.oystersaustralia.org/production-nat.

application has been made by DAF NT this cost is unlikely to be unexpected.

Conclusion of costs and benefits consideration

FSANZ's assessment is that the direct and indirect benefits that would arise from inserting a new ML for cadmium for Blacklip Rock oysters farmed in the NT, and excluding these oysters from the ML for molluscs, is likely to outweigh the associated costs.

2.4.1.3 Other 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.

2.4.1.4 Any relevant New Zealand standards

The relevant standards in the Code apply in Australia and New Zealand. There are no relevant New Zealand only standards.

2.4.1.5 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

FSANZ has also considered the 3 objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ concluded that setting a new ML of 3 mg/kg for cadmium specifically for Blacklip Rock oysters farmed in the would present a lower public health and safety risk than a complete exclusion from any ML for cadmium for the species and is consistent with establishing a ML as low as reasonably achievable in the catchment area (as shown in section 2.1 of this report and the SD1).

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

There were no issues identified with this application relevant to this objective.

2.4.2.3 The prevention of misleading or deceptive conduct

There were no issues identified with this application relevant to this objective.

2.4.3 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 their application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application. The risk assessment is provided in SD1.

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

There are not any relevant international standards for cadmium in oysters. The Codex ML for cadmium in marine bivalve molluscs of 2 mg/kg excludes oysters. Harmonisation with Codex is preferred where possible. However, harmonisation with Codex is secondary to measures put in place to protect the public health and safety of Australians and New Zealanders.

Amendment to the Code to include a specific limit for Blacklip Rock oysters of 3 mg/kg would align with the Codex CCCF development of a Code of Practice for the prevention and reduction of cadmium contamination in foods, including farmed and wild-harvested seafood. This is because it provides a limit of cadmium in a food that may contain higher levels if no ML was in place.

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

The intended market for Blacklip Rock oysters farmed in the NT is primarily domestic Australian markets. Traditional Owners in the NT have driven the development of a Blacklip Rock oyster aquaculture industry in the region to support the demand for a market of locally sourced oysters. According to the application, excluding Blacklip Rock oysters farmed in the NT from the ML for cadmium in molluscs would likely result in the establishment of new aquaculture sites due to considerable interest from remote communities in Northern Australia.

If Blacklip Rock oysters farmed in the NT were exported, the product would need to comply with the ML for cadmium set by the country that the product is imported into.

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

No issues were identified for this application relevant to this objective.

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

There are no written policy guidelines relevant to this application.

3 Draft variation

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

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

Attachments

A. Draft variation to the Australia New Zealand Food Standards Code

B. Draft Explanatory Statement

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

Food Standards (Application A1329 – Exclusion of Blacklip Rock oysters farmed in the Northern Territory from the maximum level (ML) for cadmium in molluscs) 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 dates specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Name and position of Delegate]
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 A1329 – Exclusion of Blacklip Rock oysters farmed in the Northern Territory from the maximum level (ML) for cadmium in molluscs) 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

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. Clauses 1 to 3 and anything in this instrument not elsewhere covered by this table.	The day of gazettal of this instrument.	
2. Item [1] of the Schedule.	The day of gazettal of this instrument.	
3. Item [2] of the Schedule.	The day after the end of the period of 24 months beginning on the day this instrument is gazetted.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

Schedule

Schedule 19 Maximum levels of contaminants and natural toxicants

[1] Section S19—4 (table item dealing with "Cadmium", column headed "*Food*")

Omit:

"Molluscs (excluding dredge/bluff oysters and queen scallops)"

substitute:

Molluscs (excluding blacklip rock oysters (*Saccostrea spathulata*) farmed in the Northern Territory; dredge/bluff oysters; and queen scallops)

[2] Section S19—4 (table item dealing with "Cadmium", below entry for 'Amaranth, grain)

Insert:

Blacklip rock oysters (*Saccostrea spathulata*) farmed in the Northern Territory	3

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1329 – Exclusion of Blacklip Rock oysters farmed in the Northern Territory from the maximum level (ML) for cadmium in molluscs) 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 A1329 which seeks to amend the Code to exclude Blacklip Rock oysters from the maximum level for cadmium in molluscs. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation - the *Food Standards (Application A1329 – Exclusion of Blacklip Rock oysters from the maximum level (ML) for cadmium in molluscs) Variation* (the draft variation).

2. Variation will be a legislative instrument

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

If approved, this instrument would not be subject to the disallowance or 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 has prepared a draft a variation to amend the table to section S19—4 in Schedule 19 of the Code to:

- exclude Blacklip Rock oysters (*Saccostrea spathulata)* farmed in the Northern Territory (NT) from the cadmium ML for Molluscs (excluding dredge/buff oysters and queen scallops), to commence on gazettal, and

- include a new cadmium ML for Blacklip Rock oysters *(Saccostrea spathulate)* farmed in the NT of 3 mg/kg, to commence 24 months following gazettal.

4. Documents incorporated by reference

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

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1329 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a 6-week period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues will be available in an approval report published on the Authority's website at www.foodstandards.gov.au

A Regulation Impact Statement (RIS) has not been prepared for this application. This is because the proposed regulatory option of excluding Blacklip Rock oysters farmed in the NT from the cadmium ML of 2 mg/kg for molluscs, and inserting a new ML of 3 mg/kg for cadmium specifically for Blacklip Rock oysters farmed in the NT with a delayed commencement has been assessed as safe and is considered to be minor in impact and deregulatory in nature. Therefore, the Authority's assessment is that a RIS is not required for this application.

6. Statement of compatibility with human rights

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

7. Variation

References to 'variation' in this section are references to the draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1329 – Exclusion of Blacklip Rock oysters farmed in the Northern Territory from the maximum level (ML) for cadmium in molluscs) Variation*.

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

Subclause 3(1) of the variation provides a table setting out when each provision of the variation commences or is taken to have commenced. The table has three columns headed.

Column 1 is headed “Provisions”. Column 2 is headed “Commencement” and Column 3 is headed “Date/Details”.

The table provides that clauses 1 to 3 and anything in this instrument not elsewhere covered by this table; and item [1] of the Schedule will commence on the day of gazettal of this instrument. It also provides that item [2] of the Schedule will commence on the day after the end of the period of 24 months beginning on the day this instrument is gazetted.

There is a Note under the table that states that the table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

Subclause 3(2) of the variation provides that any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

7.1 Schedule to the variation

Items [1] and **[2]** of the Schedule would amend Schedule 19 of the Code.

Schedule 19 contains maximum levels of certain contaminants and natural toxicants for the purposes of subsection 1.4.1—3(1) of the Code. Subsection 1.4.1—3(1) of the Code requires that the level of a contaminant or natural toxicant listed in section S19—4 in a food listed in relation to that contaminant or toxicant must not be greater than the corresponding amount listed in that section. Section S19—4 sets out the MLs for metal contaminants.

Item [1] of the Schedule to the variation would amend the table to section S19—4 in Schedule 19 of the Code by omitting from the table item dealing with Cadmium ‘Molluscs (excluding dredge/bluff oysters and queen scallops)’ and substituting ‘Molluscs (excluding blacklip rock oysters (*Saccostrea spathulata*) farmed in the Northern Territory; dredge/bluff oysters; and queen scallops)’.

If approved, the effect of the proposed amendment in Item 1 would be to exclude Blacklip Rock oysters farmed in the NT from the ML for cadmium in molluscs of 2 mg/kg. In accordance with clause 3 of the variation, this amendment would commence on the date of gazettal of the instrument.

Item [2] of the Schedule to the variation would amend the table to section S19—4 by inserting a new food entry and associated ML in the table item dealing with Cadmium. Specifically, the amendment would insert ‘Blacklip rock oysters (*Saccostrea spathulata*) farmed in the Northern Territory’ in column 2, and ‘3’ in column 3.

If approved, the effect of the proposed amendment in Item 2 would be to introduce a new ML of 3 mg/kg for cadmium in Blacklip Rock oysters farmed in the NT. In accordance with clause 3 of the variation, this amendment would commence on the day after the end of the period of 24 months beginning on the date of gazettal of the instrument.