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**Submission to FSANZ on Application A1243:
Harmonisation of marine biotoxins standards for bivalve shellfish**

Oysters Tasmania represents Tasmania's oyster farmers, who employ around 350 Tasmanians and produce around \$40 million worth of food-safe and welfare-enhancing oysters each year.

This submission has been sent to FSANZ as the authority considering application A1243.

We request FSANZ to 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.

This submission has also been sent to Ministers Kearney, Watt, Palmer, and Barnett as members of the Food Ministers' Meeting.

If FSANZ approve the application we will request the Food Ministers to require a review of the approval. The grounds for this request would be that any approval of the application would not be

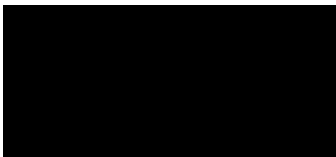


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consistent with the objectives of the legislation, would not protect public health and safety, and would place an unreasonable cost burden on industry.

Each of the grounds referred to above are explained below. The issue of consistency between domestic and international food standards is also addressed.

Yours sincerely,





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Costs in excess of benefits

Paragraph 29(2)(a) of the *Food Standards Australia New Zealand Act 1991* (the Act) requires FSANZ, in the assessment of an application, to have regard to whether costs that would arise from accepting the application outweigh the direct and indirect benefits to the community, Government or industry.

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.

These points are explained below.

Costs

Accepting the application would reduce the regulatory maximum levels (MLs) for diarrhetic shellfish toxin (DST) and paralytic shellfish toxin (PST).

The FSANZ analysis, drawing on data from 2012-2022, indicates that this would generate:

- 0.1 additional detections of prohibited levels of DST in Tasmania each year; and
- 9.2 additional detections of prohibited levels of PST in Tasmania each year.

It is reasonable to assume that each additional detection would give rise to an additional week of closure in one growing area. This indicates that accepting the application would generate 9.3 additional weeks of closures in a Tasmanian growing area each year.

- The frequency of tests in Tasmania has been less than one per week per growing area from 2012-2022, so it could be argued that a detection corresponds to more than a week of closure for a growing area. However, the receipt of a result in the range between the current and proposed MLs between 2012-2022 would tend to be associated with an above-average frequency of testing. So an assumption that an additional detection corresponds to an additional week of closure in one growing area is reasonable.

There are around 20 growing areas in Tasmania for biotoxin management purposes. With Tasmania producing around \$40 million of oysters each year, this translates to \$2 million worth of oysters on average per Tasmanian growing area.

9.3 additional weeks of closures each year represents 18 per cent of the year. It is reasonable to assume that such additional closures reduce the value of oyster sales by 18 per cent. 18 per cent of \$2 million (the average value of a Tasmanian growing area's annual production) is \$350,000.

- Assuming a one-to-one relationship between closures and sales revenue is reasonable, because oyster farming is akin to the operation of a full conveyor belt and a closure is akin to a malfunction of that full conveyor belt.
 - Once oysters reach maturity they are sold and the vacated space is filled with spat.



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- A closure means that the grower has to renege on a promise to sell. This reduces the reliability of the grower, reducing the price that the grower can attract over the long term. It also means that the buyer, who wants oysters now, either decides to not buy oysters, or to obtain oysters from elsewhere. As such, it is wrong to assume that the buyer will simply agree to purchase the stock on the same terms once the farm is reopened. Another buyer may agree to buy the stock once the farm is reopened, but at an inferior price, and receiving money later than planned is costly given the time value of money. Moreover, the stock may have spawned in the interim, or otherwise become unsuitable for sale, so no sale may arise.
- A closure also means that the grower cannot restock, as the unsold mature oysters continue to take up finite space and nutrients. This delays future sales, possibly by more than the duration of the closure given that spat and juvenile stock are not always available and the growth conditions are not even throughout the year.

This \$350,000 cost estimate is conservative.

- The 'additional detections' would tend to occur in Tasmanian growing areas with annual production above the \$2 million average, such as various East Coast growing areas.
- \$350,000 of oysters at farm gate prices amounts to a considerably greater value for consumers at retail prices.
- \$350,000 of lost income for owners, employees, and suppliers means less spending by those owners, employees, and suppliers, and so reduces the incomes of others.
- Additional closures can tip a viable business into unviability, leading to a larger-than-estimated reduction in production, consumption, employment, and incomes.
- Costs from states other than Tasmania are not included.

Some of the additional 9.3 weeks of closures in a Tasmanian growing area per year will represent extensions of existing closures. This will occur where the receipt of test results in the range between the current and proposed MLs precedes or follows the receipt of test results beyond the current MLs. Every extension of a closure increases the risks and costs of closures as outlined above.

The remainder of the additional weeks of closures will be stand-alone closures, arising when the receipt of test results in the range between current and proposed MLs does not precede or follow the receipt of test results beyond the current MLs. Such instances are a significant proportion of all instances where the receipt of test results in the range between the current and proposed MLs. Additional closures bring the fixed costs associated with reneging on promises to customers and suppliers of spat and juvenile stock.

Oysters Tasmania understands that there may be some dispute about FSANZ's calculations of 'additional detections'. If additional Tasmanian PST detections were half of what FSANZ has calculated, then we would conservatively estimate that accepting the application would reduce annual Tasmanian oyster sales by \$175,000.



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Benefits

Accepting the application would generate negligible benefits for the community, Government, or industry.

Public health and safety

Accepting the application would generate no public health and safety benefit.

The paramount objective of FSANZ in reviewing applications is the protection of public health and safety. FSANZ's own work indicates that accepting the application would not further this objective.

FSANZ's risk analysis in Supporting Document 1 states that "After reviewing the best available evidence, FSANZ concludes the current risk management strategies for commercially produced bivalve molluscs are effective measures for protecting public health and safety from PST and DST."

FSANZ's risk analysis states that, for the entire period under which the Australia and New Zealand have had their respective arrangements in place, Australian has had no confirmed or suspected case of illness, New Zealand has had one suspected case of illness, and this may represent a failure of risk management in New Zealand. This indicates that:

1. there is no evidence that Australia moving to the New Zealand approach would protect public health and safety;
2. there is evidence that such a move would not protect public health and safety; and
3. there is even evidence, albeit limited, that such a move could undermine public health and safety.

This third point relates to the suspected case of illness and possible failure of risk management in New Zealand in 2007 when a person was hospitalised and treated for paralytic shellfish poisoning after consumption of a commercially purchased oyster. New Zealand's adherence to the MLs proposed in the application may have contributed to this food safety incident. Such adherence may have created a false confidence that gave rise to a laxity in other aspects of food safety management, such as testing frequency, testing methodology, sample sizes, growing area sizes, grower cooperation, and grower risk aversion.

This all indicates that accepting the application should not be thought of as generating a consumer benefit of reduced risk of food poisoning, or generating a resulting increase in trust and demand. By the same token, accepting the application should not be thought of as generating an industry benefit from a reduced risk of food poisoning or a resulting increase in demand. And accepting the application should not be thought of as generating a government benefit from a reduced risk of food poisoning or a resulting reduction in health expenditure.

A further reason why accepting the application would not generate public health and safety benefits comes from the fact that oysters are a rich source of protein, omega 3, iron, and magnesium. Accepting the application would reduce oyster consumption and hence reduce this public health benefit.



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In determining what is best for public health and safety, the evidence from Australian experience is more direct, data-rich, and up-to-date than the position of Codex.

- The evidence from Australian experience is more direct because we have essentially conducted an experiment on Australians to determine the public health and safety of Australians.
- The evidence from Australian experience is more data-rich because:
 - As shown FSANZ's estimates of 'additional detections', between 2012 and 2022 there were dozens of instances where bivalves from a Tasmanian growing area, with PST between the proposed and current MLs, could have been, and probably were, legally harvested and sold; and
 - in each instance tens of thousands of oysters would have been consumed by thousands of Australians.
- The evidence from Australian experience is more up-to-date because, while the Australian position was struck in 1999 and the Codex position was struck in 2008, the Australian position has been and continues to be tested, so is essentially a live and current experiment.

The Australian experience generates unprecedented, continuous, census, data. In rejecting the application, FSANZ should recommend Codex investigation of the Australian experience with a view to potential updating of the Codex position. Were this investigation of such rich and important data not to occur, it would be a travesty of science and human health.

Trade

Accepting the application would generate no trade benefit.

Imagined or theoretical trade-related problems with the status quo have no basis in reality. No current nor prospective export destination, no current nor prospective exporter, for any seafood product, and no current or prospective importer to Australia, has indicated that the status quo in Australia generates barriers or costs for exporting or importing. None has raised any concerns whatsoever about the status quo.

In assessing whether accepting the application would generate a trade benefit, FSANZ should place considerable weight on submissions from industry, who would be the beneficiaries of any such trade benefit. This submission, lodged by Oysters Tasmania on behalf of Tasmanian oyster growers, contends that accepting the application would generate no trade benefit, and it is expected that no industry submission will contain a conflicting contention. If this is the case, there would be no basis for FSANZ to hold a view that accepting the application would generate a trade benefit.

Note that the stated purpose of the application by SafeFish on behalf of the Australian Shellfish Quality Assurance Advisory Committee (ASQAAC) is for FSANZ to review the MLs. Oysters Tasmania understands that 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. Moreover, the application does not argue that accepting the application would generate a trade benefit, and does not argue that any industry participant is of such a view.



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Simplified enforcement

Accepting the application would generate negligible benefit for government via simplified enforcement.

The federal government lists oyster growing areas from which exports are approved, and notes that such areas must be 'open'. Any routine work arising from differences in MLs between countries would be negligible. It is a matter for exporters to ensure that their product meets standards in the importing country.

Consistency between domestic and international food standards

Oysters Tasmania's argument that accepting the application would generate significant costs and no benefits begs the question of why the application was lodged.

Two reasons seem likely.

Firstly, regulators and researchers can put excessive weight on the 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 the 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, as outlined above. As such, in this circumstance FSANZ should not consider that moving a domestic standard to align with an international standard would be a benefit. Rather, FSANZ should defend a proven domestic rule and pursue its interest in harmonisation by encouraging Codex to investigate and possibly adopt the Australian rule.

Objectives of FSANZ's consideration of applications

The paramount objective of FSANZ in reviewing applications is the protection of public health and safety. This issue is discussed above.

FSANZ also has two other objectives when reviewing applications. FSANZ is required to provide adequate information relating to food to enable consumers to make informed choices, and to prevent misleading or deceptive conduct.

Accepting the proposal will not provide information to enable consumers to make informed choices. Rather, accepting the proposal would reduce the availability of bivalves and hence reduce the choices available to consumers.

Accepting the proposal will not prevent misleading or deceptive conduct. Rather, it would imply that current arrangements were inappropriate, which would in itself be misleading.



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The need for standards to be based on risk analysis using the best available scientific evidence

In reviewing applications FSANZ must have regard to the need for standards to be based on risk analysis using the best available scientific evidence.

FSANZ has undertaken a food safety risk analysis using the best available scientific evidence and has concluded that “After reviewing the best available evidence, FSANZ concludes the current risk management strategies for commercially produced bivalve molluscs are effective measures for protecting public health and safety from PST and DST.” 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 that those costs would be significant. This reinforces that the scientific, evidence-based approach should be to reject the application.

The desirability of an efficient and internationally competitive food industry

In reviewing applications FSANZ must have regard to the 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.

Accepting the application would also reduce the international competitiveness of the Australian food industry.

- Accepting the application would 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 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.