



20 February 2023

Ms Glenys Beauchamp

Chair of Food Standards Australia New Zealand Board

By only email: secretariat@foodregulation.gov.au

Dear Ms Beauchamp and FSANZ Board members,

RE: Updating PFAS TDIs to reduce risk exposures for the Australian population

I am writing to you and the Board seeking clarification on matters related to human health risks from PFAS contaminated food, the conclusions set by the *27th Australian Total Diet Study* and the most recent proposals and regulatory changes in the European Union to set PFAS common limit values for meat, fish and eggs.

As a brief overview, I am an informed community advocate and have a blog website, www.communityovermining.org focusing on PFAS with pages relevant to *Food Safety*¹ and *PFAS contaminated Livestock*² providing evidence how FSANZ's Tolerable Daily Intakes (TDI) are being abused. The information provided to the community via the most recent *27th Australian Total Diet Study*³ (ATDS) is outdated and a poor representative snapshot in time. The study cannot clearly establish PFAS dietary levels are safe to protect both the general populations particularly those in highly contaminated areas. Additionally, the Food Safety Code does not address producers and buyers knowingly selling PFAS contaminated livestock and produce for human consumption.

As you can see by my webpage, other peak industry associations, purporting to be independent, are defaulting back to FSANZ TDIs to justify their own position status when challenged about the risk assessments and safety of PFAS contaminated food sold to both domestic and export markets for human consumption. They are using FSANZ's non-regulatory trigger points⁴ to identify whether further investigation may be required if PFAS is detected in analysed foods. The problem is the food is not analysed. With the focus on just three PFAS compounds, PFOA, PFOS and PFHxS this is also having far-reaching consequences for both our environment and biodiversity.

The Federal Food Safety Code,⁵ does not permit foreign chemical agents in food unless they are legislated. PFAS (all compounds) are not legislated therefore the background level should be zero. This means it is unlawful in every state and territory under state-based Food Acts to knowingly sell PFAS contaminated foods for human consumption. The *criteria for the establishment of maximum levels in food*⁶ are also extremely outdated. As PFAS should not be in food, whatever FSANZ apply is based on outdated, flawed reports and criteria.

These appear to be in contradiction to the TDIs and trigger points as non-regulatory measures because FSANZ's assessment has determined a small number of PFAS compounds are safe at a certain end point which FSANZ cannot and has not proved. These are potentially culpable assertions.

- Is FSANZ prepared to consider advising the Minister[s] to reassess some/all PFAS compounds as hazardous in line with five EU national authorities⁷ and United States EPA proposal to designate PFOA and PFOS as hazardous substances?⁸

Our Australian TDIs are used as 'safe end points' for risk assessments but how safe are they when our contemporaries have declared they are not? I put the question to an online Victorian consultation forum about the draft NEMP 3 being outdated based on the new EU PFAS common limit values and if they were liaising with FSANZ. I was told '*FSANZ were involved in the process of developing the Draft NEMP 3, so the NEMP 3 takes guidance and criteria from FSANZ to inform the risk assessments which is the standard we have in Australia.*'

This means all other relevant authorities and industry sectors can declare this value, although not legally binding, as the set parameters for modelling what is safe and appropriate for risk assessments. NEMP 3 will allow PFAS contaminated sewerage sludge as biosolids applied to agricultural land to produce food for human consumption and fodder for livestock because FSANZ says it's safe.

Do the Board now consider:

- their previous advice⁹ for health-based guidance values (HBGVs) for PFOS, PFOA and PFHxS are safe?
- drafting a new food regulatory measure for the Minister[s] considerations as the most appropriate risk management response?
- If not, why?

While the TDIs are based on guidelines that are conveniently not legally binding, the *Food Standards Australia New Zealand Act 1991* is. The *State of Knowledge* on what ought to be known can clearly be established.

But for FSANZ, as a Commonwealth entity with statutory obligations, this is an entirely different story and could leave FSANZ Board members legally exposed having relevance with **section 9**, *Operation of Act*.¹⁰

I note the Board's endorsement of the three **section 18**, 'core' objectives¹¹ for the development of food standards but how are the Board applying them?

(1) *The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:*

- (a) *the protection of public health and safety; and*
- (b) *the provision of adequate information relating to food to enable consumers to make informed choices; and*
- (c) *the prevention of misleading or deceptive conduct.*

Section 3, *Objects of the Act*¹² is relevant for consumer confidence in the quality and safety of food produced, processed and sold for human consumption. Our communities need to be able to trust Commonwealth entities tasked with fulfilling policy obligation to protect public health and that of the environment. Maintaining TDIs are safe through misleading messaging is deceptive conduct. But ongoing advice¹³ from the Australian Government states the following because of the TDIs and Health-Based Guidelines Values set by FSANZ.

PFAS exposure has not been shown to cause disease in humans. However, it has been associated with mildly elevated levels of cholesterol, effects on kidney function and effects on the levels of some hormones. The differences reported for these associations have generally been small and unlikely to be important to health outcomes.

On this point, I specifically challenge the FSANZ Board on the following sections of the *Finance, Audit and Risk Management Committee Charter*,¹⁴

2. Objective *The objective of the Committee is to provide independent assurance and advice to the Board, including on the appropriateness of FSANZ's financial and performance reporting, system of risk oversight and management, compliance, governance framework, and systems of internal control.*

7.1.3 Systems of risk oversight and management; and

7.1.4 System of internal control

- *Internal control framework*
- *Legislative and policy compliance*
- *Business continuity management*
- *Delegations*
- *Ethical and lawful conduct*

as obligated and in compliance with Section 17 of the Public Governance, Performance and Accountability Rule 2014,¹⁵ section 45 and section 16 of the Performance, Governance and Accountability Act 2013¹⁶ (PGPA Act).

SECT 16 - Duty to establish and maintain systems relating to risk and control¹⁷

The accountable authority of a Commonwealth entity must establish and maintain:

- (a) *an appropriate system of risk oversight and management for the entity;*
- and
- (b) *an appropriate system of internal control for the entity;*

Victoria's Chief Environmental Scientist has stated that while long-chain PFAS are reducing in pooled blood of the general population, short-chain PFAS are increasing. However, this is not relevant for heavily contaminated areas as they are still exposed to legacy long-chain PFAS selling highly contaminated livestock and produce into the market because FSANZ have decreed the set levels are safe. Conveniently, no one is analysing PFAS levels in food from contaminated areas.

It is not happening because risk assessments based on FSANZ trigger levels ensure polluters can determine human health risk as low. No data so no problem.

- Do FSANZ continue to support the following comment –

'In Australia, exposure of the general population to perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) is low and declining, and there is no consistent evidence that this exposure has been harmful to human health.'

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PFAS research is dependent on pooled blood testing of the general population - what were PFAS levels in the past, present and how PFAS blood levels will change in the future. This highlights two very valid points that FSANZ are both misleading our communities and/or ignoring.

1. Long chain PFAS is reducing in the general population because of regulation¹⁹ which highlights political will and common-sense actions by other Statutory bodies can make a difference in reducing PFAS exposures in the general population to protect public health.
2. If short-chain PFAS compounds are increasing in pooled blood samples in the general population this would indicate there is greater exposure to PFAS from both dietary and different environmental media that FSANZ are not capturing in their surveys to provide evidence for their TDIs.

The 27th ATDS by FSANZ references their European Union equivalent, European Food Safety Authority (EFSA) 2020 journal²⁰ but selectively used data not including the assessment by EFSA to reduce the EU's Tolerable Weekly Intake (TWI) to 4.4 ng/kgbw/week for the sum of 4 PFAS compounds together FOR THE GENERAL POPULATION.

Converting TWI to TDI is 0.63ng/kgbw/day for all 4 together - PFOA, PFNA, PFHxS, and PFOS in food.

This is much lower than Australia's TDI of 20ng/kgbw/day for the sum of 2, PFOS/PFHxS plus 160ng/kgbw/day for PFOA.

- Is the Board now aware that the EU's new TWI for PFAS came into effect this year (January 2023) which will eventually have an impact on export trade of livestock and food produce?
- The Food Safety Code establishes that a foreign chemical agent should not be in food, therefore the background level for PFAS should be zero. Will FSANZ change their position and provide advice to Minister[s] that Maximum Levels (MLs) should be set now the EU has set MLs for PFAS.²¹

The food consumption data that was used²² from city and regional retail outlets is not even credible including food types chosen from where around Australia?

Similarly, is there more updated data than referenced²³ (ATDS section 4.3.4) with the 2011-12 Australian National Nutrition and Physical Activity Survey (NNPAS).²⁴

Are our diets, nutrition, physical activities and behaviours the same as a decade ago? Along with using mean data from 90th percentile dietary exposures, this survey was already outdated before the predetermined outcomes were assessed.

Table 3: Estimated mean and 90th percentile (P90) dietary exposures to PFOS for Australian consumers aged 2 years and above

Statistic	Estimated consumer dietary exposure to PFOS* (ng/kg bw/day)		
	Lower Bound	Middle Bound	Upper Bound
Mean	0.011	0.83	1.7
P90	0.032	1.3	2.6

Note: The ratio of consumers to respondents for PFOS is 77% at LB, and 100% at MB and UB.

* Based on the average of two days of consumption data from the 2011-12 NNPAS.

Australian consumption of PFOS contaminated food for both middle and upper bound ranges would be above EUs new regulatory TDIs which includes the sum of 4 PFAS compounds so the risk characterisation conclusions *that there are no public health and safety concerns for Australian consumers from dietary exposures to PFAS* can and will be challenged.

- Will FSANZ manage PFAS risk exposures from the general food supply on the same business-as-usual model claiming the levels of PFAS in the general Australian food supply are as low as reasonably achievable and acceptable from a public health and safety perspective?

Risk assessments based on TDIs, and trigger levels are being abused and need updating for hazard characterisation for all human health risks based on current scientific literature²⁵ rather than selective studies not only for PFAS in foods but for drinking water as well.²⁶

- How can FSANZ prove their trigger values are now safe when other countries are proposing PFAS be declared a hazardous substance, EU have significantly lowered their TDIs and US EPA are proposing drinking water guidelines to levels, yet unable to be detected by existing technology?

Additionally, I have read all meeting communiqués from the Food Ministers' Meetings²⁷ with no mention of PFAS. This is particularly relevant as obesity is associated with PFAS²⁸ and is one of the Food Ministers priorities²⁹ of the Food Regulation System:

- *Supporting the public health objectives to reduce chronic disease related to overweight and obesity.*

Also, there is no reason why this Minister's forum cannot develop informed labelling of potential additives of PFAS giving consumers the right to know what is in the food they purchase. Being proactive on labelling declarations for PFAS ensures producers and manufacturers are more accountable for foreign chemicals that should not be in food.

These PFAS residues potentially tainting food could be significant as the NEMP 3 noted manufacturing of food, food packaging and food preparation products as activities associated with PFAS contamination.

These include baking paper, aluminium foil, fast food wrappers, non-stick equipment including food processing facility surfaces, pipes, tanks and valves, and firefighting especially at facilities where bulk oil is used. Lack of any insights by FSANZ on fluorinated containers and wrappers leaching PFAS into food is irresponsible as the packaging issue is unchecked in Australia. Food Safety includes removing residues of PFAS and other PoPs from consumed food. The Ministerial Food Forum now needs to collaborate with ALL our international traders on the Maximum Levels for consistent international agriculture trade.

In conclusion, I believe the following has relevance for the FSANZ Board to consider regarding their due diligence.

Directors Duties - Hutley SC/Davis [the Hutley Opinion] advice on Climate Change litigation,³⁰ could potentially apply³¹ to FSANZ directors past, present and future, who may also find themselves legally liable for failing to adopt 'best practice' international TDIs. The Hutley Opinion warned that climate change being a foreseeable risk imposed a duty of care and due diligence obligation on directors under the Corporations Act 2001, s180.³² Their opinion was that "company directors who fail to consider climate change risks now could be found liable for breaching their duty of care and due diligence obligation in the future. [And that] "a negligence allegation against a director who had ignored climate risks was likely to be only a matter of time."³³

Importantly, the Hutley Opinion was adopted by the Victorian Government entitled "Guidance to Managing Climate Risk - Guidance for Board Members and Executives of Water Corporations and Catchment Authorities, June 2019."³⁴

Likewise, were FSANZ to ignore "best practice' international standards, it could find itself the subject of negligence litigation for having ignored foreseeable risks when setting its TDIs.

Class actions are increasing and defending them increasingly expensive. Inevitably, decisions made by FSANZ in relation to the safety of TDIs, based on your reports, will be used to show negligence and failure to exercise due diligence and duty of care. FSANZ witnesses will be called and, if FSANZ loses, the financial penalties could be substantial. Furthermore, the public scandal that would surround such a court case would also present significant reputational risk to FSANZ and even the Government.

I await your response with interest.

Your sincerely

Tracey Anton
Community Over Mining

References

¹ <https://communityovermining.org/pfas-food-safety.html>

² <https://communityovermining.org/pfas-livestock.html>

³ <https://www.foodstandards.gov.au/publications/Documents/27th%20ATDS%20report.pdf>

⁴ 'Trigger points are the maximum concentration level of these chemicals that could be present in individual foods or food groups so even high consumers of these foods would not exceed the relevant TDI. Trigger points were proposed for a range of food commodities which may be sourced on or near potentially contaminated sites including fish and seafood, animal products, fruit and vegetables. They may be used by authorities analysing PFAS in food to indicate when further investigation may be required (FSANZ, 2017c).'

<https://www.foodstandards.gov.au/publications/Documents/27th%20ATDS%20report.pdf>

⁵ Victorian FOOD ACT 1994 - SECT 4E - Meaning of *unsuitable food*:

(1) For the purposes of *this Act*, food is *unsuitable* if it is food that--

(d) contains a biological or chemical agent, or other matter or *substance*, that is foreign to the nature of the food.

(2) However, food is not *unsuitable* for the purposes of *this Act* merely because--

(d) it contains any matter or substance that is permitted by the Food Standards Code.

⁶ Contaminants in food are substances that serve no technological purpose and whose presence may lead to adverse health effects. Therefore, robust risk assessments and management options are used to reduce any risk from a contaminant to 'As Low As Reasonable Achievable' (ALARA) (ANZFA; 1998a; Abbott et al, 2003)).

... Proposed MLs will be consistent with Codex levels, 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 (NFA 1999).

<https://www.health.gov.au/sites/default/files/documents/2022/07/perfluorinated-chemicals-in-food-criteria-for-the-establishment-of-maximum-levels-in-food.pdf>

⁷ <https://echa.europa.eu/-/echa-publishes-pfas-restriction-proposal>

⁸ Proposed Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances <https://www.epa.gov/superfund/proposed-designation-perfluorooctanoic-acid-pfoa-and-perfluorooctanesulfonic-acid-pfos>

⁹ <https://www.foodstandards.gov.au/consumer/chemicals/Pages/Perfluorinated-compounds.aspx>

¹⁰ **Section 9 - Operation of Act**

(1) Without prejudice to its effect apart from this section, this Act has effect for any or all of the following purposes:

(a) for purposes connected with fixing:

(i) the standard of food sold by corporations; or

(ii) standards in relation to activities undertaken by corporations in respect of food before, or in connection with, its sale, where, in the case of trading corporations, those activities are undertaken for the purpose of the trading activities of the corporations;

(b) for the purpose of ensuring, to the extent that the Constitution permits, that trade and commerce in food:

(i) between Australia and places outside Australia; or

(ii) among the States;

is carried on in an efficient and profitable manner;

(c) for purposes connected with the regulation of food and food standards in the Territories;

(d) for purposes connected with controlling the standards of all food supplied to the Commonwealth, its authorities and its instrumentalities;

(e) for purposes connected with the fixing of weights and measures in respect of food...

http://classic.austlii.edu.au/au/legis/cth/consol_act/fsanza1991336/s9.html

¹¹ **Section 18 - Objectives of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures:**

(1) The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:

- (a) the protection of public health and safety; and
- (b) the provision of adequate information relating to food to enable consumers to make informed choices; and
- (c) the prevention of misleading or deceptive conduct.

(2) In developing or reviewing food regulatory measures and variations of food regulatory measures, the Authority must also have regard to the following:

- (a) the need for standards to be based on risk analysis using the best available scientific evidence;
- (b) the promotion of consistency between domestic and international food standards;
- (c) the desirability of an efficient and internationally competitive food industry;
- (d) the promotion of fair trading in food;
- (e) any written policy guidelines formulated by the Forum on Food Regulation for the purposes of this paragraph and notified to the Authority...

http://classic.austlii.edu.au/au/legis/cth/consol_act/fsanza1991336/s18.html

¹² **Section 3- Object of Act**

The object of this Act is to ensure a high standard of public health protection throughout Australia and New Zealand by means of the establishment and operation of a joint body to be known as Food Standards Australia New Zealand to achieve the following goals:

- (a) a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand;
- (b) an effective, transparent and accountable regulatory framework within which the food industry can work efficiently;
- (c) the provision of adequate information relating to food to enable consumers to make informed choices;
- (d) the establishment of common rules for both countries and the promotion of consistency between domestic and international food regulatory measures without reducing the safeguards applying to public health and consumer protection.

http://classic.austlii.edu.au/au/legis/cth/consol_act/fsanza1991336/s3.html

¹³ <https://www.health.gov.au/topics/environmental-health/what-were-doing/environmental-toxins-and-contaminants>

¹⁴ <https://www.foodstandards.gov.au/about/board/Documents/FARMC%20Charter.pdf>

¹⁵ <https://www.legislation.gov.au/Details/F2014L00911>

¹⁶ http://www6.austlii.edu.au/cgi-bin/viewdoc/au/legis/cth/consol_act/pgpaaa2013432/s45.html

¹⁷ **Section 16 - Matters that may be included in standards and variations of standards**

(1) Standards, and variations of standards, developed by the Authority may relate to any of the following:

- (a) the composition of food, including:
 - (i) the maximum amounts of contaminants or residues that may be present in the food; and
 - (ia) the maximum or minimum amounts of additives that must or may be present in the food; and
 - (ii) its microbiological status and safety; and
 - (iii) the method of sampling and testing the food to determine its composition;
- (b) the production of food;
- (c) the handling of food;
 - (ca) the prohibition of the sale of food:
 - (i) either in all circumstances or in specified circumstances; and
 - (ii) either unconditionally or subject to specified conditions;
- (d) any information about food including labelling, promotion and advertising;

...http://classic.austlii.edu.au/au/legis/cth/consol_act/pgpaaa2013432/s16.html

¹⁸ <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/pfas>

¹⁹ Study finds evidence of chemicals in Australians dating back to 1975

<https://www.uwa.edu.au/news/Article/2022/November/Study-finds-evidence-of-chemicals-in-Australians-dating-back-to-1975>

²⁰ <https://www.efsa.europa.eu/en/efsajournal/pub/6223>

²¹ 1.3.2 Regulation of PFAS in foods

For Australian and New Zealand foods, FSANZ sets MLs for specific contaminants in Schedule 19 of Standard 1.4.1 of the Code (FSANZ, 2021c). MLs are only established for contaminants that present a significant risk to public health and safety and in foods that are major contributors to total dietary exposure to those chemicals. MLs are set at levels which are as low as reasonably achievable while reducing dietary exposure to chemicals of public health concern.

There are currently no MLs for PFAS in foods in the Code or overseas regulations. In the absence of MLs, general Code provisions apply including that food must be safe and suitable and levels of PFAS should be kept as low as reasonably achievable.

²² <https://www.foodstandards.gov.au/publications/Documents/Appendix%203%20-%20Summary%20of%20PFOS%20analytical%20results%20for%2027th%20ATDS%20samples.pdf>

²³ Food consumption data used in the calculation of PFOS dietary exposures for Australians aged 2 years and above are from the 2011-12 Australian National Nutrition and Physical Activity Survey (NNPAS) component of the 2011-13 Australian Health Survey (ABS, 2014). Only those respondents with two days of food consumption data were considered in this assessment (n=7,735).

²⁴ <https://www.abs.gov.au/statistics/microdata-tablebuilder/available-microdata-tablebuilder/australian-health-survey-nutrition-and-physical-activity>

²⁵ FSANZ continues to carefully monitor the developing scientific literature on the potential health effects of PFAS.

²⁶ The recommended TDIs were used by the National Health and Medical Research Council (NHMRC) to establish health-related guideline values for drinking water. These are established for PFOA and the sum of PFOS and PFHxS at 0.56 µg/L and 0.07 µg/L respectively. While not mandatory standards, they can be used by regulators and authorities to determine the quality of Australian drinking water. They indicate a concentration "that does not result in any significant risk to the health of the consumer over a lifetime of consumption" (NHMRC, 2019).

²⁷ <https://foodregulation.gov.au/internet/fr/publishing.nsf/content/forum-communicue-2022-November>

²⁸ Certain PFAS were positively associated with greater body size and body fat, and higher rates of change over time. PFAS may be an underappreciated contributing factor to obesity risk.

<https://www.nature.com/articles/s41366-021-00848-9>

²⁹ Supporting the public health objectives to reduce chronic disease related to overweight and obesity.

³⁰ Centre for Policy Development, Noel Hutley and Mr Sebastian Hartford Davis, Supplementary Memorandum of Opinion, 26 March 2019. https://cpd.org.au/wp-content/uploads/2019/03/Noel-Hutley-SC-and-Sebastian-Hartford-Davis-Opinion-2019-and-2016_pdf.pdf

³¹ <https://cpd.org.au/wp-content/uploads/2019/02/CPD-Discussion-Paper-Public-authority-directors-duties-and-climate-change.pdf>

³² http://classic.austlii.edu.au/au/legis/cth/consol_act/ca2001172/s180.html

³³ No 2, p2/34 - THE CENTRE FOR POLICY DEVELOPMENT "Climate Change and Directors' Duties" SUPPLEMENTARY MEMORANDUM OF OPINION 26 March 2019

In the 2016 Memorandum, we expressed opinions that, as matter of Australian law, company directors can, and in some cases should be considering the impact on their business of climate change risks, to the extent they intersect with the interests of the firm. Climate-related risks (including physical, transition and litigation risks) represent foreseeable risks of harm to Australian businesses. This requires prudent directors to take positive steps: to inform themselves, disclose the risks as part of financial reporting frameworks, and take such steps as they may see fit to take, with due regard to matters such as the gravity of the harm, the probability of the risk, and the burden and practicality of available steps in mitigation. We indicated that, in our view, company directors who fail to consider climate change risks now could be found liable for breaching their duty of care and diligence in the future. Indeed, we considered then (as now) that a negligence allegation against a director who had ignored climate risks was likely to be only a matter of time.

³⁴ https://www.delwp.vic.gov.au/_data/assets/pdf_file/0023/428054/ISBN-Managing-Climate-Change-Risk-Guidance-Water-Entities-20190702-02-.pdf