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Office of the Chief Executive Officer

Ms Tracey Anton
Community Over Mining
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Dear Ms Anton

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

Thank you for your letter of 20 February 2023 to the Food Standards Australia New Zealand (FSANZ) Board and its Chair, Ms Glenys Beauchamp, regarding Tolerable Daily Intakes (TDIs) for per- and poly-fluoroalkyl substances (PFAS). Ms Beauchamp has asked me to reply on behalf of the Board.

FSANZ is an independent statutory agency established by the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) operating within the joint Australian and New Zealand food regulatory system. The primary objective of the FSANZ Act is to contribute to the protection of public health by ensuring a safe food supply.

Working within the joint food regulatory system and as part of a whole-of-government response to PFAS, FSANZ provided scientific advice including developing appropriate Australian health-based guidance values (TDIs) for certain PFAS to the Department of Health and Aged Care in 2016. FSANZ is monitoring the developing science on the health effects of PFAS, including overseas and international reports and remains confident that these TDIs are protective of public health.

As you noted, the 27<sup>th</sup> Australian Total Diet Study published in December 2021 surveyed PFAS in the Australian food supply. The survey remains the most comprehensive study of PFAS in retail food conducted to date. It provides a high level of confidence current levels of PFAS in the general Australian food supply are very low and present no public health and safety concerns relating to estimated dietary exposure for the general Australian population.

It is important to note that most consumers in the general population purchase products from the supermarket and other retail outlets that are sourced from a wide range of producers and manufacturers, consistent with FSANZ's survey. This means that most people are not expected to regularly consume produce from contaminated sites. For the general population, occasionally ingesting produce with low levels of PFAS is not considered to be a public health concern.

Site specific investigation and management actions are the responsibility of local, state, territory or nominated Commonwealth authorities. FSANZ is aware that, dependent on the site under investigation, responsible authorities have issued a range of dietary advice relevant to managing dietary exposure to PFAS. Advice has included, for example, encouraging people to consume produce from multiple sources, limiting consumption of fish sourced from specific areas and, in some cases, limiting consumption of home-grown or farmed produce from these areas.

FSANZ considers there is currently no need to consider establishing food regulatory measures such as maximum levels (MLs) for PFAS in the Australia New Zealand Food Standards Code. MLs are only proposed for contaminants that represent a significant public health and safety concern, and for those foods which are a major contributor to dietary exposure.

FSANZ continues to monitor the emerging science around PFAS, including the advice of other international regulators. We are open to revisiting our conclusions on the basis of any new evidence that indicates that levels of PFAS in the Australian food supply are of public health and safety concern. Additional information on the issues that you have raised relevant to PFAS in food and FSANZ's functions is included in the attachment to this letter.

I trust this information is of assistance.

Yours sincerely

**Dr Sandra Cuthbert** 

2 March 2023

**Encl 1 Attachment** 

**Attachment 1** 

## Australian Tolerable Daily Intakes for PFAS

Food Standards Australia New Zealand (FSANZ) (2017) developed health-based guidance values (HBGVs) in the form of tolerable daily intakes (TDIs) for PFAS. TDIs represent a level of daily oral exposure over a lifetime that is considered to be without significant health risk for humans.

FSANZ is aware that several overseas authorities, including the European Food Safety Authority (EFSA) and the United States Environmental Protection Authority (US EPA) have established HBGVs for PFAS, which are lower than the FSANZ TDIs.

Both EFSA and the US EPA's HBGVs for PFAS are based on human epidemiology studies reporting a decreased response of the immune system to vaccination (i.e. decreased antibody production following vaccination).

FSANZ continues to monitor the developing science on the health effects of PFAS, including information in the reports of other international agencies or bodies. FSANZ updated its review of the immunomodulation potential of PFAS as part of the 27<sup>th</sup> ATDS. FSANZ's review was peer reviewed by an external expert in epidemiology and published in December 2021. The review evaluated the relationship between PFAS and immune response to vaccinations, susceptibility to infections, and hypersensitivity responses, including allergy.

Our conclusions were that there are a number of substantial uncertainties and limitations in the available data. Although some statistical associations were found, there is a lack of consistent evidence that PFAS are harmful to the human immune system at levels of environmental exposure. FSANZ further updated the review in May 2022 and remains confident that the Australian TDIs for perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS) and perfluorohexane sulfonic acid (PFHxS) remain protective of public health.

# The regulation of PFAS in Australian foods

FSANZ is an independent statutory authority whose main role is to protect public health and safety through developing and maintaining the Australia New Zealand Food Standards Code (the Code). The Code includes standards, which are legal requirements for food at the point of sale in Australia. All food for sale in Australia (and New Zealand where applicable) must comply with these standards. FSANZ manages risks relating to contaminants in food through Standard 1.4.1 and Schedule 19 of the Code. Schedule 19 includes mandatory maximum levels (MLs) for specific contaminants in food which may pose a risk to public health and safety.

There are currently no MLs in the Code for PFAS. In the absence of MLs, general Code provisions apply including that food for sale must be safe and suitable for human consumption, and contamination levels should be kept as low as reasonably achievable. The Code does not specify a zero-tolerance for contaminants without MLs. Environmental contaminants may be transported through the environment via natural processes and are sometimes unavoidably found in food at low levels which don't pose a food safety concern.

While FSANZ sets food standards, the enforcement role in Australia is the responsibility of relevant state and territory authorities and the Department of Agriculture, Fisheries and Forestry (DAFF) for imported foods. Enquiries about the interpretation, implementation and enforcement of the Code are best directed to the relevant jurisdictional authority.

FSANZ applies internationally accepted and best practice criteria when considering the need for MLs in the Code. FSANZ only sets MLs to achieve specific public health and safety objectives according to the following criteria:

Only for those contaminants that represent a significant risk to public health and safety; and

- Only for those foods that significantly contribute to the dietary exposure of the contaminant; and
- To ensure that levels are as low as reasonably achievable.

## Surveillance and monitoring of PFAS in the Australian food supply

To support our role developing standards and protecting public health and safety, FSANZ coordinates surveillance and monitoring of the Australian food supply. In 2021, FSANZ completed a nationally coordinated analytical survey to investigate PFAS levels in the general food supply and to estimate the general Australian population's dietary exposure to PFAS as part of the 27<sup>th</sup> Australian Total Diet Study (ATDS). The ATDS is the most comprehensive monitoring survey of the Australian food supply and provides our best estimate of the general population's dietary exposure to various food chemicals.

A total of 112 commonly consumed foods and beverages were sampled from all Australian states and territories. Samples were collected over two sampling periods from June – September 2019 and January – April 2020. A total of 4,008 primary food samples were purchased from retail outlets and combined into 1,336 composite samples for analysis.

Food sample purchasing was undertaken by sampling officers from food regulatory agencies in capital cities and other metropolitan areas from all Australian states and territories.

Composite samples were analysed for 30 different PFAS for which there were available analytical standards including three congeners of primary interest for food safety: PFOA, PFOS and PFHxS. The comprehensive analytical screen included congeners considered as 'short' and 'long' chain PFAS, belonging to several categories including perfluoroalkyl carboxylic acids, perfuoroalkyl sulfonic acids, fluorotelomers, perfluoroalkane sulfonamides and perfluoroalkane sulfonamido substances.

The risk assessment component of the study was based on the latest evidence, data and methodologies available, and were based on international best practice. This includes using the most up to date and robust food consumption data available for the Australian population from national nutrition surveys.

#### The Study found:

- Levels of PFAS in the general Australian food supply are very low.
- PFOS was the only congener detected. PFOS was detected in five of 112 food types and in less than 2% of all samples.
- The mean levels of PFOS in these foods (assuming non-detects = 0) were mammalian offal (0.63 μg/kg), canned tuna (0.070 μg/kg), prawns (0.018 μg/kg), saltwater fish fillets (0.011 μg/kg) and chicken eggs (0.0069 μg/kg).
- PFAS levels in Australian foods were consistently lower than those found in overseas studies conducted in Europe, the United States, the United Kingdom and China.

- PFAS levels were well below Australian guidance values, including FSANZ trigger points for site investigation and National Health and Medical Research Council (NHMRC) drinking water guidelines.
- The overall dietary exposure to PFOS for the general Australian population is lower than the TDI indicating no public health and safety concerns.
- There is no current need to consider establishing food regulatory measures such as MLs for PFAS in the Code.

The migration of PFAS from food contact materials (including packaging) is considered a potential pathway for contamination of food. The 27<sup>th</sup> ATDS included sampling of a range of packaged foods. FSANZ also previously undertook two surveys (2010 and 2016) of PFAS in the Australian food supply to specifically investigate potential migration from food packaging. These studies found that migration of PFAS from food packaging was very low and posed no public health and safety concerns.

## Other monitoring and surveillance

Other agencies outside of FSANZ are also undertaking work in areas outside of FSANZ's remit, including blood testing of the Australian population. The Australian National University (ANU) have undertaken the PFAS Health Study which included blood serum analysis. The Australian Bureau of Statistics (ABS) currently has the Intergenerational Health and Mental Health Study (IHMHS) underway that includes a national nutrition survey which will be collecting updated food consumption data (currently in the field), and the National Health Measures Survey which will include PFAS analysis in blood of the general Australian population.

## European Commission MLs for PFAS in foods

FSANZ is aware that the EC have recently established MLs for PFAS in foods. These came into effect on 1 January 2023. The EC have set MLs for individual congeners including PFOA, PFOS, PFHxS and perfluorononanoic acid (PFNA), and for the sum of these four congeners, in the following foods: eggs, muscle meat of fish, crustaceans and bivalve molluscs, meat and offal of bovine animals, pig, poultry and game animals. FSANZ is not aware of any other overseas or international regulatory limits for PFAS in foods.

It is not uncommon for Australian food standards to differ with overseas and international regulations. This may be due to regional differences in risk profile, such as:

- Occurrence of contaminants in the environment/food supply.
- Dietary patterns and estimated dietary exposure which are unique for specific populations.
- There may also be differences in risk assessment methods (including established HBGVs), policy or other factors such as political influences.

The EC MLs were established after an EFSA risk assessment (2020) found concerns with estimated PFAS dietary exposure for some parts of the European population based on EFSA established HBGVs.

As mentioned previously, the 27<sup>th</sup> ATDS assessed PFAS levels (including for those congeners subject to EC MLs) in the general Australian food supply and found no food

safety concerns for the general Australian population. Hence there is no need or justification for establishing MLs for PFAS in the Australian general food supply. It should also be noted that the PFAS levels in Australian foods reported in the 27<sup>th</sup> ATDS were all below EC MLs.

## Site investigation and management activities

In the absence of MLs, FSANZ continues to support targeted contaminated site risk assessment and management measures by Commonwealth, and state and territory authorities, including:

- Providing advice concerning the application of Australian TDIs for PFOS, PFOA and PFHxS and FSANZ trigger points for site investigations, in the absence of MLs in the Code.
- Provision of other ad hoc technical food safety advice for government, business and consumers.

As previously mentioned, FSANZ is confident that the Australian TDIs for PFAS are protective of public health and safety. Therefore, the trigger points remain appropriate for use by relevant authorities when conducting contaminated site risk assessments. The trigger points are non-regulatory levels that indicate when further investigation and more detailed risk assessments may be required if concentrations in food are found to exceed the trigger point.

A summary of site specific PFAS investigations, management actions and advice across Australia can be found on the Australian Government PFAS website.

## Australian drinking water guidelines

The NHMRC have used Australian TDIs to establish health-related guideline values for drinking water. These are established for:

- PFOA 0.56 µg/L; and
- the sum of PFOS and PFHxS 0.07 μg/L.

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."

After the release of new interim US EPA Drinking Water Health Advisories it is FSANZ's understanding that the Department of Health and Aged Care is working with the NHMRC to progress an independent review of the Australian health-related guideline values for PFAS in the Australian Drinking Water Guidelines. This review will consider recent guidance and reviews from international and national jurisdictions, including the recent US Health Advisories, to determine whether they are suitable to adopt or adapt for the Australian context. FSANZ will assist with this work as required.