Release of Food Standards Australia New Zealand's (FSANZ) Report – Perfluorinated Chemicals in Food

FREQUENTLY ASKED QUESTIONS

What is the FSANZ Hazard Assessment Report—Perfluorooctane Sulfonate (PFOS), Perfluorooctanoic Acid (PFOA), and Perfluorohexane sulfonate (PFHxS)?

In June 2016, the Department of Health commissioned Food Standards Australia New Zealand (FSANZ) to develop health based guidance values for perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and perfluorohexane sulfonate (PFHxS), which belong to a group of chemicals known as per- and poly-fluoroalkyl substances (PFAS).

What did FSANZ's Hazard Assessment Report find?

The purpose of FSANZ's report was to establish final health-based guidance values for PFOS and PFOA and to consider whether there was enough data to establish a health based guidance value for PFHxS.

The report found that there was not enough suitable information in human research studies to establish a health based guidance value based on evidence of health effects in humans.

Therefore, the values were based on information found in research studies performed in laboratory animals.

FSANZ's Hazard Assessment Report agreed with other international agencies' and enHealth's assessments and concluded that to date there is no clear evidence of any adverse health effects of PFAS in human populations.

What are health based guidance values?

Health based guidance values indicate the amount of a chemical in food or drinking water that a person can consume on a regular basis over a lifetime without any significant risk to health. Health based guidance values can be expressed as a tolerable monthly intake (TMI), a tolerable weekly intake (TWI) or a tolerable daily intake (TDI). The choice of whether a TMI, TWI or TDI is set depends on the nature of the chemical.

For PFOS, PFOA and PFHxS, health based guidance values are expressed as a TDI.

What are the recommended health based guidance values in the report?

The final health based guidance values for site investigations in Australia are in the form of a tolerable daily intake or, as it is often referred to, a TDI.

The TDIs are:

- For PFOS the TDI is 20 ng/ kg bw/day or 0.02 µg/ kg bw/day; and
- For PFOA the TDI is 160 ng/kg bw/day or 0.16 µg/ kg bw/day.
- For PFHxS there was not enough toxicological and epidemiological information to justify establishing a TDI. However, as a precaution, and for the purposes of site investigations, the PFOS TDI should apply to PFHxS. In practice, this means that the level of PFHxS exposure should be added to the level of PFOS exposure; and this combined level be compared to the TDI for PFOS.

Note: bw = body weight, ng = nanograms, µg = micrograms

What is a tolerable daily intake?

A tolerable daily intake, often referred to as a TDI, is a level of daily oral exposure over a lifetime that is considered to be without significant health risk for humans. For PFAS, the major routes of exposure in communities are through contaminated drinking water and contaminated food.

The tolerable daily intake for PFAS is used specifically for conducting assessments (including, human health risk assessments) at contaminated sites.

The measurement unit used for tolerable daily intake can be either:

- *nanograms per kilogram of body weight per day* or *ng/kg bw/day* (1 nanogram = 0.001 micrograms = 0.000001 milligrams); and/or
- *micrograms per kilogram of body weight per day* or *ng/kg bw/day* (1 microgram = 1000 nanograms = 0.001 milligrams).

What are the new drinking and recreational water quality values for site investigations?

The Department of Health has calculated new drinking and recreational water quality values for site investigations based on the final tolerable daily intake levels for Australia.

- The drinking water quality value is 0.07 µg /L for PFOS and PFHxS and 0.56 µg /L for PFOA.
- The recreational water quality value is 0.7 µg /L for PFOS and PFHxS and 5.6 µg /L for PFOA.

To determine the drinking and recreational water quality values for site investigations across Australia, the Department of Health used the final health based guidance values and the methodology described in Chapter 6.3.3 of the National Health and Medical Research Council's *Australian Drinking Water Guidelines*. This approach is consistent with the one used by enHealth in developing the interim values in 2016.

Does the outcome of this report or the final health based guidance values change the health advice?

No, current health advice is that there is no consistent evidence that exposure to PFAS causes adverse health effects in humans. FSANZ's findings in reviewing the available evidence were consistent with the current health advice. The health based guidance values recommended by FSANZ are a precautionary measure while further research is conducted into potential health effects of PFAS. In the meantime, human exposure to these chemicals should continue to be minimised.

If there is no consistent evidence of health effects, how did FSANZ determine the values?

FSANZ concluded that the available epidemiological studies and data on human health effects are not suitable to derive tolerable daily intake levels for PFOS and PFOA. This finding is consistent with other international regulatory agencies across the world.

The tolerable daily intake levels for PFOS and PFOA are derived based on toxicological studies in laboratory animals using a pharmacokinetic modelling approach. This approach looks at toxicity findings in animals and extrapolates that data to humans, noting that animal physiology is not the same as human.

For PFHxS there was not enough toxicological and epidemiological information to justify establishing a tolerable daily intake level. However, as a precaution, and for the purposes of site investigations, the PFOS tolerable daily intake level should apply to PFHxS. In practice, this means that the level of PFHxS exposure should be added to the level of PFOS exposure; and this combined level be compared to the tolerable daily intake for PFOS.

Do these health based guidance values replace the health reference values adopted by the Environmental Health Standing Committee (enHealth)?

Yes, enHealth set interim health reference values so that guidance could be provided to relevant authorities to allow them to continue work to minimise the risk of unnecessary exposure to PFAS in affected communities.

The enHealth values were always meant to be interim until such time as FSANZ completed its review. The new final Australian health based guidance values have

replaced the interim values adopted by enHealth and will apply to PFAS site investigations in Australia.

The new health based guidance values for Australia are lower than the enHealth values. Does this mean that the enHealth values were wrong?

No, both sets of values are precautionary and protective of public health.

An independent review conducted by Adjunct Professor Andrew Bartholomaeus in August 2016 confirmed that the European Food Safety Authority values, adopted by enHealth, were appropriate and, as an interim measure, protective of public health.

The new Australian values take into account the data, parameters and methodology that are most suitable to Australia.

The interim values adopted by enHealth were always intended to be replaced by the final Australian values once FSANZ had completed its work.

What does this mean for the human health of communities affected by PFAS contamination?

Affected communities that have agencies and organisations currently conducting, or have recently had human health risk assessments conducted for PFAS contamination, may review their assessments and advice based on the final health based guidance values.

Advice on reducing exposure to PFAS will vary with location so you should follow the most current advice provided by the investigating agency's human health risk assessment and state or territory government advice for your area.

In the meantime, it is recommended that people in affected communities minimise their exposure and where possible, avoid, prolonged exposure to these chemicals.

Pregnancy

PFAS are not known to cause adverse health effects in unborn babies. However, as recommended for all people in affected communities, as a precaution, pregnant women in affected communities should minimise their exposure and where possible, avoid, prolonged exposure to these chemicals.

Breast feeding

Although there is evidence that PFOS occurs in breast milk, it is unclear what, if any, the risks to the baby may be from PFOS or PFOA exposure through breast milk. However, breastfeeding of babies should not be discontinued due to concerns about PFOS and PFOA exposure. The significant health benefits of breastfeeding are well established and far outweigh any potential health risks to an infant from any PFOS or PFOA transferred through breast milk.

I am in an area affected by PFAS contamination. How do I know if my water is safe to drink and food is safe to eat based on the new tolerable daily intake levels?

If a human health risk assessment is being conducted, or has been conducted in your area, the agency responsible will communicate the outcomes and will advise the affected community.

State and territory governments may also provide advice on the consumption of food. If you live in an affected community, you can check with your relevant state or territory health department or environmental protection agency, for advice regarding PFAS and food consumption in your area.

I have had my blood tested for PFAS. What does this mean for my blood test results?

Tolerable daily intake levels do not assist in explaining the concentration of PFAS in people's blood or provide an indication of a level of risk.

If you require assistance interpreting your blood test results, you should contact your GP.

What does half-life mean?

Half-life refers to the time taken for the amount of a chemical in the body to reduce by half.

For example, if the half-life is five years, then in five years' time you will have half the level of PFAS in your body than you do now, providing you have not had further exposure in that period.

The time it takes for PFOS and PFOA to be excreted is the same for adults and children. In humans, studies suggest that the half-life of PFAS could range from two to nine years.

What are epidemiological studies?

Epidemiological studies are studies of groups of people that have been exposed to a chemical or other health hazard. The aim of these studies is to determine whether these groups have a higher occurrence of a particular disease than the general population, and whether any disease occurring in this group is as a direct result of exposure.

Epidemiological studies, along with laboratory animal studies, contribute to the understanding of human health risks of exposure and the undertaking of human health risk assessments.

For PFAS, some epidemiological studies have shown an "association" between exposure and some health effects, but it is not clear that the exposure "caused" the health effect. This can be due to some epidemiological studies not accounting for uncontrolled factors in their research. For example, a number of international epidemiological studies have looked into the effects of exposure to PFAS on factory workers. However, some of the factory workers included in these studies also reported smoking or being exposed to other hazardous chemicals. This makes it difficult to determine whether it was the PFAS exposure that made them sick, or the fact they smoked or were exposed to other dangerous chemicals, or a combination of these factors.

What is a Dietary Exposure Assessment?

A Dietary Exposure Assessment assesses the potential risks related to exposure to a substance from the diet.

In this case, the Dietary Exposure Assessment for PFOS, PFOA and PFHxS is intended to be a tool that will assist state and territory governments in developing and providing advice to affected communities on food consumption.

What information did FSANZ look at for the Dietary Exposure Assessment?

FSANZ collected information on the amount of PFOS, PFOA and PFHxS in foods. Most of the data provided came from contaminated PFAS sites. This data was then consolidated into a single set of data. FSANZ also considered the data available from the 24th Australian Total Diet Study and conducted a literature review.

To determine people's normal food consumption patterns, FSANZ used information from the 2011-13 Australian Health Survey.

What did FSANZ find in the Dietary Exposure Assessment?

General Population

Due to the lack of available data, FSANZ was not able to do a formal dietary assessment for the general population. However, dietary exposure to PFAS in the general food supply is likely to be low.

Communities from or near Contaminated Sites

People consuming certain foods sourced from or near contaminated sites may reach the tolerable daily intake for PFOS or PFOS and PFHxS combined when they consume their usual amounts of that food.

Occasional exceedances of the TDI from consumption of a specific food are not of public health concern.

For PFOA, the amount of food sourced from or near contaminated sites that can be consumed before exceeding the tolerable daily intake is much higher than the amount people normally eat.

Will PFAS be regulated in food?

FSANZ concluded that there are insufficient data to recommend a regulatory approach and set maximum limits in the *Australia New Zealand Food Standards Code* (the Code). This is consistent with the findings of other international agencies. No other country in the world has set regulatory limits for PFAS in food.

FSANZ has proposed a non-regulatory tool, referred to as 'trigger points'. When measuring levels of PFAS in certain foods, state and territory governments could use this tool to identify whether further investigation may be required if PFAS is detected in analysed foods. If required, the agencies could then provide information to the community to assist them in minimising their exposure, for example, through releasing a food advisory.

Can I eat food produced on or near a contaminated site?

Advice on reducing exposure to PFAS will vary with each location so you should follow the most current advice provided by your state or territory government, and if available, the human health risk assessment for your area conducted by the investigating agency.

Is there PFAS in the general food supply?

Although there is currently limited information available on PFAS in the general food supply, dietary exposure to PFAS from the general food supply is likely to be low.