

Perfluorinated chemicals in food

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Executive Summary

A number of locations within Australia have localised contamination with perfluorinated chemicals arising from their use in firefighting foams. Three perfluorinated chemicals are the subject of this report; PFOS, PFOA and PFHxS. They belong to a group of compounds collectively referred to as per- and poly-fluoroalkylated (PFAS) substances. For the purpose of this report PFAS refers to all three contaminants that FSANZ was asked to provide advice on under contract with the Department of Health.

These chemicals are environmentally persistent and in animals, can cause liver toxicity and tumours and reproductive and developmental effects (PFOS and PFOA). Epidemiological studies have not provided convincing evidence of a correlation between PFOS and PFHxS and any cancer type in human beings. Although associations between PFOA and some human cancers have been suggested from some epidemiological studies, results have often been contradictory, and a causal relationship cannot be established with reasonable confidence.

Recommended HBGVs

FSANZ has completed its review and recommends tolerable daily intakes (TDIs) of 20 ng/kg bw/day for PFOS and 160 ng/kg bw/day for PFOA. These values are lower than the EFSA TDIs of 150 and 1,500 ng/kg bw/day, respectively, adopted on an interim basis by enHealth.

There was insufficient information to establish a TDI for PFHxS. In the absence of a TDI, FSANZ agrees with enHealth that using the TDI for PFOS is likely to be conservative and protective of public health. Effectively, this means that PFHxS and PFOS should be summed for the purposes of a dietary exposure assessment and risk characterisation.

Dietary exposure calculations

Only very limited data on the concentration of PFOS, PFOA and PFHxS in Australian foods were made available to FSANZ as inputs into dietary exposure calculations.

On the 8 August 2016, FSANZ undertook a data call seeking data on the occurrence of PFAS in food in Australia. FSANZ received 10 data sets in response with most data being environmental samples from contaminated sites. The majority of samples were seafood. All data received were included in a combined data set and, following data cleaning and transformation, used to create a final analytical data set for use in dietary exposure calculations.

The lack of data on the levels of these chemicals in the general food supply meant that it was not possible to estimate dietary exposure for the general Australian population at this time.

The available data from the 24th Australian Total Diet Study, recent results on imported fish and prawn samples purchased from Sydney retail outlets and a comprehensive review of the literature, suggests that dietary exposure to PFOS, PFOA and PFHxS from the general food supply is likely to be low as the majority of samples in studies reported in Australia and elsewhere did not detect these chemicals in testing.

Contaminated sites

FSANZ has estimated dietary exposure to PFOS, PFOA and PFHxS from individual food groups sourced in or near areas contaminated with these chemicals.

To address the uncertainty presented by poor quality of the available data, FSANZ has made very conservative assumptions and therefore the assessments are highly-protective of consumers. For example, we assigned a nominal very low level of the chemicals to foods that had none detected after testing.

FSANZ used two different approaches to calculate dietary exposure to PFOS, PFOA and PFHxS for people sourcing food from or near contaminated areas.

EXECUTIVE SUMMARY

1. Indicators of potential risk

As an indicator of potential risk, FSANZ assessed how much of an individual food or food group sourced from contaminated sites that contain PFOS, PFOA and/or PFHxS may be consumed by the Australian population without exceeding the relevant TDI, assuming background exposure from all other foods was zero.

If a calculated amount of food for a specified chemical is less than the amount people normally eat, then advice on consuming these foods may be required when they are sourced from or near contaminated sites (Refer to Supporting Document 2).

For some foods, the amount of foods containing the chemicals at the reported concentrations for food sourced from or near contaminated sites that a person can eat before reaching the relevant TDI was lower than the amounts that the average Australian would typically consume.

For PFOS, this occurred with cattle meat, rabbit meat, milk and offal for average consumers and for some vegetables and fruit for high consumers. However, FSANZ considered it extremely unlikely that a consumer would always source a specific food near a contaminated site. For example, milk does not normally come from one but from many animals and is mixed, homogenised and then distributed through retail outlets.

PFOA has a higher TDI and the amount of food that a person could eat before reaching the TDI is much higher the amount people would normally eat.

2. Trigger points for investigation

Information from the most recent nutrition survey was used to determine what level of PFOS and PFHxS combined and PFOA in individual foods would trigger further investigation by authorities. 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 are independent of occurrence data. In the calculation of these trigger levels maximum concentration levels were selected to ensure all population groups in a range of consumption scenarios are protected (refer to Supporting Document 2).

Proposed trigger points for investigation for PFOS and PFOS + PFHxS combined are lowest for milk (0.4 μ g/kg). Trigger points for investigation are lower for fruit and vegetables (0.6 and 1.1 μ g/kg respectively) than for finfish (5.2 μ g/kg), mammalian meat (3.5 μ g/kg) and eggs (11 μ g/kg).

In most commodities, the proposed trigger points for investigation for PFOA levels are higher than those for PFOS for the same food group. Like PFOS, proposed trigger points for PFOA investigation are lowest in milk, fruit and vegetables, finfish and meat.

FSANZ proposed trigger points for investigation for PFOS + PFHxS combined and PFOA could be employed by state and territory food jurisdictions when undertaking follow up analysis of PFAS in foods to identify when levels in foods exceed these values and require more research.

Risk management

There is no indication that there are public health and safety issues for consumers outside the contaminated sites. This is supported by data from: the 24th ATDS; recent results on PFAS in imported fish and prawn samples purchased from Sydney retail outlets; and a review of the literature indicating that dietary exposure from the general food supply is likely to be low.

Current at-site risk management measures consist of precautionary advice for residents sourcing food and water from or near contaminated sites to moderate their consumption of bore water, home grown fruit and vegetables, fish, meat and poultry while further work and analysis is undertaken by the Department of Defence (Defence). This is against a background of a range of remediation measures being considered by Defence.

FSANZ has considered whether additional and specific risk mitigation measures targeted at foods sourced from or near contaminated sites are likely to enhance the safety of the current measures in place.

FSANZ concludes the following:

- There are no specific regulatory limits for PFAS in food in place in Australia or any other country.
- FSANZ is unable to consider maximum limits (MLs) for PFAS in various food commodities at this point in time due to a lack of information on levels found in the general food supply.
- A range of non-regulatory options are available which could be used in parallel with existing at-site risk
 management measures by other Commonwealth and state and territory jurisdictions to manage and
 potentially reduce dietary exposure from PFAS.
- Although not site-specific, information from the dietary exposure calculations for people consuming food sourced from or near contaminated sites (presented in Supporting Document 2) could be used by Defence, public health or food regulatory officials to update food advisories. As the TDIs derived by FSANZ are lower than those previously established by EFSA; Defence, public health and food regulatory officials may revise their current advice to residents in Williamtown and Oakey.
- Trigger points of investigation could be employed by state and territory food jurisdictions when undertaking
 follow up analysis of PFAS in foods to identify when levels in analysed foods exceed these values and require
 more research.

1 Introduction/background

A number of locations in Australia have localised contamination with perfluorinated chemicals arising from their use in firefighting foams.

Perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and perfluorohexane sulfonate (PFHxS) belong to a group of compounds collectively referred to as per- and poly-fluoroalkylated (PFAS) substances.

PFAS are of concern because they do not break down in the environment and so can persist for a long time. There is presently no consistent evidence that exposure to perfluorinated chemicals causes adverse health effects in humans. However, given their persistence, bioaccumulation and toxicity to some animals, the potential for adverse human health effects cannot be excluded.

Many countries have phased out, or are in the process of phasing out the use of PFOS and PFOA due to concerns about their persistence, bioaccumulation and toxicity.

In June 2016, the Environmental Health Standing Committee (enHealth), which is a subcommittee of the Australian Health Protection Principal Committee, adopted the 2008 European Food Safety Authority (EFSA) human health reference values for two PFAS chemicals, PFOS and PFOA and set interim HBGVs.

In contrast to PFOA and PFOS, a HBGV for PFHxS has not generally been established by international regulatory agencies. This is likely to be due to a lack of sufficient toxicological information to conduct an assessment.

Nevertheless, PFHxS has, on occasion, been included as a part of consideration of other perflourinated compounds.

On 8 August 2016 the Australian Department of Defence (Defence) released its Human Health Risk Assessment (HHRA) examining possible pathways for human exposure to PFAS chemicals arising from contamination at the Williamtown RAAF Base. Defence has also released an Environmental Site Assessment which includes modelling to predict the movement of the PFAS chemicals in the environment.

On 2 September 2016 Defence released its Human Health Risk Assessment on Oakey, Queensland http://www.defence.gov.au/ID/Oakey/Documents.asp.

On 9 September 2016, an independent review of the enHealth decision, conducted by Adjunct Professor Andrew Bartholomaeus, supported the decision by Australian authorities to use European HBGVs for PFOS and PFOA as an interim approach to investigating site-specific human health risk assessments in Australia pending a formal more extensive review of the HBGVs by FSANZ.

In June 2016, the Department of Health commissioned FSANZ to:

- Develop final HBGV for PFOS, PFOA and PFHxS, which belong to a group of compounds collectively known as PFAS.
- Make an assessment as to whether a food regulatory measure should be further considered as the most appropriate risk management response and conduct a dietary exposure assessment.

INTRODUCTION/BACKGROUND

2 Previous investigations into PFAS contamination in food

The 24th Australian Total Diet Study (ATDS) which analysed PFOS and PFOA in a range of foods in the general food supply in Australia identified no public health and safety concerns¹.

In 2015, the NSW Food Authority asked FSANZ to provide advice on the TDI for PFOS established by the European Food Safety Authority (EFSA) in 2008, and on safe levels of PFOS in seafood. The request was made in relation to areas of localised contamination in NSW. Based on a comparison of potential estimated dietary exposure to PFOS from consuming oysters sourced from the area of interest in NSW with the EFSA TDI, FSANZ's preliminary conclusion was that there was low health risk concern for the general population.

For people who may consume large amounts of other seafood from the areas of interest in NSW, FSANZ found there was a potential to exceed the EFSA HBGV for PFOS for some species of fish or crustacea. However, this is not likely to be the case for the general population. The preliminary assessment indicated further research is required on levels of PFOS, PFOA and PFHxS in seafood and other commodities in the general food supply (NSW EPA report).

On 27 November 2015 the Department of Agriculture and Water Resources requested advice from FSANZ regarding levels of PFOS in animal derived foods that could be used for risk management purposes.

On 8 June 2016, FSANZ responded with advice on PFOS guideline levels² for a range of food commodities. Consumption of foods with concentrations of PFOS above the guideline levels for each food category over a long period of time could potentially result in an exceedance of the TDI derived by EFSA. A full dietary exposure assessment based on PFOS occurrence data was not undertaken in order to provide this advice. Rather, guideline levels for investigation of PFOS in animal commodities were derived by calculating the maximum allowable concentration of PFOS in each food category before the TDI was exceeded for high consumers of those commodities, assuming no exposure from other foods.

3 Potential public health risks

Whether PFOS, PFOA or PFHxS cause adverse health effects in humans is currently unknown. Overall, at this time, studies do not clearly establish a causal relationship between PFAS exposure and adverse health effects in humans, even where there has been occupational exposure at levels which are orders of magnitude higher than the general population (Priestly, 2015).

3.1 Hazard identification and characterisation

To meet the objectives of the hazard identification and characterisation, the following key questions were posed:

- Are there sufficient data available to allow Health Based Guidance Values (HBGVs) to be established?
- What are the most appropriate HBGV that should be applied to PFOS, PFOA and PFHxS?
- Can a group HBGV be established?

Data for setting HBGVs

FSANZ considered a number of comprehensive international assessments on the health effects of PFAS. These assessments established TDIs ranging from 20–300 ng/kg bw/day for PFOS and 20–1,500 ng/kg bw/day for PFOA. TDIs for PFHxS have generally not been established due to a lack of data.

FSANZ has also had regard to the June 2016 enHealth Statement: Interim national guidance on human health reference values for per- and poly-fluoroalkyl substances for use in site investigations in Australia, and the August 2016 independent Procedural Review of Health Reference Values Established by enHealth for PFAS.

Most international agencies have concluded that there is no clear evidence of any adverse health effects of PFAS in humans, including in highly exposed occupational populations.

http://www.foodstandards.gov.au/publications/Pages/24th-ATDS-Phase-2.aspx

² In this report 'guideline levels' are referred to as 'trigger points for investigation'.

However, the United States Environmental Protection Agency (US EPA) has noted that there appears to be an association between increased serum cholesterol and decreased body weight at birth. FSANZ has reviewed the available human epidemiological information and concluded that while there is evidence of this association, it is not possible to determine whether PFAS causes the changes, or whether other factors are involved.

A literature review commissioned by FSANZ concluded that there are both positive and negative studies showing associations for increasing PFOS and PFOA concentrations to compromise antibody production in humans. However, to date there is no convincing evidence for increased incidence of infective disease associated with PFOS or PFOA effects on human immune function.

Epidemiological studies have not provided convincing evidence of a correlation between PFOS and PFHxS and any cancer type in human beings.

Although associations between PFOA and some human cancers have been suggested from some epidemiological studies, results have often been contradictory, and a causal relationship cannot be established with reasonable confidence.

FSANZ concluded that available human epidemiology data are not suitable to support the derivation of TDIs for PFOS or PFOA. This is consistent with the findings of other regulatory agencies. Therefore, FSANZ has recommended TDIs based on extensive toxicological databases in laboratory animals.

TDIs for PFOS and PFOA

For PFOS, the TDI is 20 ng/kg bw/day based on decreased parental and offspring body weight gain in a reproductive toxicity study in rats. Pharmacokinetic modelling was applied to the serum concentrations at the no observed adverse effect level (NOAEL) to calculate the human equivalent dose (HED). An uncertainty factor of 30 was applied to the HED, which comprised a factor of 3 to account for inter-species differences in toxicodynamics and a factor of 10 for intra-species differences in the human population.

For PFOA, FSANZ has recommended a TDI of 160 ng/kg bw/day based on a NOAEL for fetal toxicity in a developmental and reproductive study in mice. Pharmacokinetic modelling was applied to the serum concentrations at the NOAEL to calculate the HED. An uncertainty factor of 30 was applied to the HED, which comprised a factor of 3 to account for

inter-species differences in toxicodynamics and a factor of 10 for intra-species differences in the human population.

There was not enough toxicological and epidemiological information to justify establishing a TDI for PFHxS. In the absence of a TDI, it is reasonable to conclude that the enHealth 2016 approach of using the TDI for PFOS is likely to be conservative and (as an interim measure) will protect public health. Effectively, this means that PFHxS and PFOS exposure should be summed for the purposes of risk assessment.

For the full report see Supporting Document 1.

3.2 Dietary exposure calculations

The preliminary dietary exposure assessment (DEA) sought to address the following key questions:

- Based on the HBGVs established and information on current levels of the chemicals in food both
 representative of the general food supply and in areas with contamination, what is the potential exposure to
 those chemicals?
- What does this exposure represent compared to the agreed HBGV?
- In the absence of suitable occurrence data, what would be the trigger levels for investigation for individual commodities for the three contaminants?
- What are the limitations of the preliminary dietary exposure assessment?
- Are there any other contributors to exposure other than diet?

3.2.1 PFAS analytical data received

FSANZ received 10 datasets in response to its data call for analytical data (refer to SD 2), the majority of which related to foods sourced from or near contaminated sites. Based on these limited occurrence data for contaminated sites, mean upper bound PFOS concentrations were highest for rabbit meat, finfish livers, cattle meat and mammalian offal. PFOA concentrations were below reporting limits for most samples.

Mean upper bound analytical results for foods with PFOA detections were highest for molluscs and freshwater fish. There was less data available on PFHxS analyses than for PFOS or PFOA analyses. Mean upper bound PFHxS concentrations were highest for cattle meat, rabbit meat and eggs.

3.2.2 Dietary exposure for the general population

There was insufficient information to estimate total dietary exposure to PFOS, PFOA and PFHxS for the general population as the majority of the submitted data on the amount of these chemicals in food and water were from contaminated sites.

However, the limited data available from the 24th Australian Total Diet Study (ATDS) and a review of the literature indicate that dietary exposure from the general food supply is likely to be low. In addition, following the publication of the 24th ATDS the NSW Food Authority undertook further research on PFOS, PFOA and PFHxS in fish in February 2016, analysing imported fish and prawn samples purchased from Sydney retail outlets. Results were consistent with the ATDS and no further dietary exposure assessment was undertaken.

3.2.3 Preliminary dietary exposure to foods sourced from contaminated sites

As it is unknown how much food consumed by populations living near contaminated sites is sourced locally it was not possible to estimate total dietary exposure for this specific subgroup. Rather, the preliminary dietary exposure assessment investigated how much of an individual food or food group sourced from contaminated sites that contain PFOS, PFOA and/or PFHxS may be consumed by the Australian population without exceeding the relevant TDI, assuming background exposure from all other foods was zero. If a calculated amount for a specified chemical/food group(s) combination is less than people normally eat then public advice on consuming these foods may be required when they are sourced from or near contaminated sites.

For PFOA the amount of each 'contaminated site' food that could be consumed before the relevant TDI was exceeded was much greater than amounts usually eaten by high consumers even assuming upper bound median concentrations of PFOA. Usual food consumption patterns were as reported in the 2011-12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011-13 Australian Health Survey.

PFOS has a lower TDI than PFOA so the outcome of these calculations was different. For PFOS and PFOS + PFHxS combined for the food groups assessed, the amount of foods containing PFOS or PFOS + PFHxS combined at reported levels from contaminated sites that may be consumed without exceeding the relevant TDI was lower than the usual amounts of food consumed. For PFOS this occurred for the whole population with cattle meat, rabbit meat, milk and offal assuming low, middle and upper bound median concentrations. For children aged 2-6 years this applied to cattle meat and milk assuming low, middle and upper bound median concentrations and in addition, at the upper bound median concentration for some vegetables. Occasional exceedances of the TDI from consumption of a specific food on one day or over a short period are not of public health concern.

It is considered extremely unlikely that food consumption of a specific food group, for example meat, over a period would all be from food sourced locally from a contaminated site. This is particularly true for milk and milk products because milk doesn't normally come from one animal but is collected from many animals and several sources, mixed and homogenised and then distributed through retail outlets.

3.2.4 Trigger points for investigation

Trigger points for investigation were derived for each food or food group assessed for PFOS + PFHxS combined and PFOA. 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 have dietary exposures exceeding the relevant TDI.

Public health and/or food regulatory officials may use the trigger points for investigation of specified chemicals to identify when levels in analysed foods exceed these values and require more research.

Proposed trigger points for investigation for PFOS + PFHxS combined are lower for milk (0.4 μ g/kg), fruit and vegetables (0.6 and 1.1 μ g/kg respectively) than for finfish (5.2 μ g/kg), mammalian meat (3.5 μ g/kg) and eggs (11 μ g/kg). Proposed trigger points for investigation for PFOS + PFHxS combined for other seafood, honey and offal are substantially higher than those proposed for other commodities.

In most commodities, the proposed trigger points for investigation for PFOA are an order of magnitude higher than those for PFOS. Like PFOS, proposed trigger points for investigation are lowest in fruit and vegetables, finfish and meat. Trigger points for PFOS + PFHxS combined and for PFOA for all food groups for which FSANZ received occurrence data are set out in Table 1.

Table 1. Proposed trigger points for investigation

Food	Food classification	Proposed trigger points for investigation (μg/kg)		Derivation
		PFOS, PFOS+ PFHxS combined	PFOA	
Fish and Seafood	Crustaceans#	65	520	Children 2-6 years, median consumption
	Finfish (all)	5.2	41	Children 2-6 years, P90 consumption
	Fish liver#	280	2240	Population 2+ years, median consumption assumed to be 5 g (weight of one liver)*
Animal Products	Meat mammalian	3.5	28	Children 2-6 years, P90 consumption
	Milk	0.4 or LOD if higher	2.8	Children 2-6 years, P90 consumption
	Honey	33	264	Children 2-6 years, P90 consumption
	Offal mammalian#	96	765	Population 2+ years, median consumption
	Poultry eggs	11	85	Children 2-6 years, P90 consumption
Fruits and vegetables	Fruit (all)	0.6 or LOD if higher	5.1	Children 2-6 years, P90 consumption
	Vegetables (all)	1.1 or LOD if higher	8.8	Children 2-6 years, P90 consumption

[#] occasionally consumed food, trigger points for investigation for crustaceans applied to molluscs due to the small number of consumers of molluscs

^{*} no food consumption data available, source: FSANZ report on Edith River, Northern Territory 2013, https://dpir.nt.gov.au/__data/assets/pdf_file/0006/260187/TraceElementsNTFish.pdf

3.2.5 Preliminary dietary exposure assessment limitations

FSANZ aims to make as realistic an estimate of dietary exposure as possible. However, where significant uncertainties in the data exist, conservative (or 'worst-case') assumptions are generally used to ensure that exposure estimates are protective of consumers.

It is highly uncertain whether the occurrence data made available to FSANZ in response to its call for data are representative of the contamination of food with PFOS, PFOA and PFHxS. The data points were from a variety of foods sourced from contaminated sites or areas in close proximity to such sites and provide the most significant limitation in this assessment because there is very limited data on occurrence of PFOS, PFOA and PFHxS in Australian foods generally for sale.

A number of limitations in the occurrence data are described below:

- There is a very high number of records where concentration data has not been detected; in the case of PFOA and PFHxS this is the majority of records, consequently all calculations are highly sensitive to limits of determination (LOD).
- Most data are based on environmental sampling and do not necessarily reflect food as sold to the public (e.g. raw milk).
- Sampling was targeted (in proximity to contaminated sites) rather than randomised and is unlikely to be representative of the food supply, therefore results are likely to overestimate potential dietary exposure.
- Most animal data used to estimate occurrence in meat and offal were estimated from blood serum measurements using a conversion factor.
- There are major gaps in the data including for offal, poultry meat, cereal grains, oils and fats. Not all of
 these foods could be matched to a raw commodity classification where occurrence data were available,
 hence concentration levels were assumed to be zero.
- Some of the data included in the database had poor metadata and limited auditing or validation.
 For example in some cases it is unclear whether the data were duplicates and/or composite samples, and in the latter case how many raw samples were included in each composite.

As occurrence data are a significant input into estimates this is a major source of uncertainty in this assessment. The overall uncertainty in the model estimations due to the low quality of the occurrence data is therefore considered to be high. FSANZ addressed this by using lower, middle and upper bound concentration levels for PFOS, PFOA and PFHxS in the different food groups for which data were available. The lower bound median is a 'best case' scenario that assumes for a non-detect result the food is free of the component. The upper bound median is a 'worst case' scenario that assumes for a non-detect result the component is present at the limit of detection (LOD). The middle bound is halfway between the other bounds. The use of the upper bound median levels in calculations is very conservative as a high proportion of results for PFOS, PFOA and PFHxS were non-detects (< LOR).

For the full report see Supporting Document 2.

3.2.6 Other contributors to exposure to PFAS

The key exposure route to PFAS is via the diet. Other routes of exposure occur by consumption of water, inhalation and dermal contact. This is via the use of PFAS in products that resist heat, stains, grease and water, such as stain and water resistant treatments for furniture, carpets and clothing, make up and personal care products and cleaning products.

4 Risk management

To meet the objectives of risk management for PFAS contamination in food, the below key questions were posed when initial scoping of the project was undertaken:

- What specific geographic areas are affected and what is the extent of contamination?
- What are the types of commodities (crops/foods) produced in the potentially contaminated areas including their volume, value and where they are sold (domestic or international)?
- What are the trade impacts and /or concerns already encountered as a result of the contamination? In light of the potential trade impacts what is the likely or possible value of the export markets protected as a result of having a defensible science based HBGV with appropriate risk management measures in place?
- What other control measures are in place in Australia or could be put in place to control exposure to the chemicals in question, including non-regulatory measures (self-regulation or coregulatory measures)?
 This should also consider whether remediation is feasible.
- What risk management options are available to manage potential dietary risks?

Contaminated sites in Australia

Investigations are being undertaken into PFAS at a number of sites around Australia. Defence is continuing to investigate other sites that may be contaminated with PFAS in Australia.

Types of commodities affected by PFAS contamination

PFAS have been detected in various environmental media and matrices, including food. Unlike other persistent organic pollutants, due to the physical and chemical properties of PFAS they do not accumulate in fatty tissues of animals so may be found in a variety of foods and water. FSANZ has only limited data and information on PFOS, PFOA and PFHxS in foods sourced from or near contaminated sites in Australia and is only able to provide dietary exposure calculations for those foods for which data were submitted (refer to Supporting Document 2).

Potential trade impacts

In August 2016, the Department of Agriculture and Water Resources advised FSANZ that it is unlikely that residues of PFAS in livestock, grain and horticultural commodities would give rise to export market disruption. FSANZ has insufficient information to consider what potential impacts of the contamination have been for domestic trade in food.

Other controls in place for PFAS

There are other controls for PFAS in water and the environment and recent recommendations from the National Industrial Notifications and Assessment Scheme (NICNAS) are available (See Supporting Document 3).

States, territories and local government retain primary responsibility for implementing and managing policies and guidelines relating to chemical management according to their relevant state or territory legislation. Environmental health is a state and territory responsibility and the Commonwealth has no legislative powers in this area. However, the Australian Government is actively collaborating at the whole-of-government level to engage state and territory health departments and other appropriate authorities to manage the potential effects of PFAS contamination.

The Australian Government Department of the Environment is leading development of an Environmental Management Guidance on PFOS and PFOA contamination at Commonwealth sites. It takes into consideration relevant international standards under the Stockholm and Basel Conventions to determine appropriate levels for high content waste disposal, as well as the National Environment Protection (Assessment of Site Contamination) Measure 1999 (as amended in 2013) and The Australian and New Zealand Guidelines for Fresh and Marine Water Quality where appropriate. The guidance will potentially inform national approaches on managing PFOS and PFOA contamination.

Defence is researching a number of management and remedial technologies as part of its national PFAS Investigation and Management program. Defence's priority is to engage with industry experts both nationally and internationally, to identify the best management and remedial options for PFAS.

RISK MANAGEMENT 10

4.1 Interim at-site risk management measures for PFAS

Drinking or consumption of surface and groundwater is a major exposure pathway for contamination in animals and contamination may occur in crops grown using this water.

Precautionary advice has been given that incidental swallowing, particularly by children, should be avoided when showering, bathing and swimming in groundwater or surface water.

For residents at Williamtown and Oakey precautionary advice to residents to moderate their consumption of home grown fruit and vegetables, fish, meat and poultry are currently in place while further work and analysis is undertaken by Defence.

As a precautionary measure Defence continues to provide alternative sources of drinking water to properties in the Oakey area that do not use town water for drinking purposes.

Defence has implemented a National PFAS Environmental Management Program and has undertaken environmental site assessments and human health risk assessments at the RAAF Base Williamtown, NSW and the Army Aviation Centre at Oakey, Qld.

Formulation changes in fire-fighting foams have been made at civilian airports. In 2014, Airservices and the Department of Infrastructure and Regional Development (DIRD) engaged GHD Pty Ltd to develop a risk-based framework, 'Managing Perfluorinated compounds contamination at Airports', to guide decision-making when dealing with contamination issues on airport sites.

The framework was finalised in June 2015. GHD reviewed international screening levels and other guidance to develop screening levels that could be used in this management framework. Airservices has adopted this framework in its civilian operations nationally. The framework has been provided by Airservices to DIRD, and it has subsequently been distributed to the airport lessee companies and DIRD's Airport Environment Officers as well as the Department of the Environment and the Department of Health. However, the draft interim framework and screening levels have no regulatory authority³.

4.2 Potential risk management measures

Legislative requirements in Australia and New Zealand, including state and territory Food Acts, aim to keep food safe and suitable. State and territory Food Acts and the New Zealand Food Act contain general provisions that make it an offence to sell food that is unsafe, and food businesses must comply with requirements in the Code.

The Code contains food standards which have been developed, approved and gazetted by FSANZ. The Code applies to all food sold or prepared for sale in Australia and New Zealand (except where specified 'Australia or New Zealand only'). In accordance with state, territory and New Zealand food legislation, it is an offence to supply food that does not comply with the Code.

The standard of direct relevance to PFAS is Standard 1.4.1 Contaminants and Natural Toxicants. This Standard sets out the maximum levels (MLs) of specified metal and non-metal contaminants and natural toxicants in specific foods. However, there are no limits prescribed for PFOA, PFOS or PFHxS in the Standard. In setting MLs in the Code, FSANZ adheres to agreed policy principles as detailed in Supporting Document 4.

FSANZ has limited data on the occurrence of PFAS in the general food supply; therefore, it was not possible to calculate dietary exposure for the general Australian population. Based on the limited data available from the 24th ATDS, recent data in imported seafood and prawns and a review of the literature, dietary exposure to PFOS, PFOA and PFHxS from the general food supply is likely to be low.

However, consumers of contaminated food (using data from contaminated sites) may reach the TDI when they consume their usual amounts of that food. This was relevant for populations (including children) consuming foods contaminated with PFOS and PFOS + PFHxS (see Supporting Document 2).

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³ Airservices submission to Senate Inquiry Part B: Contamination at Commonwealth, state and territory sites in Australia where fire fighting foams containing PFOS and PFOA were used.

Prescriptive approach

FSANZ does not have sufficient information at this stage to consider whether a prescriptive approach would be appropriate by proposing MLs in the Code to minimise/control dietary exposure from PFAS contamination.

Furthermore, for FSANZ to set a ML we would also have to consider the following broader issues:

- The types of commodities (crops/foods) produced in the potentially contaminated areas including their volume, value and where they are sold (domestic or international).
- The costs and benefits of establishing a ML via a Regulatory Impact Analysis.

Non-regulatory measures

Another option considered was providing advice on consumption of food and trigger points for investigation levels. The amount of individual foods or food groups that could be consumed at the reported concentration levels for PFOS, PFOA and PFHxS without exceeding the relevant TDI derived by FSANZ was calculated for populations consuming foods sourced from or near contaminated sites.

These calculations could lead to consideration of targeted consumer advice by risk managers in the states/territories, similar to the interim advice being provided to populations living near to Oakey and Williamtown. An example is the current advice on methyl mercury in fish on the FSANZ website⁴.

Specific trigger points for investigation (derived by calculating the maximum concentration of PFOS, PFOS+PFHxS and PFOA in each food category before the relevant TDI was exceeded), have been calculated to assist public health officials to identify when further investigation of foods and/or sites may be required. This may assist in further reducing PFAS exposure from contaminated food.

4.3 Other measures outside of FSANZ's remit

FSANZ has identified a range of other measures that could be considered by other agencies that would complement state and territory advisory statements on food consumption and use of trigger points for investigation that would assist in reducing potential dietary exposure to PFAS. These are as follows:

- Other legislation in place in environmental law and/or requirements (e.g. the National Environment Protection Measures) that could be used to mitigate risk at the source of the contamination⁵.
- Adherence to Environment Australia's Environmental Management Guidance on PFOS and PFOA
 contamination at Commonwealth sites and to international standards in place under Stockholm conventions
 and measures in place in other countries (See Supporting Document 3).
- At site remediation by Defence, Air Services Australia and Environment Australia.
- A recommendation to prohibit foods from specific at site contaminated areas which would need to be implemented by other available legislation.
- Minimising use of contaminated land via the development and Application of Codes of Practice (COP).

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⁴ http://www.foodstandards.gov.au/consumer/chemicals/mercury/Pages/default.aspx

⁵ http://www.nepc.gov.au/nepms

5 Conclusions

FSANZ understands the widespread community concerns around the potential adverse health effects from exposure to water, soil and food contaminated by PFAS in affected areas. FSANZ's core objective under the FSANZ Act is the protection of public health and safety and it continues to work closely with other Commonwealth, state/territory agencies on a broad framework to manage PFAS contamination.

FSANZ has considered whether additional and specific risk mitigation measures targeted to foods consumed at contaminated sites are likely to enhance the safety of the current at site measures.

Taking into account the identified dietary exposure estimates from PFAS in food, FSANZ concludes the following:

- There are no specific regulatory limits for PFAS in food in place in Australia or any other country.
- FSANZ is unable to consider maximum limits (MLs) for PFAS in various food commodities at this point in time due to a lack of information on levels found in the general food supply.
- A range of non-regulatory options are available which could be used in parallel with existing at-site risk
 management measures by other Commonwealth and state and territory jurisdictions to manage and
 potentially reduce dietary exposure from PFAS.
- Although not site-specific, information from the dietary exposure calculations for people consuming food sourced from or near contaminated sites (presented in Supporting Document 2) could be used by Defence, public health or food regulatory officials to update food advisories. As the TDIs derived by FSANZ are lower than those previously established by EFSA, Defence, public health and food regulatory officials may revise their current advice to residents in Williamtown and Oakey.
- Trigger points for investigation could be employed by state and territory food jurisdictions when undertaking
 follow up analysis of PFAS in foods to identify when levels in analysed foods exceed these values and require
 more research.

6 References

Priestly B (2015) Health affects of perfluorinated compounds (PFCS). Frequently asked questions. Professor Brian Priestly MPharm, PhD, FACTRA December 2015

For more information see:

- Department of Defence
- AirServices Australia
- National Industrial Chemicals Notification and Assessment Scheme
- Department for the Environment and Energy
- Department of Health

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