NSW GOVERNMENT | Chief Scientist & Engineer

OUT15/35851

17 December 2015

Secretariat
Foreign Affairs, Defence and Trade Committee
Department of the Senate
PO Box 6100
Parliament House
Canberra ACT 2600
fadt.sen@aph.gov.au

Dear Secretariat

Questions on Notice – Hearing 3 December 2015

I am writing in response to questions on notice from the hearing of the inquiry into contamination caused by firefighting foams at RAAF Base Williamtown and other sites held on 3 December 2015. I request that my responses be kept confidential due to the sensitive nature of some of the material.

With regard to the questions on notice, and as discussed with your Committee, I have formally referred these questions to the enHealth committee that met on 11 December 2015 to discuss human health issues related to PFOS and PFOA. I asked for a response by 15 December 2015.

I have been informed by several people that attended that meeting that the matter of blood testing was the subject to significant debate and that a final position has not been reached.

The matter of blood testing is now subject to further refinement by the Australian Health Protection Principal Committee which is meeting on Friday 18 December 2015. Once a final position has been reached I will forward the information to the Committee.

On other matters, during my meeting with the Committee, in response to a question, I mentioned that the Health Risk Assessment Working Group of the Expert Panel does not keep formal minutes. I looked into this matter further and discovered that minutes are kept but they are not transmitted to the Expert Panel.

In relation to other matters raised I have included the following documents:

- The Guidance and Scoping Information for the Human Health Risk Assessment provided by the NSW EPA to the Department of Defence on the recommendation of the Expert Panel.
- Preliminary Dietary Exposure Assessment Reports for Commercial Oysters and Seafood.

Please let me know if you require any further information.

Yours sincerely

Mary O'Kane
NSW Chief Scientist & Engineer

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NSW EPA

Our Reference: DOC15/422510

Brigadier Mark Holmes
R2-4-D035 - Office of the Chief of Staff
Australian Defence Headquarters
Russell Officers - Russell Drive
RUSSELL ACT 2601

Dear Brigadier Holmes

RAAF Williamtown – Guidance and Scoping Information for the Human Health Risk Assessment for PFC Contamination

As foreshadowed in our letter on the Stage 2 report, the Expert Panel has considered the draft Defence Sampling Strategy, the available information on the nature of the contamination emanating from the Williamtown RAAF Base, and the information recently collected by NSW Agencies in order to install appropriate precautionary measures to protect the local community from this offsite contamination.

Please find enclosed the advice of the NSW Expert Panel (and the Human Health Risk Assessment (HHRA) Scoping Document - dated 26th October 2015) that reflects the recommended approach that should be applied by Defence and its consultants in order to develop a more complete understanding of the risks to human health and the environment posed by the offsite contamination and the necessary long term control strategies.

As the uncertainty associated with this offsite contamination is having a demonstrable impact upon the livelihood and wellbeing of the local community, it is important that the required investigations are scheduled to optimise the effective delivery of the required information. The EPA and the agencies on the Expert Panel remain willing to be engaged at the relevant junctions during these studies to assist in relevant technical decision making. The Risk Assessment Working Group of the Williamtown Expert Panel found the recent direct engagement with your consultants, AECOM, ToxConsult and URS to be a very effective mechanism to ensure a common understanding of preferred methodologies.

You will note that there are a number of milestones within the enclosed HHRA scoping document that seeks effective engagement with the local community in developing the HHRA. It is important that the study takes full advantage of the communities' local knowledge and such engagement will help to ensure the outcomes are understood and supported by the affected community.

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The EPA in consultation with the Expert Panel will encourage engagement with the established Williamtown Contamination Community Reference Group as a mechanism to achieve these objectives.

I look forward to an effective engagement with Defence and its consultants to address these important issues.

Yours sincerely

BARRY BUFFIER AM
Chair and CEO 27/10/15
Environment Protection Authority

Enclosure

1. DOC15/422510-01 – RAAF Williamtown Human Health Risk Assessment Scoping Document – 26th October 2015

cc. Williamtown Contamination Community Reference Group c/- DPC Hunter Office

Preliminary Dietary Exposure Assessment – Commercial Oysters – Tilligerry Creek and Fullerton Cove, Williamtown NSW

20 October 2015

Executive Summary

In August 2015 the Department of Defence advised of the detection of perfluorooctane sulfonate (PFOS) and perfluorooctanic acid (PFOA) in and around the Williamtown RAAF base.

The NSW Food Authority enacted a precautionary closure of the Tilligerry Creek Harvest Area pending testing of farmed oysters.

This report provides the analysis of oyster testing results. It shows that oysters from the Tilligerry Creek Harvest Area do not present a food safety risk and are safe to eat. This is based upon toxicology and dietary exposure advice from Food Standards Australian New Zealand (FSANZ).

Analysis included an estimate of dietary intake of oysters for age class and sex and whether people were large consumers of oysters. This information was considered by the Expert Panel and they recommended that the ban on the sale of farmed oysters could be lifted.
As a further precaution, the NSW Food Authority will continue to monitor and sample oysters in the Tilligerry Creek area and across other areas of the Port Stephens.
Farmed oysters are sold under the stringent guidelines of the NSW Shellfish Program to safeguard public health. Wild oysters are no grown under the same strict control as farmed oysters and as such it is advised not to consume wild oysters.

Preliminary Dietary Exposure Assessment – Commercial Oysters – Tilligerry Creek and Fullerton Cove, Williamtown NSW

20 October 2015

Background

Perfluorooctane sulfonate (PFOS) and perfluorooctanic acid (PFOA) are perfluorinated compounds that are components in fire-fighting foams that were used at the Williamtown RAAF based prior to 2011. Since 2013 the Australian Defence Force (ADF) has been investigating the presence of these compounds in and near the base. Recently these compounds were detected in three samples of biota (fish and small shellfish) from a local drain and creek.

NSW Health advised that based on the levels detected, seafood caught or collected from the local area (upper Tilligerry Creek and Fullerton Cove) should not be consumed until more is known about the presence of these substances in seafood. As such, DPI Fisheries enacted a one month fishing (commercial and recreational) closure till 3 October 2015 for upper Tilligerry Creek and Fullerton Cove. DPI Food Authority issued a precautionary ban on the sale of oysters from the Tilligerry Creek Harvest Area also till 3 October 2015.

During the closure period, the NSW Government is undertaking more extensive analysis of seafood to better inform what impact the chemicals may have had on seafood caught or harvested from areas of interest.

Tilligerry Creek Harvest Area

The Tilligerry Creek Harvest Area is located within the Port Stephens Shellfish Program Area. Tilligerry Creek is approximately 17 kilometres long. Upper Tilligerry is divided into two oyster production zones. Zone 5A is in the upper reaches of the creek and is a nursery area only, meaning oysters must be relocated to another area for ongrowing prior to harvesting for sale. The Tilligerry Creek Harvest Area can be used for the growing of oysters for harvest and sale and is classified as “conditionally restricted”, meaning prior to sale, oysters must either be depurated (purged) for 36 hours in filtered UV treated seawater, or moved to an Approved harvest area for 14 days prior to sale.

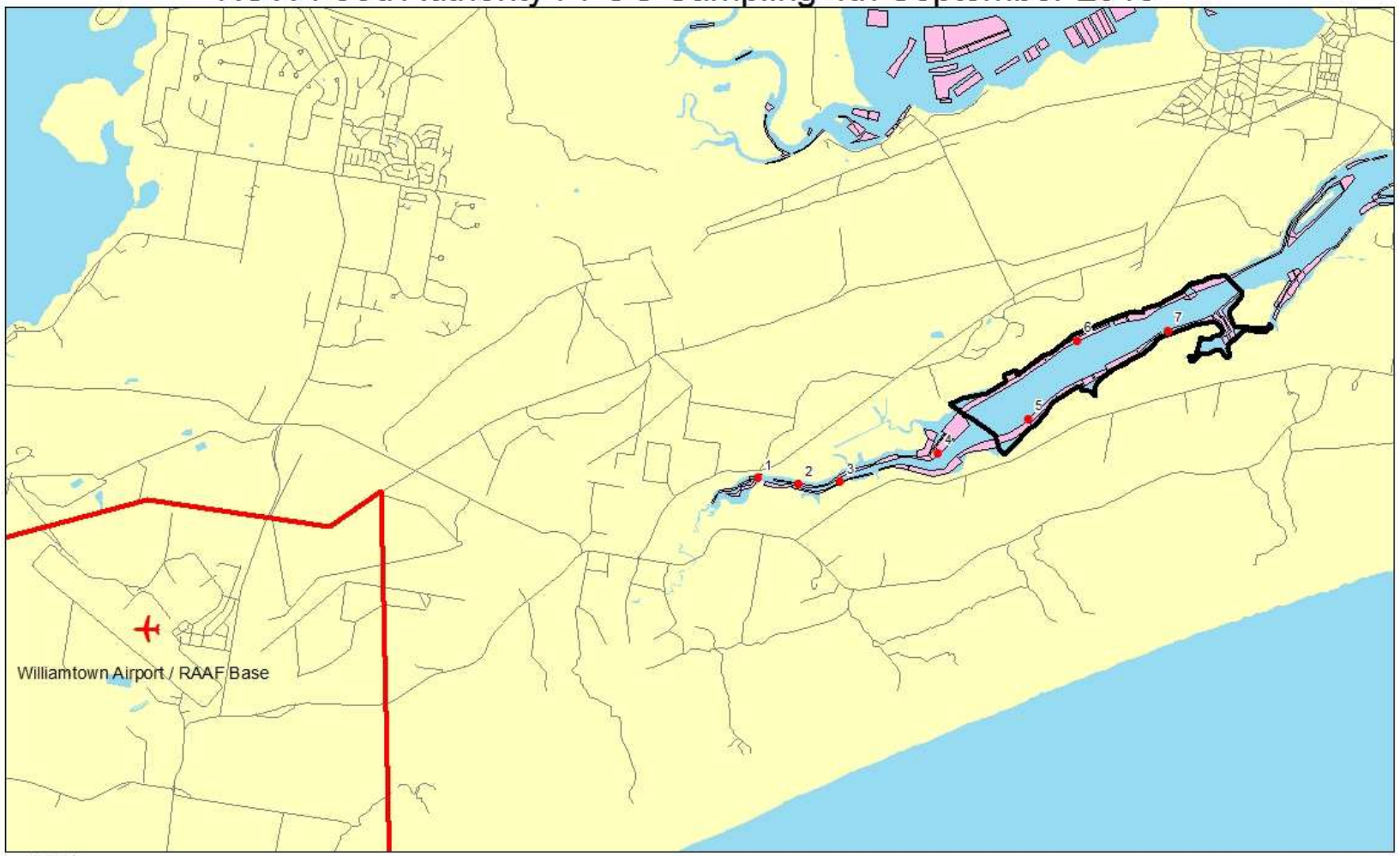
DPI Fisheries also commenced a trial to determine how quickly the chemicals of concern are purged from Sydney Rock Oysters should testing results return an elevated level of the chemical above agreed standards in oysters.

Sampling

On 4 September 2015 oyster samples were collected from upper Tilligerry Creek (both Zone 5A and Tilligerry Creek Harvest Area) by DPI Fisheries and DPI Food Authority staff. The locations of the samples are presented in the map below.

Six composited samples of Sydney Rock Oysters and one composited sample of Pacific Oysters (labelled 1 to 7 on the map) were collected from various locations in upper Tilligerry Creek. Samples 1 to 4 are from Zone 5A and Samples 5 to 7 are from the Tilligerry Creek Harvest Area.

NSW Food Authority PFOS Sampling 4th September 2015



Analysis

Samples were sent to the National Measurement Institute (NMI) laboratory at North Ryde for analysis of perfluorinated compounds by Solid Phase Extraction and Liquid Chromatography/tandem Mass Spectrometry (LC/MS/MS) using reference method USEPA 537. While the laboratory does not have NATA accreditation for the method, the method uses an international standard method and has been used over the past three years for environmental projects and a large food project. NMI will be submitting an application for NATA accreditation in 2015. No other laboratory has NATA accreditation for the analysis.

Results

The results are presented in Appendix 1. The main perfluorinated compound detected in the samples was PFOS.

In the oyster samples collected from upper Tilligerry Creek, PFOS levels ranged from <0.0003 mg/kg to 0.002 mg/kg.

The highest levels were detected in Zone 5A, 0.002-0.0016 mg/kg. Oysters are not harvested for sale in this area.

The lowest levels were detected downstream from Zone 5A in the Tilligerry Creek Harvest Area where oysters are harvested for sale <0.0003-0.00071mg/kg.

Interpretation and Assessment of Results

In a risk assessment of chemical contaminants, estimated exposure is compared to a relevant health based guidance value. Exposure may arise from several sources, in this report only dietary exposure is assessed. In a dietary exposure assessment estimated exposure, derived from combining food consumption data from national population surveys and food chemical concentration data, is compared to the appropriate health based guidance value.

To assist within interpreting the results, DPI Food Authority approached Food Standards Australia New Zealand (FSANZ), whose staff have expertise in toxicology and dietary exposure assessment.

Health based guidance values

The European Food Safety Agency (EFSA) established a Tolerable Daily Intake (TDI) of 150 ng/kg bw[1]/day (0.00015 mg/kg bw/day) for PFOS based on a no observed adverse effect level (NOAEL) identified in sub-chronic, chronic and reproduction/developmental toxicity studies in laboratory animals (EFSA 2008). The TDI for PFOA established by EFSA at the same time was 1.5 µg/kg bw/day (0.0015 mg/kg bw/day).

FSANZ considers these values appropriate health based guidance values to use for chronic dietary exposure assessments (see Attachment 1 for details). As adverse effects from PFOA and PFOS are thought to occur following long term exposure no acute health based guidance values need to be established. Consequently, there is no need for an acute dietary exposure assessment.

[1] bw = human body weight

Food consumption data

Food consumption data for the general human population aged 2 years and over and for the 2-6 year old human sub-group for consuming fish, crustacean and molluscs were derived from the 2011-12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011-13 Australian Health Survey (Table 1). The figures in Table 1 are based on day 1 of the NNPAS, this is a conservative assumption as calculation of 'usual' or habitual intakes of fish and seafood would result in lower daily consumption amount estimates.

It is standard international practice in food chemical risk assessments to assess young children separately due to relatively higher food consumption amounts per kilogram bodyweight compared to older children and adults. In many cases this places them at higher risk of exceeding health based guidance values, however, in the case of crustacean and molluscs, which are not as commonly consumed by young children as the rest of the population, they would tend to be of lower risk of exposure from consumption of these foods.

In this report, dietary exposure estimates were not undertaken for young children for crustacean (only 8 consumers/779 respondents) or molluscs (0 consumers) as the numbers would not be statistically valid due to small numbers of consumers.

PFOS concentration data used in the dietary exposure assessment

For this assessment, analytical results for PFOS in oysters from the areas where harvesting occurs (Tilligerry Creek Harvest Area) only were used (three composite oyster samples 5, 6 and 7, Upper Tilligerry Creek, refer Appendix 1). There was one non-detect value (LOD[2] = 0.0003 mg/kg) resulting in a mean value of 0.000467 mg/kg, assuming the non-detect value to be at the LOD; or mean value of 0.000367 mg/kg assuming the non-detect value to be zero. The median value was 0.00039 mg/kg (rounded to 0.0004 mg/kg).

For PFOA all samples from the harvesting area were non-detects (three composite oyster samples 5, 6 and 7, Upper Tilligerry Creek, refer Appendix 1).

For contaminants, the international convention for chronic dietary exposure estimates is to use the median concentration value. For this report, dietary exposure estimates based on the median and the highest analytical value are reported, as requested.

[2] LOD = limit of detection

Table 1: Fish, crustacean and mollusc consumption data for the general population (2+ years) and children (2-6 years)

NNPAS Food Code	Food Group Name	Age Group (years)	Number of consumers	Consumers as percentage of respondents* (%)	Consumption (g/day)					
					Mean all respondents	Mean consumers only	P50 (median) consumers only	P90 consumers only	P95 consumers only	P97.5 consumers only
15101	Finfish	2+	543	4.5	5.8	131	110	255	294	366
		2-6	26	3.3	3.3	98	66	220	255	**
15201	Molluscs	2+	76	<1	0.5	79	63	146	180	248
		2-6	0	0						
15202	Crustacean	2+	117	<1	0.9	94	66	250	336	336
		2-6	8	1	0.3	26	17	**	**	**

** Total number of respondents: 2 years and above = 12 153; 2-6 years = 779.*

*** Too few consumers to derive reliable percentile.*

Notes: 2011-2012 NNPAS (National Nutrition and Physical Activity Survey), a 1 day 24-hour recall survey on all respondents with 64% of respondents undertaking a second 24-hour recall on a second non-consecutive day. Day 1 only survey results used for this analysis.

The data was filtered using specific survey food group classification codes: Finfish- fresh or frozen were included; however other types of finfish such as packed finfish (e.g. canned) and battered or crumbed finfish were excluded. Similarly, fresh or frozen crustacean and molluscs were included but packed or crumbed crustacean and molluscs were excluded.

For chronic dietary exposure estimates, results are generally reported for the whole population, that is the mean dietary exposure is derived from data for all survey respondents (eaters and non-eaters of the foods of interest), assuming median contamination levels.

However, for sub populations who may consume more than the average amount for the whole population more often, for example families of recreational or commercial fishermen, dietary exposure estimates can be undertaken for consumers (eaters) only of the food of interest. For a food such as fish, crustacean and molluscs, which are not staples, known to be seasonal and therefore unlikely to be consumed every day over a long period of time even by this sub population group, the best estimate for a 'worst case' scenario would be based on median consumption of these foods (consumers only) combined with median concentration levels. The use of the median concentration level reflects the fact that there will always be a distribution of the contaminant in the foods eaten over time or even in one meal, for example in a plate of a dozen oysters (~150 g), so it is considered unrealistic to expect each food item consumed to be contaminated at the highest reported level on every eating occasion. However, for this report the estimated dietary exposure or consumers assuming 90th percentile of food consumption as well as median consumption is presented, as requested.

Chronic dietary exposure estimates for the whole population and consumers only for PFOS in fish, crustacean and molluscs are given in Table 2. A dietary exposure assessment was not undertaken for PFOA as no oysters in the harvest area were found to contain this chemical.

Table 2: Dietary exposure assessment (DEA) for PFOS from oyster consumption

	Food consumption (kg/day)	**Estimated dietary exposure, median concentration level* (mg/day)**	**% TDI#**	**Estimated dietary exposure, highest concentration level* (mg/day)**	**% TDI#**
General population (eaters and non-eaters)	0.0005	0.0000002	0.002	0.0000004	0.004
Median consumers (eaters only)	0.063	0.000025	0.251	0.000045	0.445
90th centile consumers (eaters only)	0.146	0.000058	0.581	0.00010	1.031

*Median concentration PFOS in oysters 0.0004 mg/kg; highest level reported 0.00071 mg/kg.
#PFOS TDI 0.00015 mg/kg bw

Risk characterisation

Comparison of the estimated chronic dietary exposure with the TDI for PFOS for all population groups assessed indicates that consumption of oysters would not result in the health based guidance value being exceeded.

For the general population, estimated dietary exposure from consumption of oysters combined was 0.002% TDI assuming the median PFOS concentration and 0.004% TDI assuming the high concentration. For fishing communities who may consume higher amounts of these foods more often, high level consumption of oysters will also not lead to an exceedance of the TDI for PFOS (median percentile oyster consumers had an estimated dietary exposure that was 0.3% TDI assuming the median PFOS concentration and 0.4% TDI assuming the high concentration; 90th percentile oyster consumers had an estimated dietary exposure that was 0.6% TDI assuming the median PFOS concentration and 1.0% TDI assuming the high concentration). This does not take background dietary exposure from other foods or drinking water into account, however, fish and other seafood are reported to be the major contributors to the diet elsewhere (EFSA 2008). For all populations it is desirable to eat a balanced diet overall.

FSANZ notes that in the general population an odd meal or day when a high amount of fish and/or seafood containing PFOS is consumed is not a concern because PFOS has such a long plasma half-life in humans (~5 years). This means it is the total PFOS dietary exposure over a long period of time (circa 20 years) that is of interest in terms of determining the risk to public health and safety.

Maximum allowable concentrations

There are no national or international limits for PFOS in foods. Preliminary advice from FSANZ is that a maximum allowable concentration may be calculated to assist in risk management action. The maximum allowable concentration is the level at which if you ate a certain amount of fish per day you would not exceed the TDI.

Assuming a standard serve of fish, crustacean or molluscs for adults (150 g per day) and of fish for young children (75 grams per day)

- A maximum allowable concentration for PFOS in fish is
    - 0.038 mg/kg for children
    - 0.067 mg/kg for entire population
- A maximum allowable concentration for PFOS in molluscs and crustacean is 0.067 mg/kg for the entire population.

Consumption of a serve of fish above the maximum allowable concentration for PFOS per day over a long period of time would result in an exceedance of the Tolerable Daily Intake (TDI) derived by the European Food Safety Authority (EFSA) and endorsed by FSANZ and NSW Health.

Results below the maximum allowable concentration may require further assessment including further dietary exposure assessment taking into account the whole of the diet and high seafood consumers.

All results from oyster samples taken from the Tilligerry Creek Harvest Area were below the proposed maximum allowable concentration. Therefore no further analysis is required.

Maximum amount of oysters able to be consumed at reported PFOS levels

The results were further assessed by conducting a back calculation to determine the maximum amount of oysters that could be consumed when the PFOS concentration in the oysters harvested in the Tilligerry Creek Harvest Area was at the median and highest level reported. This involved calculating the kilograms of seafood the different age groups (male and female) would be required to consume before the TDI for PFOS was exceeded. Table 3 shows the estimated maximum consumption amounts for oysters collected from Tilligerry Creek Harvest Area or the general population would be 25 kg per day assuming the median concentration level and 14 kg per day assuming the high concentration level.

Table 3: Maximum consumption amounts – Tilligerry Creek Oysters

Tilligerry Creek Samples 4 Sept (Samples 5, 6 and 7)		**Maximum food consumption (kg) calculated such that PFOS TDI is not exceeded***				
Sample	**PFOS level (mg/kg)**	**All (2-6 yrs)**	**All (7-12 yrs)**	**All (13-17 yrs)**	**All (18+ yrs)**	**All (2+ yrs)**
Body weight (kg) 2011-12 NNPAS		19	36	62	78	70
Median concentration	0.0004	7	13	23	29	26
Highest concentration	0.00071	4	7	13	16	14

*Assumes no background PFOS exposure from other foods

The dietary exposure calculations for oysters collected from the Tilligerry Creek Harvest Area demonstrate that large quantities of oysters would need to be consumed to exceed the TDI. For children aged 2 to 3 consumption rates range from 3 kg (females highest concentration level) to 5 kg (males median concentration level) per day and for adults range from 14 kg (females highest concentration level) to 30 kg (males median concentration level) per day. Children are not known to be high consumers of oysters (no reported consumers for children aged 2-6 years reported in the 2011-12 NNPAS) and the consumption rate for adults would clearly be unachievable.

Conclusion

Based on these results it is concluded that oysters from the Tilligerry Creek Harvest Area do not present a food safety risk.

From Consideration

Reopen the Tilligerry Creek Harvest Area for the harvest, depuration and sale of oysters.

To support the reopening, NSW government will continue to monitor PFOS in oysters. Oysters from Tilligerry Creek, both pre and post-depuration, as well as oysters from other areas in the Port Stephen Shellfish Program will be sampled. 5 to 6 composited samples will be collected each month for six months.

The results will be assessed against the EPA screening criteria (9.1 µg/kg). If above this level, dietary exposure assessment similar to that conducted in this report will be undertaken and reported back to the Expert Panel for consideration. All results will also be reported back to the Expert Panel

Appendix 1: Seafood Results

Upper Tilligerry Creek

	Oyster 1	Oyster 2	Oyster 3	Oyster 4	Oyster 5	Oyster 6	Oyster 7
Units	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg
PFHxA Q	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
PFHpA Q	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005
PFOA Q	<0.0003	<0.0003	<0.0003	<0.0003	<0.0003	<0.0003	<0.0003
PFNA Q	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
PFDA Q	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005
PFUdA Q	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005
PFBS Q	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
PFHxS Q	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005
PFOS R	0.0016	0.0013	0.002	0.00089	0.00071	<0.0003	0.00039
6:2 FTS Q	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0005
8:2 FTS Q	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005

Control oysters (from a different estuary)

PFOS <0.0003 mg/kg

Advice from FSANZ on a health based guidance value for PFOS

EFSA established a Tolerable Daily Intake (TDI) for PFOS based on the lowest no observed adverse effect level (NOAEL) identified in sub-chronic, chronic and reproduction/ developmental toxicity studies in laboratory animals (EFSA 2008).

The lowest NOAEL, 0.03 mg/kg bw/day, was identified in a sub-chronic (6-month) oral gavage study in cynomolgus monkeys. Changes in serum lipids and thyroid hormones were observed at doses of 0.15 and 0.75 mg/kg bw/day and treatment-related deaths were observed at 0.75 mg/kg bw/day (Seacat et al 2002).

Other NOAELs cited by EFSA were not substantially higher than the above NOAEL of 0.03 mg/kg bw/day. For example, in a chronic (2-year) dietary study in rats, NOAELs were 0.04 and 0.14 mg/kg bw/day for males and females respectively, based on liver histopathology observed at the next higher doses of 0.14 mg/kg bw/day (males) and 0.37 mg/kg bw/day (females). In males, a significant increase in the incidence of hepatocellular adenomas was noted in the high-dose group (7/60; 1.4 mg/kg bw/day) compared to the control (0/60). In the females, a significant increase in the incidences of hepatocellular adenomas (5/60) and combined hepatocellular adenomas and carcinomas (6/60) was observed in the high-dose group (1.5 mg/kg bw/day) compared to the control group (0/60) (Thomford 2002, unpublished; subsequently published as Butenhoff et al 2012).

Based on the above study, EFSA concluded that PFOS is carcinogenic in rats, inducing tumours of the liver. Based on a lack of genotoxicity in a wide range of *in vitro* and *in vivo* assays, EFSA concluded that the weight of evidence indicates an indirect (non-genotoxic) mechanism for carcinogenicity.

Adverse effects have also been observed at relatively low doses in reproduction/ developmental toxicity studies. For example, in a two-generation oral gavage study in rats, a NOAEL of 0.1 mg/kg bw/day was identified based on reduced birthweight at the next higher dose (0.4 mg/kg bw/day). Reduced survival was observed in offspring at doses of 1.6 and 3.2 mg/kg bw/day (the top dose). In the 1.6 mg/kg bw/day group, 26% of the offspring died within 4 days after birth. In the 3.2 mg/kg bw/day group, 45% of the pups died within one day after birth and 100% died thereafter (Christian et al 1999).

EFSA established a TDI of 150 ng/kg bw/day (i.e. 0.00015 mg/kg bw/day) by applying an overall uncertainty factor (UF) of 200 to the NOAEL of 0.03 mg/kg bw/day observed in the cynomolgus monkey study. A UF of 100 was used for inter and intra-species differences and an additional UF of 2 to compensate for the relatively short duration of the study and for uncertainties in the internal dose kinetics.

A search was conducted for toxicity studies on PFOS published after the EFSA search cut-off (February 2008). No reliable studies were located reporting adverse effects at doses lower than the lowest observed adverse effect levels (LOAELs) reported above. Effects on immune parameters were reported in a mouse study, with a LOAEL of 0.0017 mg/kg bw/day and a NOAEL of 0.00017 mg/kg bw/day (Peden-Adams et al 2008), however these findings are not supported by the results of other immunotoxicity studies on PFOS.

FSANZ concludes that the TDI for PFOS of 150 ng/kg bw/day (0.00015 mg/kg bw/day) established by EFSA in 2008 was appropriately derived and that subsequent toxicity data do not indicate a need to amend the TDI. However, FSANZ notes that a TDI is probably not the

appropriate Health Based Guidance Value for a compound which has a long half in several mammalian species (~5 years in humans; Olsen et al 2007). A Tolerable Weekly Intake would be more appropriate.

References

Butenhoff JL, Chang SC, Olsen GW, Thomford PJ (2012) Chronic dietary toxicity and carcinogenicity study with potassium perfluorooctanesulfonate in Sprague Dawley rats. Toxicology, 293(1-3):1-15.

Christian MS, Hoberman AM, York RG (1999) Combined oral (gavage) fertility, developmental and perinatal/postnatal reproduction toxicity study of PFOS in rats. Argus Research Laboratories, Inc., Horsham, PA U.S EPA. Docket 8EHQ-0200-00374.

EFSA (2008) Perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts. Scientific Opinion of the Panel on Contaminants in the Food Chain. The EFSA Journal (2008) 653, 1-131.

Olsen GW, Burris JM, Ehresman DJ, Froehlich JW, Seacat AM, Butenhoff JL, Zobel LR (2007) Half-life of serum elimination of perfluorooctanesulfonate, perfluorohexanesulfonate, and perfluorooctanoate in retired fluorochemical production workers. Environ Health Perspect. 115(9):1298-305.

Peden-Adams MM, Keller JM, Eudaly JG, Berger J, Gilkeson GS, Keil DE (2008) Suppression of humoral immunity in mice following exposure to perfluorooctane sulfonate. Toxicol Sci. 104(1):144-54.

Seacat AM, Thomford PJ, Hansen KJ, Olsen GW, Case MT, Butenhoff JL (2002) Subchronic toxicity studies on perfluorooctanesulfonate potassium salt in cynomolgus monkeys. Toxicol Sci. 68(1):249-64.

Relationship between EPA screening criteria and FSANZ exposure calculations

The EPA screening criteria for biota of 9.1 ug/kg is based on Dutch work undertaken by RIVM (National Institute for Public Health and the Environment) [1]. The methodology used to develop this value is similar to that used by FSANZ. The TDI used is the same but fish consumption and body weights are Dutch rather than Australian. RIVM use a further factor to limit the proportion of the TDI attributable to fish to 10%. This factor appears to be related to data from a Dutch Total Dietary Survey. No comparable dietary survey of PFOS or other PFCs is available for Australia.

The authors note the limit is a screening value and not a health value. We believe the limit has value as a screening criterion with appropriate conservatism to account for other possible sources of PFCs such as contaminated drinking water and locally grown produce/meat. We recommend Defence should consider adopting the 9.1 ug/kg screening value for their studies. However, food exposure assessments should be undertaken by FSANZ.

1. Moermond C, Verbruggen E, Smit C. Environmental risk limits for PFOS A proposal for water quality standards in accordance with the Water Framework Directive. RIVM National Institute for Public Health and the Environment; 2010.

Preliminary Dietary Exposure Assessment – Seafood – Tilligerry Creek and Fullerton Cove, Williamtown NSW

3 November 2015

Executive Summary

Throughout September 2015, as part of a broader sampling program to determine the level of exposure to fire fighting chemicals perfluorooctane sulfonate (PFOS) and perfluorooctanic acid (PFOA) in and around the Williamtown RAAF base (see map for area) the NSW Government, led by NSW DPI Fisheries, undertook preliminary sampling of fish, prawn and mud crabs.

The Tilligerry Creek and Fullerton Cove areas were subject to a precautionary closure to commercial and recreational fishing while this assessment was undertaken.

The preliminary results showed PFOS to be present in the samples taken, no PFOA was detected in any sample.

The analysis of the results showed that based upon dietary exposure as determined by health based guidance values of Tolerable Daily Intake (TDI) there was low health risk concern for the general population (see Tables 3 and 4 in the full report) however for people who may consume large amounts of seafood from the areas, there is a potential to exceed the health based guidance values. Further, while health based guidance values are not exceeded for the general population, some species of fish and crustacea have the potential to significantly contribute to a person exposure to PFOS.

On consideration of these results the Williamtown Expert Panel has identified need for further analysis of a wider selection of seafood, as part of the Human Health Risk Assessment.

These findings will be reviewed in light of any scientific developments in TDI standards.

Preliminary PFOS Risk Assessment for Seafood – Tilligerry Creek and Fullerton Cove

Background

Perfluorooctane sulfonate (PFOS) and perfluorooctanic acid (PFOA) are perfluorinated compounds that are components in fire-fighting foams that were used at the Williamtown RAAF base prior to 2011. Since 2013 the Australian Defence Force (ADF) has been investigating the presence of these compounds in and near the base. Recently these compounds were detected in three samples of biota (fish and small shellfish) from a local drain and creek.

NSW Health advised that based on the levels detected, seafood caught or collected from the local area (upper Tilligerry Creek and Fullerton Cove) should not be consumed until more is known about the presence of these substances in seafood. As such, DPI Fisheries enacted a fishing (commercial and recreational) closure while the issue is investigated. .

During the closure period, the NSW Government is undertaking more extensive analysis of seafood to better inform what impact the chemicals may have had on seafood caught or harvested from areas of interest.

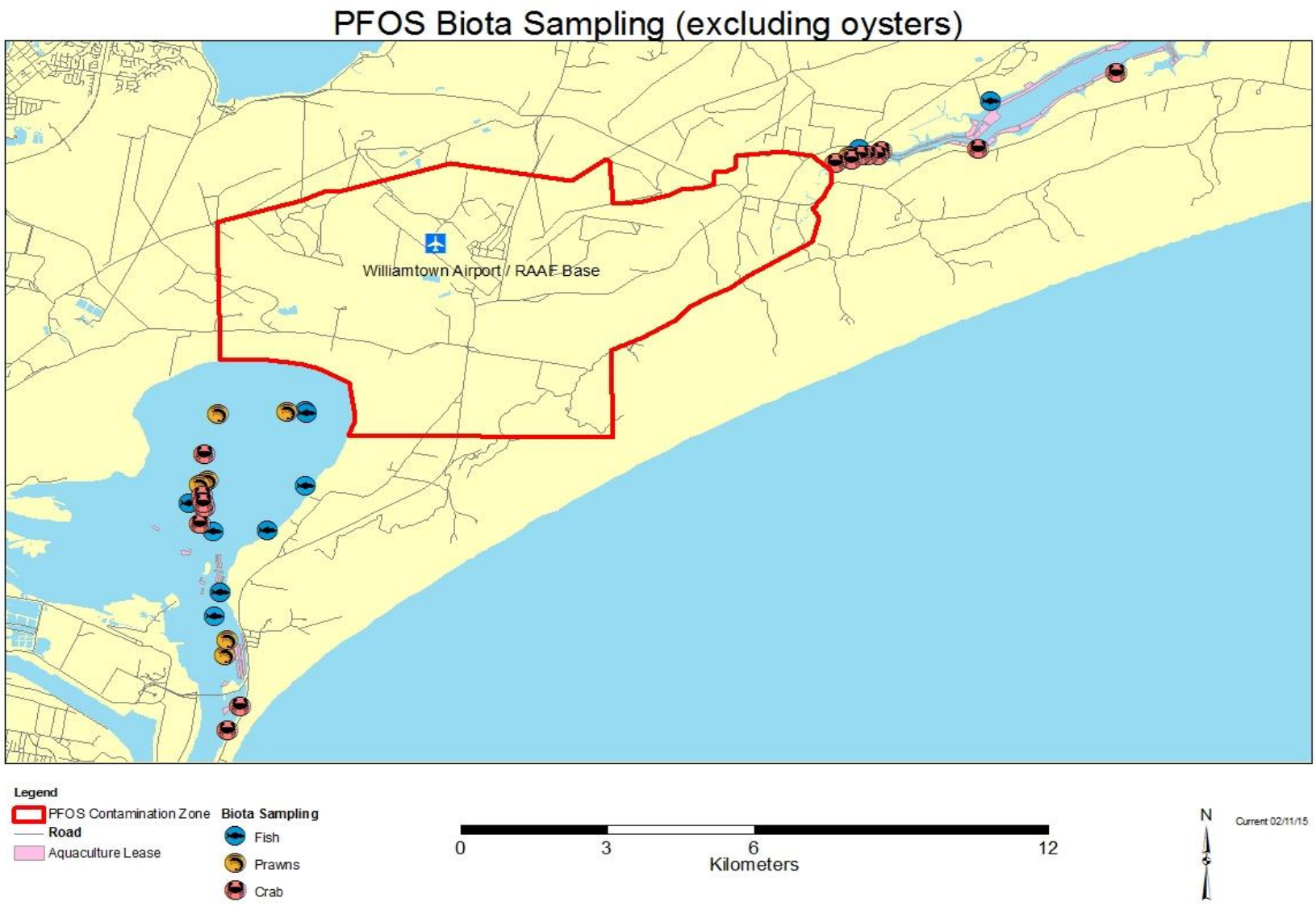
Sampling and Processing

During September 2015 fish, prawn and mud crab samples were collected from both Tilligerry Creek and Fullerton Cove by DPI Fisheries, both independently and with the assistance of commercial fishers. The locations where these samples were collected are presented in the following map.

Samples were processed and dissected on the day following capture at Port Stephens Fisheries Institute. Biometric information was recorded, and tissue samples were dissected from the organisms collected. Skin was removed from the muscle tissue samples of fish, and all processed samples were placed in small, individually tagged, snap-lock bags. These processed samples were then shipped to National Measurement Institute (NMI) generally within 4 days of sampling/processing.

Analysis

Samples were sent to the National Measurement Institute (NMI) laboratory at North Ryde for analysis of perfluorinated compounds by Solid Phase Extraction and Liquid Chromatography/tandem Mass Spectrometry (LC/MS/MS) using reference method USEPA 537. While the laboratory does not currently have NATA accreditation for this method for food and seafood, the method is an international standard method which is used extensively in the US and Europe and has been used here in Australia over the past three years for environmental projects and a large food project. NMI will be submitting an application for NATA accreditation in 2015.



Note: the two prawn samples caught downstream of Fullerton Cove were not analysed due to insufficient sample size

Results

The summary of the results is presented in Table 1. The main perfluorinated compound detected in the samples was PFOS. No PFOA was detected in any sample.

Table 1: Fish and crustacea results from Fullerton Cove and Tilligerry Creek

Site	Common name	Count	Minimum (mg/kg)	Mean (mg/kg)	Median (mg/kg)	Maximum (mg/kg)
Fullerton Cove	Fish	14	0.0003	0.003	0.0015	0.019
	Prawns	8	0.0096	0.017	0.017	0.025
	Crabs	9	0.0005	0.002	0.0024	0.003
Tilligerry Creek	Fish	23	0.0003	0.003	0.001	0.018
	Prawns	2	0.036	0.042	0.042	0.048
	Crabs	8	0.0011	0.004	0.0036	0.011

Interpretation and Assessment of Results

In a risk assessment of chemical contaminants, estimated exposure is compared to a relevant health based guidance value. Exposure may arise from several sources, in this report only dietary exposure is assessed. In a dietary exposure assessment, estimated exposure, derived from combining food consumption data from national population surveys and food chemical concentration data, is compared to the appropriate health based guidance value.

Health based guidance values

The European Food Safety Agency (EFSA) established a Tolerable Daily Intake (TDI) of 150 ng/kg bw[1]/day (0.00015 mg/kg bw/day) for PFOS based on a no observed adverse effect level (NOAEL) identified in sub-chronic, chronic and reproduction/developmental toxicity studies in laboratory animals (EFSA 2008). The TDI for PFOA established by EFSA at the same time was 1.5 µg/kg bw/day (0.0015 mg/kg bw/day).

FSANZ considers these values to be appropriate health-based guidance values to use for chronic dietary exposure assessments (see Attachment 1 for details). As adverse effects from PFOA and PFOS are thought to occur following long term exposure no acute health based guidance values need to be established. Consequently, there is no need for an acute dietary exposure assessment.

Food consumption data

To evaluate the consumption of fish and crustacea in all people aged 2 years and over as well as children specifically in the 2-6 year old age group, food consumption data from the 2011-12 National Nutrition and Physical Activity Survey (NNPAS) component of the 2011-13 Australian Health Survey (Table 2). The figures in Table 3 are based on day 1 of the NNPAS, this is a conservative assumption as calculation of 'usual' or habitual intakes of fish and seafood would result in lower daily consumption amount estimates.

It is standard international practice in food chemical risk assessments to assess young children separately due to relatively higher food consumption amounts per kilogram

[1] bw = human body weight

bodyweight compared to older children and adults. In many cases this places them at higher risk of exceeding health based guidance values, however, in the case of crustacean and molluscs, which are not commonly consumed by young children, they would tend to be of lower risk of exposure from consumption of these foods.

In this report, dietary exposure estimates were not undertaken for young children for crustacean (only 8 consumers/779 respondents) as the numbers would not be statistically valid due to small numbers of consumers.

Table 2: Fish, crustacean and mollusc consumption data for the general population (2+ years) and children (2-6 years)

NNPAS Food Code	Food Group Name	Age Group (years)	Number of consumers	Consumers as percentage of respondents* (%)	Consumption (g/day)					
					Mean all respondents	Mean consumers only	P50 (median) consumers only	P90 consumers only	P95 consumers only	P97.5 consumers only
15101	Finfish	2+	543	4.5	5.8	131	110	255	294	366
		2-6	26	3.3	3.3	98	66	220	255	**
15201	Molluscs	2+	76	<1	0.5	79	63	146	180	248
		2-6	0	0						
15202	Crustacean	2+	117	<1	0.9	94	66	250	336	336
		2-6	8	1	0.3	26	17	**	**	**

** Total number of respondents: 2 years and above = 12 153; 2-6 years = 779.*

*** Too few consumers to derive reliable percentile.*

Notes: 2011-2012 NNPAS (National Nutrition and Physical Activity Survey), a 1 day 24-hour recall survey on all respondents with 64% of respondents undertaking a second 24-hour recall on a second non-consecutive day. Day 1 only survey results used for this analysis.

The data was filtered using specific survey food group classification codes: Finfish- fresh or frozen were included; however other types of finfish such as packed finfish (e.g. canned) and battered or crumbed finfish were excluded. Similarly, fresh or frozen crustacean and molluscs were included but packed or crumbed crustacean and molluscs were excluded.

PFOS concentration data used in the dietary exposure assessment

For this assessment, summary analytical results for PFOS in seafood from the areas were used. There were four non-detect values (LOD[2] = 0.0003 mg/kg) for Yellowfin bream samples, two from each area. In assessing the results it was assumed that these with levels below the limit of reporting actually contained PFOS at the limit of reporting to be conservative, i.e. 0.0003 mg/kg.

For contaminants, the international convention for chronic dietary exposure estimates is to use the median concentration value. For this report, dietary exposure estimates based on the median and the highest analytical value are reported, as requested.

Dietary Exposure

For chronic dietary exposure estimates, results are generally reported for the whole population, that is the mean dietary exposure is derived from data for all survey respondents (eaters and non-eaters of the foods of interest), assuming median contamination levels.

However, for sub-populations who may consume more than the average amount and consume on more occasions than the average consumer, for example families of recreational or commercial fishermen, dietary exposure estimates can be undertaken for consumers (eaters) only of the food of interest. Food such as fish, crustacean and molluscs are not staples and are only available seasonally, so they are not likely to be consumed every day over many years even for the most exposed group. The risk assessment is, therefore, based on a worst case scenario where the median consumption of these foods (for people who eat them) is combined with the median concentration levels to estimate exposure. The use of the median concentration level reflects the fact that there will always be a distribution of the contaminant in the foods eaten over time or even in one meal, for example seven to eight prawns (each with a different level of chemical contamination) (~150 g), so it is considered unrealistic to expect each food item consumed to be contaminated at the highest reported level on every eating occasion. However, for this report the estimated dietary exposure for consumers assuming 90th percentile of food consumption is presented as well as median consumption, as requested.

Chronic dietary exposure estimates for PFOS for the whole population and for seafood consumers only are given in Table 3 (all ages) and 4 (children).

[2] LOD = limit of detection

Table 3: Estimated dietary exposure assessment (DEA) for PFOS from fish, prawn and crab consumption – all age groups (2+ years)

Location	Common Name	General population (eaters and non-eaters)		Median consumers (eaters only)		90th centile consumers (eaters only)	
		Median concentration	Highest concentration	Median concentration	Highest concentration	Median concentration	Highest concentration
		%TDI	%TDI	%TDI	%TDI	%TDI	%TDI
Fullerton Cove	**Fish**	0.08	1.0	1.6	19.9	3.6	46.1
Fullerton Cove	**Prawns**	0.1	0.2	11.0	15.7	41.7	59.5
Fullerton Cove	**Crabs**	0.02	0.03	1.5	1.9	5.7	7.3
Tilligerry Creek	**Fish**	0.06	1	1.0	18.9	2.1	38.5
Tilligerry Creek	**Prawns**	0.4	0.4	26.4	30.2	100	114.3
Tilligerry Creek	**Crabs**	0.03	0.09	2.3	6.9	8.7	26.2

Table 4: Estimated dietary exposure assessment (DEA) for PFOS from fish, prawns and crabs consumption – children (2-6 years)

Location	Common Name	General population (eaters and non-eaters)		Median consumers (eaters only)		90th centile consumers (eaters only)	
		Median concentration	Highest concentration	Median concentration	Highest concentration	Median concentration	Highest concentration
		%TDI	%TDI	%TDI	%TDI	%TDI	%TDI
Fullerton Cove	**Fish**	0.2	2.2	3.5	44.0	11.6	146.7
Fullerton Cove	**Prawns**	0.2	0.3	10.4	14.9	nd[1]	nd[1]
Fullerton Cove	**Crabs**	0.03	0.03	1.4	1.8	nd[1]	nd[1]
Tilligerry Creek	**Fish**	0.1	2.1	2.3	41.7	7.7	138.9
Tilligerry Creek	**Prawns**	0.4	0.5	25	28.6	nd[1]	nd[1]
Tilligerry Creek	**Crabs**	0.04	0.1	2.2	6.6	nd[1]	nd[1]

nd = not determined

Risk characterisation

Fish

For the general population, all age groups, estimated dietary exposure from consumption of fish ranges from 0.02-0.27% of the TDI assuming the median PFOS concentration and 0.05-1.05% of the TDI assuming the high concentration, given the results to date. For fishing communities who may consume higher amounts of these foods more often, high level consumption of fish will not lead to an exceedance of the TDI for PFOS, although people in this higher exposure group may be exposed to up to 46% of the TDI.

For children in the general population, estimated dietary exposure from the consumption of fish ranges from 0.05-0.89% of the TDI at the median concentration. For children consuming higher amounts of fish, an exceedance of the TDI did occur for one species of fish (Dusty Flathead) from both areas, although it is noted that this would require a single child to exclusively eat at 220 gram of Dusty Flathead per day, which is not likely.

Prawns and crabs

For the general population, estimated dietary exposure from consumption of either prawns or mud crab ranges from 0.02-0.4% of the TDI assuming the median PFOS concentration and 0.03-0.4% of the TDI assuming the high concentration. For fishing communities who may consume higher amounts of these foods more often, high level consumption of prawns would result in an exceedance of the TDI at both the median and highest concentration (100% and 114.3% respectively). Consumption of mub crab by high consumer will not lead to an exceedance of the TDI (range 5.7-26.2%).

These calculations do not take background dietary exposure from other foods or drinking water into account, however, fish and other seafood are reported to be the major contributors to the diet elsewhere (EFSA 2008). For all populations it is desirable to eat a balanced diet overall.

It is noted that in the general population an odd meal or day when a high amount of fish and/or seafood containing PFOS is consumed would not pose a concern because PFOS has such a long plasma half-life in humans (~5 years). This means it is the total PFOS dietary exposure over a long period of time (circa 20 years) that is of interest in terms of determining the risk to public health and safety.

Maximum amount of fish and crustacea able to be consumed at reported PFOS levels

The results were further assessed by conducting a back calculation to determine the maximum amount of fish or crustacea that could be consumed when the PFOS concentration in the samples were at the median and highest level reported. This involved calculating the kilograms of seafood the different age groups (male and female) would be required to consume before the TDI for PFOS was exceeded. Table 5 shows the estimated maximum consumption amounts for fish and crustacea respectively.

For fish, consumption rates before exceeding the TDI ranged from 150 g (for children aged 2 to 6 at the highest concentration detected) to 11.7 kg (for adults 18 years old plus at the median concentration). Depending on the age group, 60 to 700 grams of prawns would need to be consumed before exceeding the TDI and for crabs, between 300 grams and 4.9 kg would need to be consumed.

Some samples of fish and crabs were collected in close proximity to the current fishing closure. While PFOS was detected in these samples, dietary analysis demonstrates that the TDI was not exceeded by any age group even for high consumers in seafood. For example for the highest fish result, an adult would need to eat 1.9 kg of fish per day and a child (2-6 years old) would need to eat 500g every day to exceed the TDI. These results will continue to be assessed as part of the ongoing investigation of the Williamtown incident.

Table 5: Maximum consumption amounts (kg)

		Age Group (years)									
		2 to 6		7 to 12		13 to 17		18 +		2+	
Location	**Species**	Median concentration	Highest concentration	Median concentration	Highest concentration	Median concentration	Highest concentration	Median concentration	Highest concentration	Median concentration	Highest concentration
Fullerton Cove	**Fish**	1.9	0.15	3.6	0.3	6.2	0.5	7.8	0.6	7.0	0.5
	Prawns	0.16	0.1	0.3	0.2	0.5	0.4	0.7	0.5	0.6	0.4
	Crabs	1.2	0.9	2.2	1.7	3.9	3.0	4.9	3.8	4.4	3.4
Tilligerry Creek	**Fish**	2.8	0.2	5.4	0.3	9.3	0.5	11.7	0.6	10.5	0.6
	Prawns	0.07	0.06	0.1	0.1	0.2	0.2	0.3	0.2	0.2	0.2
	Crabs	0.8	0.3	1.5	0.5	2.5	0.8	3.2	1.1	2.9	0.9

Discussion

This paper provides a preliminary analysis of the results from the limited sampling of fish and crustacea from both Tilligerry Creek and Fullerton Cove that has been undertaken in the last month. It was undertaken primarily to inform the design of a more comprehensive sampling program as part of the larger human health risk assessment. The results demonstrate that some species of fish and crustacea do contribute significantly to the exposure people may have to PFOS and warrant further investigation to ensure sufficient information is available for the comprehensive human health risk assessment.

Over interpretation of these preliminary results at this time should be avoided as:

- The species collected do not represent all species that may be collected for human consumption
- Only one or two samples were collected for some species
- Fish samples relate to an individual fish and not a composited sample of 5 to 6 fish, which is the usual practice when analysing fish for substances such as PFOS to assess dietary exposure.

Conclusion

Based on these results it is concluded that further analysis of a wider selection of seafood is required to inform any further health risk assessment. Further, samples should be collected from a wider area.

Appendix 1: Seafood Results (PFOS)

Site	Common name	Count	Minimum (mg/kg)	Mean (mg/kg)	Median (mg/kg)	Maximum (mg/kg)
Fullerton Cove	Dusky Flathead	4	0.003	0.008	0.005	0.019
	Mud Crab	9	0.001	0.002	0.002	0.003
	School Prawn	8	0.010	0.017	0.018	0.025
	Sea Mullet	2	0.002	0.003	0.003	0.005
	Yellowfin Bream	8	0.0003	0.001	0.001	0.002
Tilligerry Creek	Dusky Flathead	8	0.003	0.008	0.008	0.018
	Eastern King Prawn	2	0.036	0.042	0.042	0.048
	Mud Crab	8	0.001	0.004	0.004	0.011
	Sand Whiting	8	0.001	0.001	0.001	0.004
	Yellowfin Bream	7	0.0003	0.0004	0.0004	0.001

Control results

Fish and seafood were collected from the Fish Markets to provide information on the presence of PFOS in organisms from other locations. The results for these samples are provided below. It is noted that one sample of sea mullet reported a detection.

Common name	PFOS (mg/kg)
Dusky Flathead	<0.0003
Yellowfin Bream	<0.0003
Sand Whiting	<0.0003
Sea Mullet	0.00037
Eastern King Prawn	<0.0003
School Prawn	<0.0003
Mud Crab	<0.0003
Mud Crab	<0.0003

Attachment 1

Advice from FSANZ on a health based guidance value for PFOS

EFSA established a Tolerable Daily Intake (TDI) for PFOS based on the lowest no observed adverse effect level (NOAEL) identified in sub-chronic, chronic and reproduction/ developmental toxicity studies in laboratory animals (EFSA 2008).

The lowest NOAEL, 0.03 mg/kg bw/day, was identified in a sub-chronic (6-month) oral gavage study in cynomolgus monkeys. Changes in serum lipids and thyroid hormones were observed at doses of 0.15 and 0.75 mg/kg bw/day and treatment-related deaths were observed at 0.75 mg/kg bw/day (Seacat et al 2002).

Other NOAELs cited by EFSA were not substantially higher than the above NOAEL of 0.03 mg/kg bw/day. For example, in a chronic (2-year) dietary study in rats, NOAELs were 0.04 and 0.14 mg/kg bw/day for males and females respectively, based on liver histopathology observed at the next higher doses of 0.14 mg/kg bw/day (males) and 0.37 mg/kg bw/day (females). In males, a significant increase in the incidence of hepatocellular adenomas was noted in the high-dose group (7/60; 1.4 mg/kg bw/day) compared to the control (0/60). In the females, a significant increase in the incidences of hepatocellular adenomas (5/60) and combined hepatocellular adenomas and carcinomas (6/60) was observed in the high-dose group (1.5 mg/kg bw/day) compared to the control group (0/60) (Thomford 2002, unpublished; subsequently published as Butenhoff et al 2012).

Based on the above study, EFSA concluded that PFOS is carcinogenic in rats, inducing tumours of the liver. Based on a lack of genotoxicity in a wide range of *in vitro* and *in vivo* assays, EFSA concluded that the weight of evidence indicates an indirect (non-genotoxic) mechanism for carcinogenicity.

Adverse effects have also been observed at relatively low doses in reproduction/ developmental toxicity studies. For example, in a two-generation oral gavage study in rats, a NOAEL of 0.1 mg/kg bw/day was identified based on reduced birthweight at the next higher dose (0.4 mg/kg bw/day). Reduced survival was observed in offspring at doses of 1.6 and 3.2 mg/kg bw/day (the top dose). In the 1.6 mg/kg bw/day group, 26% of the offspring died within 4 days after birth. In the 3.2 mg/kg bw/day group, 45% of the pups died within one day after birth and 100% died thereafter (Christian et al 1999).

EFSA established a TDI of 150 ng/kg bw/day (i.e. 0.00015 mg/kg bw/day) by applying an overall uncertainty factor (UF) of 200 to the NOAEL of 0.03 mg/kg bw/day observed in the cynomolgus monkey study. A UF of 100 was used for inter and intra-species differences and an additional UF of 2 to compensate for the relatively short duration of the study and for uncertainties in the internal dose kinetics.

A search was conducted for toxicity studies on PFOS published after the EFSA search cut-off (February 2008). No reliable studies were located reporting adverse effects at doses lower than the lowest observed adverse effect levels (LOAELs) reported above. Effects on immune parameters were reported in a mouse study, with a LOAEL of 0.0017 mg/kg bw/day and a NOAEL of 0.00017 mg/kg bw/day (Peden-Adams et al 2008), however these findings are not supported by the results of other immunotoxicity studies on PFOS.

FSANZ concludes that the TDI for PFOS of 150 ng/kg bw/day (0.00015 mg/kg bw/day) established by EFSA in 2008 was appropriately derived and that subsequent toxicity data do not indicate a need to amend the TDI. However, FSANZ notes that a TDI is probably not the

appropriate Health Based Guidance Value for a compound which has a long half in several mammalian species (~5 years in humans; Olsen et al 2007). A Tolerable Weekly Intake would be more appropriate.

References

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Attachment 2

Relationship between EPA screening criteria and FSANZ exposure calculations

The EPA screening criteria for biota of 9.1 ug/kg is based on Dutch work undertaken by RIVM (National Institute for Public Health and the Environment) [1]. The methodology used to develop this value is similar to that used by FSANZ. The TDI used is the same but fish consumption and body weights are Dutch rather than Australian. RIVM use a further factor to limit the proportion of the TDI attributable to fish to 10%. This factor appears to be related to data from a Dutch Total Dietary Survey. No comparable dietary survey of PFOS or other PFCs is available for Australia.

The authors note the limit is a screening value and not a health value. We believe the limit has value as a screening criterion with appropriate conservatism to account for other possible sources of PFCs such as contaminated drinking water and locally grown produce/meat. We recommend Defence should consider adopting the 9.1 ug/kg screening value for their studies. However, food exposure assessments should be undertaken by FSANZ.

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26 October 2015

RAAF Williamtown – Guidance and Scoping Information for the Human Health Risk Assessment

1.0 Background

Investigations at RAAF Williamtown have identified the presence of contamination by perfluorinated and polyfluorinated carbon compounds (PFCs) in soil, groundwater, surface waters and biota on and off the site. These chemicals are present due to leaching/ leakage following the use of aqueous film-forming foams (AFFFs) for fire-fighting during training and operations.

The NSW Contaminated Land Management Act and the National Environment Protection (Assessment of Site Contamination) Measure (and supporting policy documents from the NSW EPA) provide the regulatory framework that should be used whenever contamination is to be investigated in NSW (NEPC 1999 amended 2013a, 1999 amended 2013b, 1999 amended 2013c; NSW Government 1997).

The National Environment Protection (Assessment of Site Contamination) Measure (ASC NEPM) provides technical guidance about how to investigate site contamination. Schedule B7 outlines the standard scenarios used in calculating health investigation levels. These standard scenarios cover urban residential sites (low and high density), parklands and commercial/industrial sites. These standard scenarios cover the majority of sites in urban areas. Schedule B4 explains how to undertake site specific risk assessments when a site doesn't fit into these standard scenarios and/or is contaminated with levels of chemicals above the generic health investigation levels (NEPC 1999 amended 2013a, 1999 amended 2013b).

Guidance for human health risk assessment in Australia is also available from enHealth – the national committee of all state, territory and commonwealth health authorities (enHealth 2012).

Schedule B4 from the ASC NEPM and the enHealth guidance outline that a human health risk assessment involves the following steps:

- Problem formulation/issue identification
- Hazard/toxicity assessment
- Exposure assessment
- Risk Characterisation

Data Review, Evaluation and Issue Identification

This initial process involves reviewing all the available data to define the risk issues (including chemicals of potential concern [CoPC]) that require detailed evaluation within the HHRA. Typical data to be considered here includes information about chemicals present, the levels present, geology, hydrogeology, site history, site remediation, land use (on-site and in surrounding areas). A conceptual site model should be developed as part of this step.

Hazard / Toxicity Assessment

Once the chemicals present at a site have been identified a review of the characteristics of the chemical and the toxicity of the chemical is required. A toxicity and dose response assessment is conducted to identify the potential human health effects and appropriate quantitative guidelines or toxicity reference values for the chemicals being investigated that can be used to evaluate the risk issues identified.

Exposure Assessment

A human health risk assessment (HHRA) needs to determine what concentration of a chemical people might be exposed to as they interact with the site, or in the surrounding area where contamination has moved off-site. The exposure assessment involves consideration of the chemical concentrations of PFCs in relevant environmental media (like soil, groundwater, food) and uses relevant models (see below) to estimate the

amount of chemical to which a person may be exposed. The presence and levels of other chemicals, known to be hazardous to human health and likely sourced from the RAAF base, will be determined in ground water.

Risk Characterisation

The findings of the previous steps are used to provide a quantitative assessment of health risk. The concentration/dose to which people are exposed is compared to the concentration/dose that is likely to be safe to determine the acceptability of the risk. The characterisation of risk also includes consideration of the uncertainties in the assessment when presenting conclusions and any recommendations.

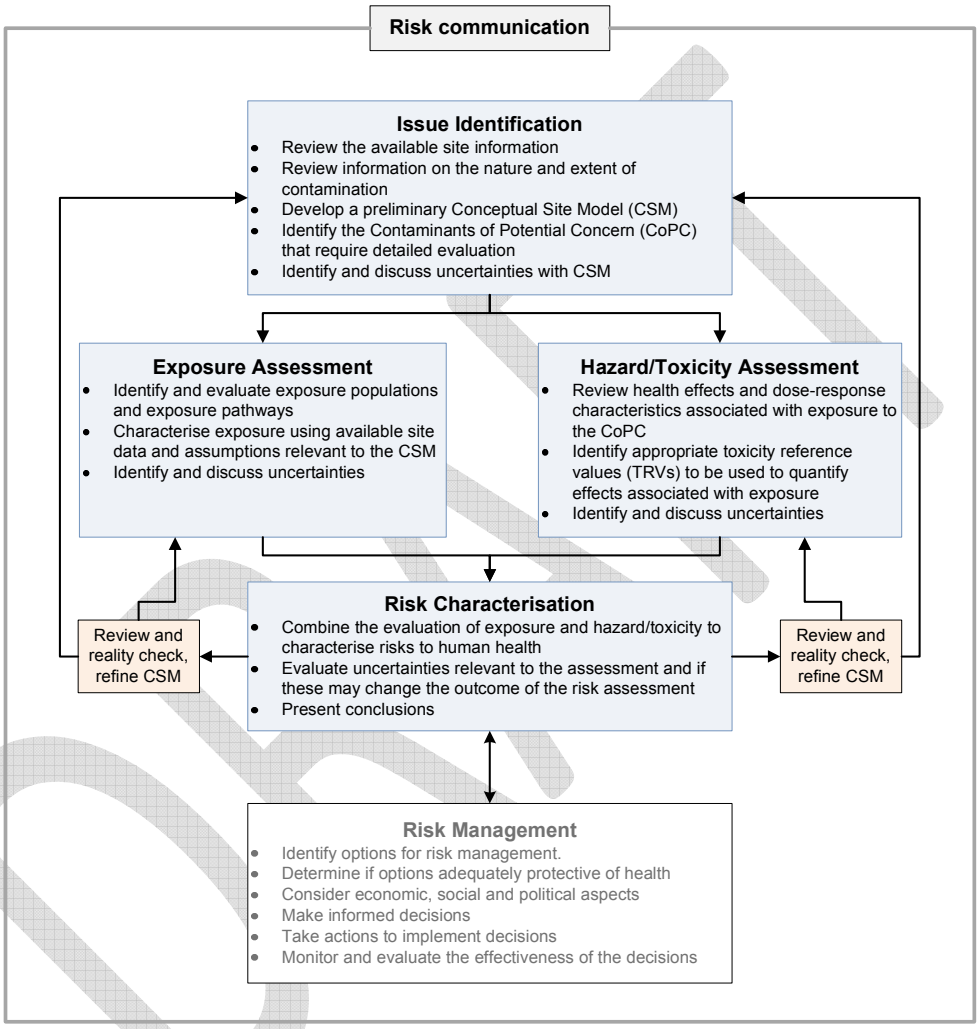

Figure 1 **Human Health Risk Assessment Framework** (enHealth 2012)

2.0 Considerations for the Site Specific Risk Assessment

The area surrounding the RAAF Williamtown site does not really meet the description for low density urban residential areas (the most conservative scenario) used in the ASC NEPM. The Williamtown area is more rural than assumed in the ASC NEPM. Community consultation and government agencies have identified that there are a range of commercial food production activities occurring in the area (crops, livestock and seafood). Also recreational fishing, significant home vegetable gardens and the keeping of small numbers of livestock for personal use all occur in the affected area.

A human health risk assessment to be undertaken as part of the contamination investigation for this site needs to consider a much wider range of potential exposure pathways than is normally required for urban sites. Exposure pathways that may need to be considered include:

Off-site

- Consumption of fish or other seafood (oysters, prawns, crabs, pippi, shellfish, etc) from affected waterways (commercial and recreational production)
- Consumption of affected water for drinking and other potable uses
- Direct contact with surface water
- Direct contact with groundwater
- Dermal absorption when swimming in pools filled with groundwater
- Dermal absorption from water when wading or swimming in Tilligerry Creek or Fullerton Cove
- Consumption of eggs produced by potentially affected fowl (commercial and domestic production)
- Consumption of milk produced by potentially affected livestock (commercial and domestic production)
- Consumption of meat from potentially affected livestock (commercial and domestic production)
- Consumption of vegetables grown using the affected water for irrigation (commercial and domestic production)
- Consumption of fruit grown using the affected water for irrigation (commercial and domestic production)
- Consumption of crops grown using the affected water for irrigation (commercial production)
- Consumption of traditional food items produced using affected water or harvested from affected areas (e.g. pippi or wild oysters)
- Consumption of honey produced by bees in contact with affected surface water (commercial and domestic production)
- Consumption of juices produced using fruit and/or vegetables grown using affected water for irrigation (juice production has potential to concentrate the chemicals)
- Inhalation of dust
- Inhalation of volatilised chemicals during use in sprinklers or showers
- Direct contact with soil (unlikely off-site)
- Direct contact with sediments

It has not been determined that all of these pathways of exposure are expected to be significant for people living near the RAAF Williamtown base nor has it been established that commercial food production occurs in the area in all the categories listed.

The human health risk assessment for the current situation will need to consider each of these pathways. This may involve a full assessment of a particular exposure pathway based on sampling results and relevant models or it may involve justification as to why the pathway is unlikely to be important. The need to consider such a wide range of exposure pathways means that the environmental investigation being undertaken to inform the human health risk assessment will need to target a wide range of sample types to provide the data required.

The other issue that will need to be considered in the risk assessment that is somewhat different to normal urban contaminated land assessments is how to combine the numerous exposure pathways in a sensible fashion covering the more extreme end of possible exposures as well as the average case. Normal methods of risk assessment would take the largest risk for each relevant exposure pathway and sum the risks to determine the total risk posed by the contamination. Such an approach won't work here because the contamination is widespread and different activities occur in different parts of the affected area.

Prior to proposing how the risks will be combined, it will be important to seek input from the community about what exposure pathway combinations make sense for them. Once such input has been received and considered a proposal for combining the risks should be discussed with the regulators. Along with one or more maximum cases, the inclusion of one or more average cases should also be proposed.

3.0 Physico-chemical characteristics

Perfluorinated compounds have an unusual mix of characteristics that make them likely to be present in a wide range of environmental compartments. The fire-fighting foams are made up of a large number of different chemicals. PFOS and PFOA are present in the foams and are breakdown products of many of the other chemicals in the foams so they are important to target. Initial investigations have also highlighted that PFHxS may also be present at sufficient levels to be added to the list of primary analytes.

Under environmental conditions (neutral pH) PFOS and PFOA are in ionised form. They are likely to remain in ionised form even if the pH drops in the presence of acid sulfate soils. These chemicals are also both hydrophobic and lipophilic (i.e. able to act as surfactants/detergents). These characteristics mean they behave differently to other types of organic compounds. Other chemical characteristics are provided in **Table 1**.

Table 1 Physico-Chemical Characteristics of some PFCs

Characteristic	PFOS	PFOA
Molecular Weight	500 g/mol	414 g/mol
Water Solubility	0.21 mg/L	1.74 mg/L
Vapour Pressure	3.46 Pa	4.19 Pa
Unitless Henrys Law Constant	0.004	0.004
Log Kow	2.45	1.92
Bioconcentration Factor (Fish Carcass)	1100	4
pKa	--	1-2

Notes:

Sourced from RAIS (http://rais.ornl.gov/) (RAIS) or (Ding & Peijnenburg 2013)

The characteristics of these chemicals mean the major route of exposure is likely to be ingestion.

The presence of PFOS and PFOA as ionised molecules or having surfactant characteristics under environmental conditions means they are unlikely to be volatile. However, quite a number of the other PFCs that can be present in firefighting foams (e.g. teleomer alcohols) are considered volatile so exposure via inhalation of vapours will need to be explored in the risk assessment.

There is some evidence that only very small amounts of PFOS and PFOA are absorbed through the skin so exposure via the dermal route is likely to be small especially when they are in ionised form. It will need to be included in the calculations. Also the potential for some of the other PFCs to be absorbed via the skin will need to be considered in the risk assessment as other PFCs may be more readily absorbed through the skin given that they may not be ionised (ATSDR 2015; deWitt. J.C. 2015).

Animals take up these chemicals via the food they eat, the water they drink or the water in which they live. Environmental monitoring of a wide range of animals has found that PFCs are often present (deWitt. J.C. 2015). Studies have also shown that PFCs may be taken up into plants. Some studies have shown that they are more concentrated in the vegetative parts of a plant (leaves and stems) rather than in storage organs (deWitt. J.C. 2015; Stahl et al. 2009). Exposure to PFCs via consumption of plants and animals that may have been contaminated will need to be considered in the risk assessment.

It is likely that a comprehensive suite of PFCs are present due to the source, therefore the full list of PFCs should be analysed for in an agreed percentage of samples. Additionally, airports also use a range of other chemicals for operation and maintenance of aircraft including fuels, degreasers etc. Groundwater and surface water samples should also include analysis of volatile organic compounds (VOCs) to assess concentrations of benzene, toluene, ethylbenzene, xylenes, trichloroethene and tetrachloroethene.

4.0 Fate and Transport of the Contamination

A priority for the investigation is to determine where the contamination is present, where it is not present, where it may move to in the future and how fast it may be moving. This information is critical to determining where monitoring should occur and what media/biota should be monitored to provide adequate information for the risk assessment.

The hydrogeology beneath and in the vicinity of RAAF Williamtown is dominated by aquifers hosted within the Quaternary Tomago and North Stockton Sandbeds, which in cross-section are presented as south-east dipping inner and outer barrier sand deposits within the Newcastle Bight. The aquifers within the sandbeds are partially separated by an estuarine mud aquitard consisting of the Tilligerry Mud Member (although this deposit is inferred to pinch out towards the southeast). The Tomago Sandbeds are underlain by the Meadowie Clay Member consisting of low permeability estuarine deposits containing channel-fill sand lenses. The unconsolidated deposits are underlain by rocks of the Permian-age Tomago Coal Measures.

The aquifers associated with the sandbeds consist predominantly of fine-grained marine and Aeolian dune sand deposits, and are broadly characterised as high permeability, high yielding aquifers. Groundwater recharge occurs via direct rainfall infiltration into the sandbeds, with groundwater flow in the vicinity of the RAAF base regionally depicted as southeast towards the coast. Groundwater discharge is likely to occur at the coast, and into surface water bodies such as Fullerton Cove and Tilligerry Creek. A network of agricultural drains is also present in the vicinity of the RAAF base, which may variably act as sources and sinks for groundwater depending on the flood stage in the drains.

Experience in similar depositional settings suggests that the relatively simple regional-scale conceptual hydrogeological model is likely to exhibit a greater degree of complexity on a local scale due to (for example) small-scale depositional variations and the presence of indurated layers within the sand profile. These features may be negligible with regard to regional groundwater flow, but have the potential to be significant for site-scale contaminant fate and transport. Groundwater flow is also expected to be locally influenced by an extensive water supply borefield operated by Hunter Water within the Tomago Sandbeds.

To suitably inform the development of the HHRA, sufficient samples will need to be collected to:

- Define the limits of the impacted area;
- Fill gaps in the spatial coverage;
- Obtain samples from a number of depths at some locations in order to assess variability due to small-scale lithological hydraulic conductivity variations; and
- Target locations where there is a need for better understanding of connectivity between surface water and groundwater.

To meet the objectives of the HHRA, the groundwater sampling locations will need to provide:

- Data to develop an acceptable conceptual site model; and
- Exposure-point concentrations required for the initial HHRA.

5.0 Monitoring

A wide range of monitoring will be needed for this investigation. Also the monitoring will need to be designed with sufficient statistical considerations to properly inform the risk assessment.

Water

Groundwater and surface water monitoring in the affected area needs to be sufficient to:

- determine where these chemicals are present;
- determine the maximum and average concentrations of the chemicals; and
- inform the hydrological modelling.

As a result, it is possible that monitoring will be required in some locations for the purpose of hydraulic modelling and in quite different locations to determine concentrations relevant for use in the risk assessment.

The number of locations and the frequency of monitoring at each location for surface and groundwater will need to be determined based on the conceptual site model developed by the Water Sub-Group and the variability information that can be determined in analysing the existing groundwater and surface water dataset. Based on the current understanding of the surface and groundwater hydrology, both systems

change rapidly in response to rainfall events, with surface water–groundwater interactions influenced by the operation of the flood gates on the agricultural drains. A number of rounds of monitoring will be required to get a robust estimate of average exposure and also to assess concentrations in surface and groundwater before, during and after rainfall to ensure appropriate understanding of the worst case conditions.

Biota – Fish/Seafood

Previously, a large study of persistent chemicals in fish in Sydney Harbour involved the collection of up to 50 fish at each location which were composited into 5 replicates of 10 fish. Each of the five composites was analysed to get a robust estimate of the average concentration people might be exposed to when they consume fish. These average concentrations were then used in assessing risk and determining the need for closures or advisories.

Fish and seafood are likely to be a more significant contribution to people's exposure so more extensive sampling is needed to fully understand the extent of exposure that needs to be considered in the risk assessment. Given the results to date, detailed investigation of levels in fish and other seafood will be needed. Monitoring needs to make use of composite samples of a wide range of species from a number of impacted and non-impacted estuaries. **Figures 1** and **2** show the locations which should be targeted in the impacted estuaries – a total of 10 locations. The locations extend out into Port Stephens and up river to Hexham to enable mapping of the potential extent of the contamination. For each targeted location 4 composite samples will be required for each species. The composites should be made up of 6-10 individual animals for fish and crabs. For prawns each composite should be made up of sufficient animals to an appropriately sized sample. The laboratory needs approximately 20 g wet weight for the analysis. The fish should be analysed with skin on but with scales removed. The prawns should be shelled, but analysed without deveining.

The species that should be targeted include:

- sea mullet
- school prawns
- king prawns
- bream
- sand whiting
- mud crab
- blue crab
- dusky flathead
- luderick
- silver biddy

This sampling design involves the collection of 40 composite samples (10 species x 4 composites) at each of 10 locations. Sampling needs to commence immediately as many of the required species are available at this time but will not be as readily available in a few months' time. Due to seasonality and species habitat preferences, all species may not be able to be collected from all sites.

Collection of the fish and seafood needs to be arranged and supervised by DPI-Fisheries.

Lake Macquarie is not a suitable reference location as there are large range of other types of industries that may use these chemicals so measurements in fish from Lake Macquarie may not indicate background levels. Wallis Lake and/or locations on the far south coast of NSW (such as Batemans Bay) are relevant reference locations for sites that are unlikely to be affected by PFCs (negative controls/background).

Biota – Agricultural Products

Given the rural nature of the affected area, a wide range of foods will need to be assessed to determine if they are contaminated with PFCs and whether they are consumed at a rate that could make a significant contribution to exposure. The foods that may make a contribution to exposure which have been identified to date, other than fish and other seafood, include:

- eggs
- milk – dairy, goat
- meat – beef, goats, sheep, chickens, pigs
- vegetables – green/leafy, root, tuber
- fruits – tree, ground
- traditional foods – to be identified through consultation
- honey
- crops – cereals

In the first instance potential worst case locations will need to be identified informed by the conceptual site model developed by the Water Sub-Group and by the results from the groundwater and surface water monitoring. Consultation with the community and relevant sub-groups (e.g. Aboriginal community) will then be needed to map what is being grown in what areas across the affected area. Once the worst case locations are identified, a range of species must be chosen for monitoring guided by the mapping of what occurs in the relevant locations.

The questions that need to be answered to allow this program to be appropriately designed include:

- what is being grown or kept?
- what are people eating?

For each species in each food type at least 6 composite samples should be collected made up of at least 4 individual samples (plants, animals or substances) to get a robust estimate of average concentrations.

It should be noted that in the affected area food production occurs on both a domestic basis and a commercial basis for some food types. Both types of production will need to be individually targeted as they may involve different activities (e.g. levels and frequency of watering) which may increase or decrease the potential for exposure to these chemicals.

The potential for concentrating the contamination when juicing fruits or vegetables will also need to be considered in the monitoring program.

If samples from agreed appropriate locations indicate that some food types are not affected by PFCs, those food types will not require further assessment.

For food types that are affected by PFCs additional monitoring locations may be required to determine the geographical extent to which they are affected.

Other types of samples

There are a range of other sample types that do not need to be collected **at this stage** but which are likely to be needed at a later stage in the investigation. Soil, sediments, suspended sediments and pore water do not need to be collected in this first phase of the investigation as current monitoring needs to focus on direct estimates of exposure to minimise the use of modelling. This approach is required given that analysis of samples at the laboratory is the rate limiting step. In the first instance, the laboratory needs to be analysing the samples most necessary for the HHRA.

Ongoing Monitoring

The monitoring program to be conducted over the next three months will inform a comprehensive human health risk assessment of the current situation but, as with other large contamination issues in NSW, ongoing regular monitoring will also be needed.

Another large groundwater contamination incident in NSW (the Orica Botany Groundwater Plume) is required to undertake quarterly monitoring of groundwater and surface water to ensure that the pump and treat remediation being used is achieving containment and that no other changes are occurring in the aquifer that would change the risk profile. Initially, this regular monitoring included a large number of groundwater wells and other types of monitoring. For this other site as understanding of the aquifer and

contamination has increased and confidence in the remediation tools has improved, the size of the regular monitoring program has been reduced to a much smaller number of critical wells and parameters.

For the Williamtown area, the ongoing regular monitoring will need to be quite broad initially. Once a more complete understanding of the hydrology affecting the contamination and the extent of the contamination is achieved, along with which types of food may be most affected, the size of the ongoing program can be revisited.

Laboratory

The samples collected in September and October 2015 have been analysed at the National Measurement Institute in North Ryde. To maintain consistency it would be preferred that the fish and seafood continue to be monitored at this laboratory. The use of other laboratories should be discussed prior to commencement.

6.0 Timeline

The temporary bans and advisories that have been put in place are impacting on the local community. The comprehensive human health risk assessment is needed to determine what risk control measures, if any, need to be put in place more permanently. It is, however, understood that there are limitations as to how quickly the assessment can be undertaken.

It is expected that the work will require a timeline as outlined in the following table.

Task	Time Required
1. Sample collection	2-3 months
2. Laboratory analysis (50 biota samples per week plus time for equipment maintenance)	5-6 months (occurring simultaneously with 1.)
3. Data analysis	1 month
4. Consultation and preparation of report	1 month

Some of these tasks can be undertaken in parallel which will contract the timeline somewhat. The number of biota samples expected is of the order of 1000-1200 initially making the time required by the laboratory to complete the analysis the rate limiting step for completion of this work.

This timeline is already quite long given the need to provide advice to the community. It will be important that no delays in this timeline occur. This will require proactive project management and regular meetings with the regulator.

7.0 Models, Exposure Assumptions and Toxicological Profiles

A range of models are available to calculate human exposure for use in risk assessments. Guidance is available from the ASC NEPM but also in a range of other documents from Australia and other jurisdictions.

The models to be used and the values to be used for the various exposure assumptions required for the modelling need to be discussed with the regulator prior to beginning the risk assessment calculations. Which models and which exposure assumption parameter values are most appropriate for use in this risk assessment will be determined by the type of exposure scenarios to be assessed. The detail of the exposure scenarios will depend on how all the exposure pathways are to be combined which must come out of community consultation given the inclusion of many less common exposure pathways. This aspect of the risk assessment process requires further consideration and discussion.

The toxicological profiles for these chemicals can be prepared and discussed with the regulator while the laboratory is analysing the samples. It will be important to reach agreement about which toxicity reference values are to be used in the human health risk assessment prior to any calculations.

The use of surrogates – such as estimating meat concentrations from blood measurements – would need detailed validation to be acceptable for use in this human health risk assessment. Given the novel chemistry and the limited available toxicological information, using surrogates or other methods for filling data gaps will be of limited use.

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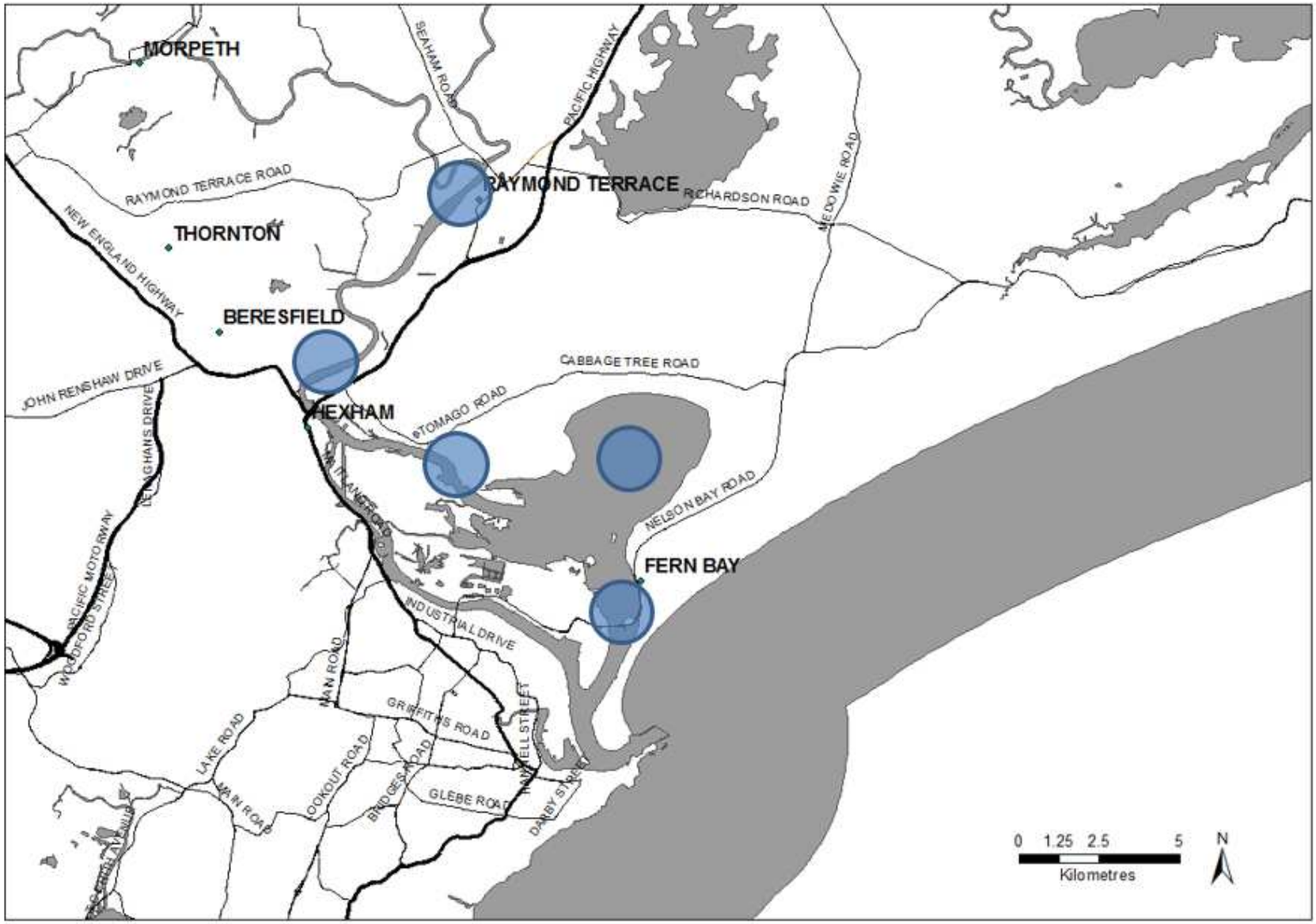
FIGURE 1

Five locations in Port Stephens, 4 composite samples from each location. Each composite comprised of 6-10 animals (or ~100 grams of prawns). Species to include from all locations: sea mullet, school prawns, king prawns, bream, sand whiting, mud crab, blue crab, dusky flathead, luderick and silver biddy.

FIGURE 2



Five locations in Hunter River, 4 composite samples from each location. Each composite comprised of 6-10 animals (or ~100 grams of prawns). Species to include from all locations (if possible): sea mullet, school prawns, king prawns, bream, sand whiting, mud crab, blue crab dusky flathead, luderick and silver biddy.