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 not grown under the same strict control as farmed oysters and as such it is advised not to consume wild oysters.

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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

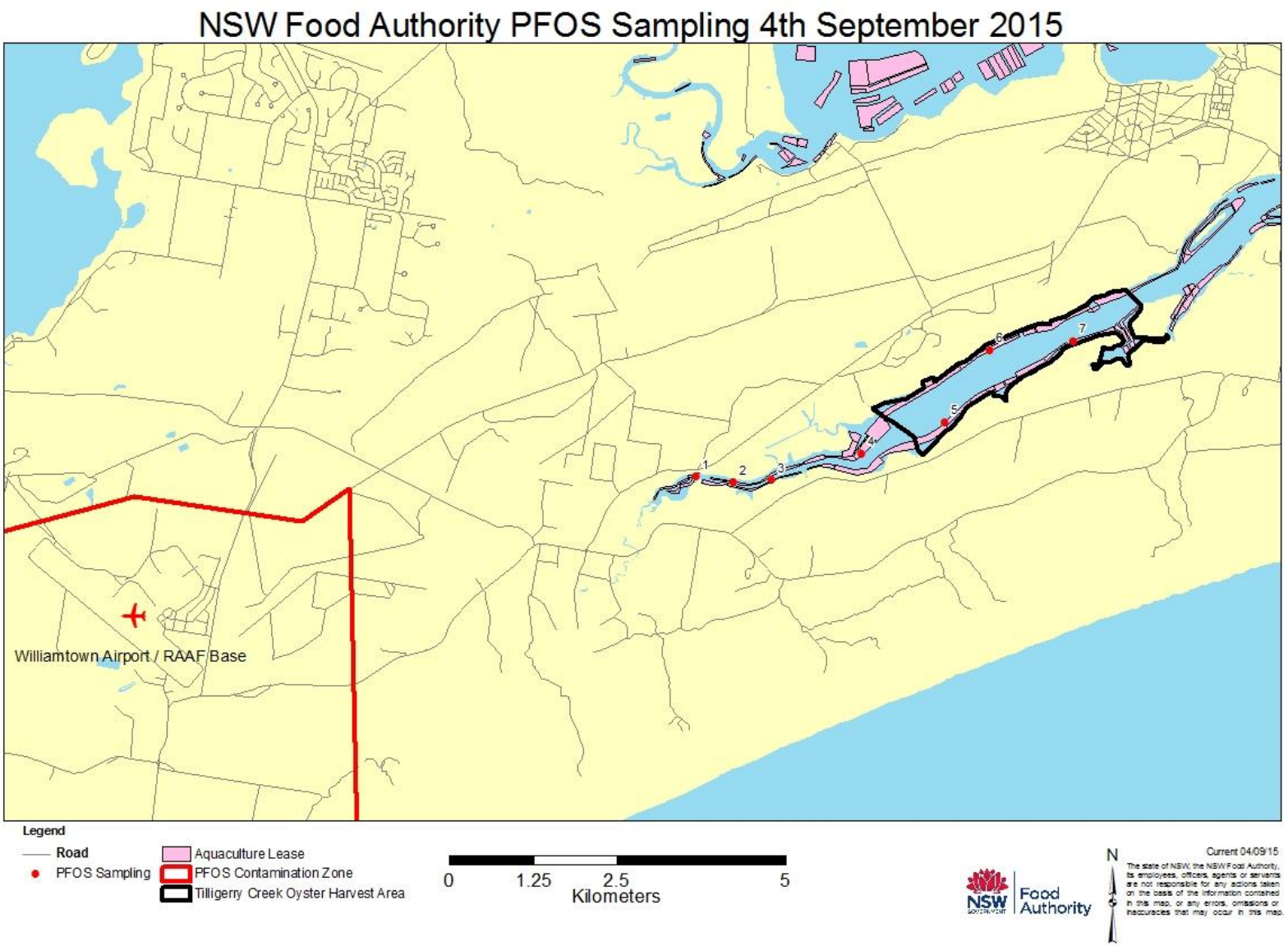
The Tilligerry Creek Harvest Area is located within the Port Stephens Shellfish Program Area. Tilligerry Creek is approximately 17 kilometres long. Upper Tilligerry is divided into two oyster production zones. Zone 5A is in the upper reaches of the creek and is a nursery area only, meaning oysters must 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 over the page.

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
Williamtown Airport / RAAF Base
1
2
3
4
5
6
7
Legend
Road
PFOS Sampling
Aquaculture Lease
PFOS Contamination Zone
Tilligerry Creek Oyster Harvest Area
0
1.25
2.5
5
Kilometers
NSW Food Authority
N
Current 04/09/15
The state of NSW, the NSW Food Authority, its employees, officers, agents or servants are not responsible for any actions taken on the basis of the information contained in this map, or any errors, omissions or inaccuracies that may occur in this map.

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

[1] bw = human body weight

guidance values need to be established. Consequently, there is no need for an acute dietary exposure assessment.

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.

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 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

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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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.