Contamination of Australian Defence Force facilities and other Commonwealth, state and territory sites in Australia

Submission 122

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Via Website Submittal

Mr. David Sullivan Committee Secretary Senate Foreign Affairs, Defence and Trade References Committee P.O. Box 6100 Parliament House CANBERRA ACT 2600

Subject: The Submission to the Senate Standing Committee on Foreign Affairs, Defence and Trade – Contamination of Australia's Defence Force Facilities and other Commonwealth, State and Territory Sites in Australia – Submission for Part B of the Terms of Reference

Dear Mr. Sullivan:

Thank you for allowing the public to provide comments to the Senate Committee on Foreign Affairs, Defence and Trade inquiry relating to the environmental presence of perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) at certain Australian Defence Force facilities and other sites in the country.

3M has already been in contact with representatives of various Australian agencies, including the New South Wales EPA, about these chemicals and its aqueous film-forming foam (AFFF) products. We recently provided comments to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) in connection with its analysis of the chemical compounds in question.

A. The Science of Perfluorinated Compounds

For more than 40 years 3M manufactured a class of eight-carbon perfluorinated compounds (PFCs¹) that were used in life improving products, including AFFF.

These chemicals are important because their unique properties make them effective as, among other things, fabric and carpet treatments, surfactants, fire extinguishing agents, and high performance materials used in the aviation industry.

¹ The acronym PFCs appears to be commonly used by Australian agencies and will be used herein for consistency. However, this class of compounds is also accurately referred to as Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS, Buck et al. 2011).

3M Light Water AFFF, a fire suppressant, was widely recognized as the best product in its class. Often referred to as a "miracle product," it was utilized by the military, airports, fire brigades, and others in Australia and around the world to suppress fuel-fed fires. The products are widely credited with saving lives.

The chemical bond between carbon and fluorine atoms in perfluorinated compounds is exceptionally strong, so the molecules do not easily degrade. These compounds are widely distributed in the environment. Like many other substances we have in our bodies, certain perfluorinated compounds remain in the blood of humans for several years.

In the late 1990s, 3M learned that trace amounts (at parts-per-billion levels) of certain perfluorinated compounds, including a "C8" compound², PFOS, were detected in the blood of the general population. At that time, 3M correctly believed that these compounds are not hazardous to human health at the levels typically found in the environment or in human blood.

Nonetheless, in May 2000, 3M announced that it would voluntarily exit the production and use of these long-chain perfluorinated chemistries. This decision by 3M was well ahead of its competitors and ahead of any regulatory action requiring such action. Thereafter, 3M voluntarily exited the AFFF market in Australia and the rest of the world (approximately a decade ago).³

Since it phased out of these chemistries, 3M continued to research the health effects, or lack thereof, resulting from typical exposure to PFOS and PFOA. The findings that have come from this research are widely accepted in the scientific community and used in the development of regulatory guidance in other jurisdictions.

B. Human Health Research

After more than 30 years of medical surveillance and epidemiological studies, 3M's research indicates no adverse health effects in its employees resulting from occupational exposure to these compounds. This is important because the level of PFC exposure in the general population is hundreds, if not thousands, of times lower than that of 3M production employees who worked directly with these materials.

We believe that PFOS and PFOA do not present health risks at the levels they are typically found in the environment or in human blood. According to a significant body of scientific literature, there is no proven causal relationship between PFC exposure and adverse human health effects.

Some entities have stated that there is evidence that exposure to PFOS and PFOA "causes" cancer. Such representations usually come from a lack of understanding of the scientific literature.

² C8 compounds are those fluorinated compounds that have eight carbons in their carbon chain.

³ We notice this inquiry, in part, pertains to PFOA and its salts. Please note that 3M's Light Water AFFF products did not contain these compounds. However, AFFF products manufactured and sold by others may have contained PFOA or PFOA-based compounds.

There are many reasons why a particular health effect may be seen as more prevalent when PFOS or PFOA exposure is greater without that statistical association being the result of a causal connection. For example, using too small a number of observations or having another unknown factor influence both variables at the same time. Many scientific authors acknowledge this in their papers. However, these limitations are not always fully appreciated by the general public.

For example, the findings of the C8 Science Panel are often referenced to support statements of causal links between PFOA and cancer. The C8 Science Panel (now disbanded) was a group of three epidemiologists commissioned by a state court in the state of West Virginia in the United States, in the context of the settlement of a lawsuit involving DuPont (http://www.c8sciencepanel.org/). Their charge was to assess whether a "probable link" exists between PFOA exposure and 47 human diseases.

The study involved approximately 70,000 people (from a Mid-Ohio Valley community) who were reportedly exposed to elevated levels of PFOA for an extended period of time.

In the few instances where the C8 Science Panel purportedly found "probable links" between PFOA exposure and human illnesses, its researchers acknowledged that "...as more scientific evidence accumulates, some associations may not be confirmed." Accordingly, the only entities that agreed to abide by the C8 Science Panel's conclusions were the settling parties to the lawsuit.

The six disease categories for which the C8 Science Panel concluded that there was a "probable link" to PFOA exposure are: high cholesterol, ulcerative colitis, thyroid disease, testicular cancer, kidney cancer, and pregnancy-induced hypertension.

A "probable link" is not a "causal link" between exposure and disease. A "probable link" is merely a "more likely than not" association between exposure and a given disease in the cohort being studied. Such an association says nothing about causation between disease and exposure to PFOA. Importantly, many other studies have failed to demonstrate these same associations.

Overall, the C8 Science Panel findings do not change the position of 3M that PFCs, such as PFOS and PFOA, do not cause illness in humans at typical levels of environmental exposure.

Please note that Chang et al. (2014) performed a critical review of cancer risk based on multiple epidemiological studies, including the C8 studies, and concluded: "Taken together, the epidemiologic evidence does not support the hypothesis of a causal association between PFOA or PFOS exposure and cancer in humans." Subsequently, Chang et al. (2016) performed a critical review of immunological health conditions, also based on multiple epidemiological studies, including the C8 studies, and concluded: "Thus, the available evidence is insufficient to conclude that a causal relationship has been established between PFOA or PFOS exposure and any immune condition in humans."

Similarly, Kennedy and Symons (2015) conclude: "Studies of specific tumor types among populations exposed to low levels of PFOA and PFOS have shown equivocal results for a variety of specific cancer outcomes with no consistent associations reported."

In recognition of the specific nature of the C8 Science Panel's charge, the Minnesota Department of Health (MDH) has stated that the findings of the panel "are part of a court settlement and not a definitive scientific conclusion." With respect to the many other studies that have occurred, the MDH has stated, "...results have not shown consistent evidence that exposure to PFCs causes specific illnesses in people."

Beyond the C8 Science Panel, some researchers and media reports have cited the results of animal studies as "proof" that PFCs may be harmful to humans.

Such reports often fail to mention that animals, to the extent they were affected, were typically exposed to extremely high doses of PFCs. In fact, the very purpose of such animal studies is to escalate the administered dosage of the PFCs under laboratory conditions *until* an adverse biological response is observed.

In the view of 3M and many researchers, these animal studies confirm that PFCs, such as PFOS and PFOA, do not present harm to human health at typical environmental levels of exposure.

C. Findings of Third-Party Experts

Many regulatory agencies, scientists and researchers have responded to public interest in PFCs and the health effects associated with their presence in the environment and in human blood.

For example, the Minnesota Pollution Control Agency reports on its website that: "Studies of 3M workers exposed to PFOS and PFOA during manufacturing show no apparent impact on their health."

In addition, according to a Minnesota Department of Health report, "PFC Risk Assessment," dated May 30, 2007, "There are no specific levels of PFCs in human blood that have been associated with adverse health effects." The MDH has recognized that the mere presence of PFCs does not equal harm.

The U.S. Centers for Disease Control and Prevention states clearly, "Finding a measurable amount of PFCs in serum does not imply that the levels of PFCs cause an adverse health effect."

In Sweden, where there has been ongoing interest in the presence of PFCs in the environment and in human blood, researchers have repeatedly assured the public there is no health concern.

A report authored by Kristina Jakobsson, MD, Ph.D. an associate professor at the Department of Occupational and Environmental Medicine at Lund University in Sweden, dated June 12, 2014, observed, "The new results do not change the previous risk assessment – that there is no risk of urgent negative health effects and there is no expectancy of individual cases of sickness connected directly to the drinking water."

In July 2015, the IVL Swedish Environmental Research Institute announced its final report of the RE-PATH project, titled, "Risks and Effects of the dispersion of PFAS on Aquatic, Terrestrial and Human populations in the vicinity of International Airports" (Norstöm et al. 2015)

The research project, conducted from 2009 – 2014, examined the long-term consequences of the use of AFFF at Göteborg Landvetter Airport and Stockholm Arlanda Airport. The report stated, "No risk for human health effects caused by intake of PFOS via water or fish consumption has been identified in the studied areas, using the current TDI level (150 ng/kg body weight)."

D. In Summary

Limited information is available regarding the presence of PFOS and PFOA in the Australian environment (Houde et al. 2011, CRC CARE 2014). However, one study completed by Thompson et al. (2011a) suggests concentrations of these chemicals in Australian urban areas is similar to international urban concentrations.

This study measured PFOS and PFOA concentrations in several environmental media in Sydney Harbor, which is surrounded by the largest urban center in Australia. The average PFOS and PFOA concentrations in surface water were 14 ng/L and 5.7 ng/L, respectively. These measurements are comparable with concentrations in urban areas from Germany, Korea, and Japan (Thompson et al. 2011a). The maximum PFOS concentration in sediment (6.2 nanograms per gram [ng/g]) is comparable with the higher end of the range of international studies from urban areas (including studies in Korea, Japan, China, and the United States) and PFOA was only detected in 20% of samples, at low concentrations (Thompson et al. 2011a).

The PFOS and PFOA concentrations in sea mullet from Sydney Harbor are in the midrange of concentrations measured in Korea, Brazil, and the Mediterranean Sea (Thompson et al. 2011a). The study concluded that: "In all media the concentrations were comparable with similar samples internationally. Based on the concentrations observed, coupled with the currently limited evidence for adverse biological effects at these concentrations, we found little evidence of potential risks to humans or wildlife due to the presence of [PFOA, PFOS, and related chemicals] in Sydney waterways."

In sum, data from Sydney Harbor suggest environmental concentrations in Australia are on par with average concentrations worldwide. In addition, typical drinking water concentrations are far below the guidance levels set in other jurisdictions like the United States and Germany (Thompson et al. 2011b) and human blood serum concentrations are declining (Toms et al. 2014), much like in many other countries (Kato et al. 2015).

3M thanks the Committee for allowing us to submit these comments. Our company has long been at the forefront of researching these compounds – and will continue to work collaboratively with scientists, regulators, and other stakeholders to promote the research of a broad range of chemicals. There is nothing as important to 3M as the safety of its people, its customers, and the public at large.

Thank you for the opportunity to share this information.

Sincerely,

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References Cited

Chang, E.T., H.O. Adami, P. Boffetta, P. Cole, T.B. Starr, and J.S. Mandel, 2014. A critical review of perfluorooctanoate and perfluorooctane sulfonate exposure and cancer risk in humans. *Crit Rev Toxicol* 44(Suppl 1):1–81.

Chang, E.T., H.O. Adami, P. Boffetta, H.J. Wedner, and J.S. Mandel, 2016. A critical review of perfluorooctanoate and perfluorooctanesulfonate exposure and immunological health conditions in humans. *Crit Rev Toxicol* DOI: 10.3109/10408444.2015.1122573.

CRC CARE, 2014. *Environmental impact of priority contaminants: A literature review.* Cooperative Research Centre for Contamination Assessment and Remediation of the Environment, Technical Report series, no. 29. January 2014.

Houde, M., A.O. De Silva, D.C. Muir, and R.J. Letcher, 2011. Monitoring of perfluorinated compounds in aquatic biota: an updated review. *Environ Sci Technol* 45:7962–7973.

Jakobsson, K., K.K. Diab, C. Lindh, B. Persson, and B. Jönsson, 2014. Exposure to Perfluoride Substances (PFAS) in Drinking Water in Ronneby Municipality. Occupational and Environmental Medicine, Medicine Services, Region Skåne, in collaboration with the Faculty of Medicine at Lund University, June 2014.

Kato, K., X. Ye, and A.M. Calafat. 2015 PFASs in the General Population. In *Toxicological Effects of Perfluoroalkyl and Polyfluoroalkyl Substances*, edited by Jaime C. DeWitt. New York: Humana, 51-76.

Kennedy, G.L. and J. M. Symons, 2015. Carcinogenicity of Perfluoroalkyl Compounds. In *Toxicological Effects of Perfluoroalkyl and Polyfluoroalkyl Substances*, edited by Jamie C. DeWitt. New York: Humana, 265-304.

Norstöm, K., T. Viktor, A.P. Cousins, and M. Rahmberg, 2015. Risks and Effects of the dispersion of PFAS on Aquatic, Terrestrial and Human populations in the vicinity of

International Airports, Final report of the RE-PATH project 2009-2014. Swedish Environmental Research Institute, January 2015.

Thompson, J., A. Roach, G. Eaglesham, M.E. Bartkow, K. Edge, and J. Mueller, 2011a. Perfluorinated alkyl acids in water, sediment and wildlife from Sydney Harbour and surroundings. *Marine Pollution Bulletin* 62:2869–2875.

Thompson, J., G. Eaglesham, G., and J. Mueller, 2011b. Concentrations of PFOS, PFOA and other perfluorinated alkyl acids in Australian drinking water. *Chemosphere* 83:1320–1325.

Toms, L.-M.L., J. Thompson, A. Rotander, P. Hobson, A.M. Calafat, K. Kato, X. Ye, S. Broomhall, F. Harden, and J.F. Mueller, 2014. Decline in perfluorooctane sulfonate and perfluorooctanoate serum concentrations in and Australian population from 2002 to 2011. *Environ Int* 71:74-80.