

FINAL REPORT
Epidemiology, 220-3W-05
Medical Department
3M Company
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Title: Descriptive Analysis of Serum Perfluorooctanoate (PFOA) and
Perfluorooctanesulfonate (PFOS) Concentrations of Antwerp Employee
Participants from the 2003 Fluorochemical Medical Surveillance Program

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ABSTRACT

Thirty Antwerp employees participated in the 2003 fluorochemical medical surveillance program. The serum PFOA concentrations ranged from 0.92 to 5.69 ppm with a mean (arithmetic) of 2.63 ppm (95% CI 2.17 - 3.09) and a geometric mean of 2.35 ppm (95% CI 1.96 - 2.82). Two participants' serum PFOA concentrations (5.40 and 5.69 ppm) exceeded the 3M Biologic Limit Value (BLV) of 5 ppm for PFOA. All thirty employees participated in the BLV program in 2001. These employees' 2001 PFOA values ranged from 0.88 to 4.44 ppm with a mean of 2.31 ppm (95% CI 1.94 - 2.69) and a geometric mean of 2.09 ppm (95% CI 1.76 - 2.49). The mean paired difference in PFOA values (2003 minus 2001 concentration) was +0.32 ppm (95% CI 0.11 - 0.52). The 30 employees' 2001 PFOS values ranged from 0.20 to 2.22 ppm with a mean of 0.87 ppm (95% CI 0.64 - 1.09) and a geometric mean of 0.70 ppm (95% CI 0.54 - 0.90). The mean paired difference in PFOS values between 2003 and 2001 was -0.37 ppm [95% CI (-0.51) - (-0.23)]. Twenty of the 30 employees also participated in the 2000 fluorochemical medical surveillance program. Their mean PFOA difference (2003 minus 2000 concentration) was +0.65 ppm (95% CI 0.16 - 1.13). Their mean PFOS difference (2003 minus 2000 concentration) was -0.31 ppm [95% CI (-0.48) - (-0.14)]. A cautious interpretation is warranted of any trend in serum concentrations because potential occupational exposure information was not considered in these analyses.

INTRODUCTION

The 3M Company offers periodic fluorochemical medical surveillance examinations for its production employees. At 3M's Antwerp (Belgium) manufacturing plant, serum perfluorooctanoate (PFOA) and perfluorooctanesulfonate (PFOS) have been measured in employees' serum since 1995 (Olsen et al. 1999; 2003a). As a consequence of 3M's phase-out of the manufacture of perfluorooctanyl-related materials, the number of employees engaged in the production of perfluorooctanoic acid (salts) and perfluorooctanesulfonyl fluoride (POSF)-related materials has declined since 2000. Beginning in 2003 3M Corporate Occupational Medicine and Industrial Hygiene adopted exposure triggers for inclusion in the fluorochemical medical surveillance program. These exposure triggers were 0.05 mg/m^3 (8 hour-Time Weighted Average (TWA) for PFOS and 0.005 mg/m^3 8-hr Time Weighted Average (TWA) for PFOA. The latter is one-half the Threshold Limit Value (TLV) for PFOA established by the American Conference of Government Industrial Hygienists (ACGIH). In addition, 3M has a Biologic Limit Value (BLV) of 5 parts per million (ppm, $\mu\text{g/ml}$) of PFOA in serum (3M Company 2001). The purpose of this report is to describe the serum PFOA and PFOS concentrations obtained in the 2003 fluorochemical medical surveillance program and compare these data to serum concentrations from the BLV program offered in 2001 and the previous fluorochemical medical surveillance program conducted in 2000.

METHODS

Antwerp employees who were considered to have occupational exposures that likely met the exposure trigger for PFOA (described above) were encouraged to

participate in the 2003 fluorochemical medical surveillance program. Other fluorochemical production-related employees, if so desired, could also participate. As part of this program, a blood sample was collected from each participating employee for the determination of PFOA and PFOS. The two fluorochemicals were determined by high performance liquid chromatography electrospray tandem mass spectrometry methods (Hansen et al. 2001). Analyses were conducted at Tandem Labs (Salt Lake City, UT) using validated methods that have been detailed elsewhere (Tandem Labs 1999; 2001a; 2001b). Fluorochemical concentrations are reported as parts per million ($\text{ppm} = \mu\text{g/mL}$).

RESULTS

Presented in Figure 1 is the distribution of the 30 employees' serum PFOA concentrations. The serum PFOA concentrations ranged from 0.92 to 5.69 ppm with a mean (arithmetic) of 2.63 ppm (95% CI 2.17 - 3.09) and a geometric mean of 2.35 ppm (95% CI 1.96 - 2.82). Two participants' serum PFOA concentrations (5.40 and 5.69 ppm) exceeded the 3M Biologic Limit Value of 5 ppm for PFOA. Also presented in Figure 1 is the serum PFOS concentration distribution for the 30 employee participants. Serum PFOS concentrations ranged from 0.19 to 1.35 ppm with a mean of 0.50 ppm (95% CI 0.39 - 0.60) and a geometric mean of 0.43 ppm (95% CI 0.35 - 0.52).

All thirty employee participants in 2003 also participated in the BLV program in 2001. These employees' 2001 PFOA values ranged from 0.88 to 4.44 ppm with a mean of 2.31 ppm (95% CI 1.94 - 2.69) and a geometric mean of 2.09 ppm (95% CI 1.76 - 2.49). Twenty-three (77%) of these 30 employees had 2003 serum PFOA concentrations

that were higher than those measured in 2001 (Figure 2). The mean paired difference in PFOA values (2003 minus 2001 concentration) was +0.32 ppm (95% CI 0.11 - 0.52). The 30 employees' 2001 PFOS values ranged from 0.20 to 2.22 ppm with a mean of 0.87 ppm (95% CI 0.64 - 1.09) and a geometric mean of 0.70 ppm (95% CI 0.54 - 0.90). All but one of these 30 employees' 2003 serum PFOS concentrations were lower than those measured in 2001 (Figure 3). The mean paired difference in PFOS values between 2003 and 2001 was -0.37 ppm [95% CI (-0.51) - (-0.23)].

Twenty (67%) of the 30 employee participants in 2003 also participated in the 2000 Antwerp fluorochemical medical surveillance program. These 20 employees had a mean serum PFOA concentration in 2000 of 2.12 ppm (95% CI 1.50 - 2.74). The range was from 0.10 - 5.31 ppm. Sixteen of these 20 employees (80%) had higher serum PFOA concentrations in 2003 than 2000 (Figure 4). The range of differences (2003 minus 2000 concentration) was -0.99 ppm to +3.26 ppm. The mean PFOA difference (2003 minus 2000 concentration) was +0.65 ppm (95% CI 0.16 - 1.13). The mean PFOS serum concentration in 2000 was 0.79 ppm (95% CI 0.52 - 1.05) with a range from 0.21 to 2.28 ppm. Of these 20 employees who participated in both the 2003 and 2000 fluorochemical medical surveillance programs, 19 (95%) had a decline in their serum PFOS concentrations in 2003 compared to their 2000 assessment (Figure 5). The range of differences in PFOS (2003 minus 2000 concentration) was -1.25 ppm to +0.06 ppm. The mean PFOS difference (2003 minus 2000 concentration) was -0.31 ppm [95% CI (-0.48) - (-0.14)].

DISCUSSION

The 30 employee participants' mean serum PFOA concentration in 2003 (2.63 ppm) was slightly higher than that measured in 2001 (2.31 ppm) and higher yet than their mean PFOA value measured in 2000 (2.12 ppm). The 2000 mean PFOA serum concentration was 1.06 ppm for the 206 male employees who participated in the fluorochemical medical surveillance program at that time (Olsen et al. 2003). This increase in PFOA concentration measured in 2003 is likely due to several factors including: 1) ongoing potential for occupational exposure from production activities of PFOA (salts) between 2000 and mid 2002; 2) potential non-production related exposures in the workplace into 2003; 3) the long serum elimination half-life of PFOA; and 4) restriction of the 2003 fluorochemical medical surveillance program to those employees with the highest potential for occupational exposure to PFOA, similar to the 2001 BLV program but unlike the 2000 fluorochemical medical surveillance program which included many Antwerp employees with non-production exposure to PFOA, (e.g., administrative and research workers). Also, it is important to acknowledge that the validation methods for the analysis of PFOA and PFOS were developed with acceptable criteria of ± 26 and ± 20 percent, respectively (Tandem Labs 1999; 2001a; 2001b). Therefore, some upward, or downward, individual employee values over time may be comparable as they are within the error of the validated analytical methods.

In 2003, two participants had serum PFOA concentrations that were just above the BLV of 5 ppm (5.40 and 5.69 ppm). The purpose for the PFOA BLV program is explained, in detail, elsewhere (3M Company 2001). Basically, 3M established the BLV (5 ppm serum PFOA) to represent the best estimate of a level of a chemical substance or

its metabolite in a biological fluid that if present, even on a chronic basis, would not be expected to pose, or correlate with, a significant risk of adverse health effects to the worker(s). By establishing this BLV at 5 ppm for PFOA, the 3M exposure guideline committee did not intend to imply that serum levels of PFOA greater than the BLV immediately impose a significant risk of adverse health effects. However, if employees serum PFOA level exceed the BLV, it should be understood that corrective actions (which may include temporary removal from the immediate work area) may need to be applied, on a case-by-case basis, at the direction of 3M Corporate Occupational Medicine. Implementation of the BLV program by 3M Corporate Occupational Medicine did not allow for employees with serum PFOA concentrations ≥ 10 ppm to be directly engaged in the production of PFOA (Olsen et al. 2003c). 3M Antwerp, Cottage Grove (Minnesota) and Decatur (Alabama) employees' serum PFOA concentrations have not been associated with adverse measurements in hepatic clinical chemistry enzymes, cholesterol, lipoproteins, plasma cholecystokinin, reproductive hormones or thyroid hormones (Gilliland and Mandel 1996; Olsen et al. 1998; 2000; 2003a; 2003b).

The 30 participants' average serum PFOS concentration (0.49 ppm) in 2003 was lower than the mean previously reported in 1995 (1.93 ppm), 1997 (1.48 ppm) and 2000 (0.96 ppm) at the Antwerp manufacturing site for the fluorochemical medical surveillance program (Olsen et al. 1999; 2003). These previous medical surveillance years involved considerably more male employee participants (88, 65 and 206, respectively) than in 2003. We suspect that the primary reason for the reduction in mean serum PFOS concentrations is the result of the selection process that occurred in the 2003 fluorochemical medical surveillance program. The 2003 fluorochemical medical

surveillance program concentrated on employees with potential exposures to PFOA. By March 2003, perfluorooctanesulfonyl fluoride-related production had essentially ceased and thus the greatest proportion of employee participants would have been those employees engaged in PFOA-related production activities. As observed at the Cottage Grove (MN) plant, the workplace production area is a primary factor in whether employees' PFOA or PFOS serum concentrations may predominate (Olsen et al. 2003b). Antwerp and Decatur employees' serum PFOS concentrations have not been associated with adverse measurements in hepatic clinical chemistry enzymes, cholesterol, lipoproteins or thyroid hormones (Olsen et al. 1999; 2003a).

There are several limitations to the analyses presented in this report. The results arise from a small subset of employees who voluntarily participated in the 2003 Antwerp fluorochemical medical surveillance program. The number of employees in the 2003 fluorochemical medical surveillance program is almost 90 percent less than those who participated (male and female) in the 2000 fluorochemical medical surveillance program (n = 255). Attrition of employees due to production cessation of PFOA and POSF-related materials occurred between 2000 and 2003. Unlike the 2000 Antwerp fluorochemical medical surveillance program in which employee interview workplace data were collected and analyzed in relation to serum PFOA and PFOS concentrations (Olsen et al. 2001), such data were not collected in 2003. Therefore, it was not possible to associate serum fluorochemical concentrations to potential workplace exposures in the 2003 time period. Knowledge regarding the serum elimination half-life remains sparse but is suggestive of a long serum elimination rate (i.e., years) (Burriss et al. 2002). As a consequence of these limitations, there needs to be cautious interpretation of any trend

analysis of the serum fluorochemical concentrations of the 30 Antwerp employees who participated in the 2003 fluorochemical medical surveillance program.

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Figure 1. Serum PFOA (ascending order) and PFOS Concentrations for Employees (N = 30) Who Participated in the 2003 Antwerp Fluorochemical Medical Surveillance Program

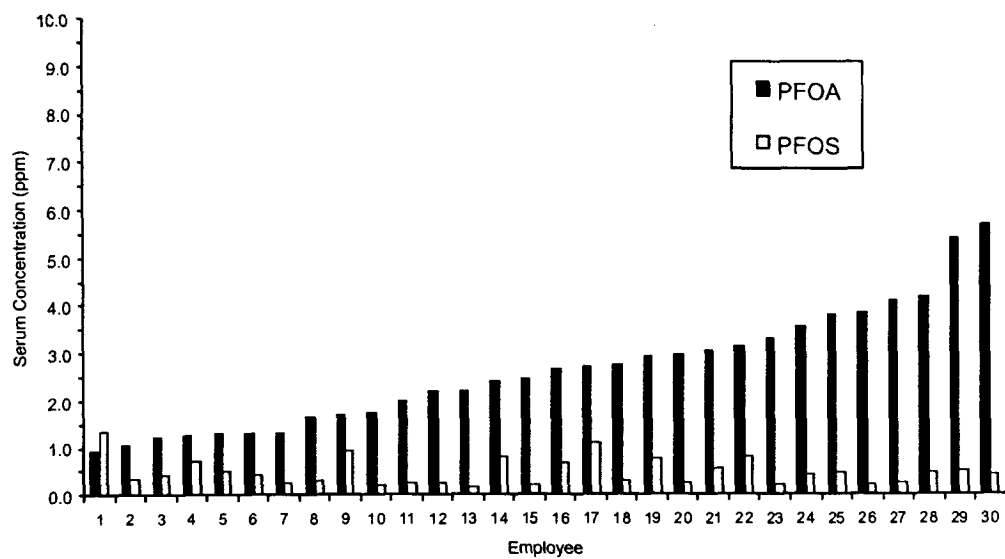


Figure 2. Ascending Distribution of Serum PFOA Concentrations in 2003 Compared to Antwerp Employees' (N = 30) 2001 PFOA Serum Concentrations

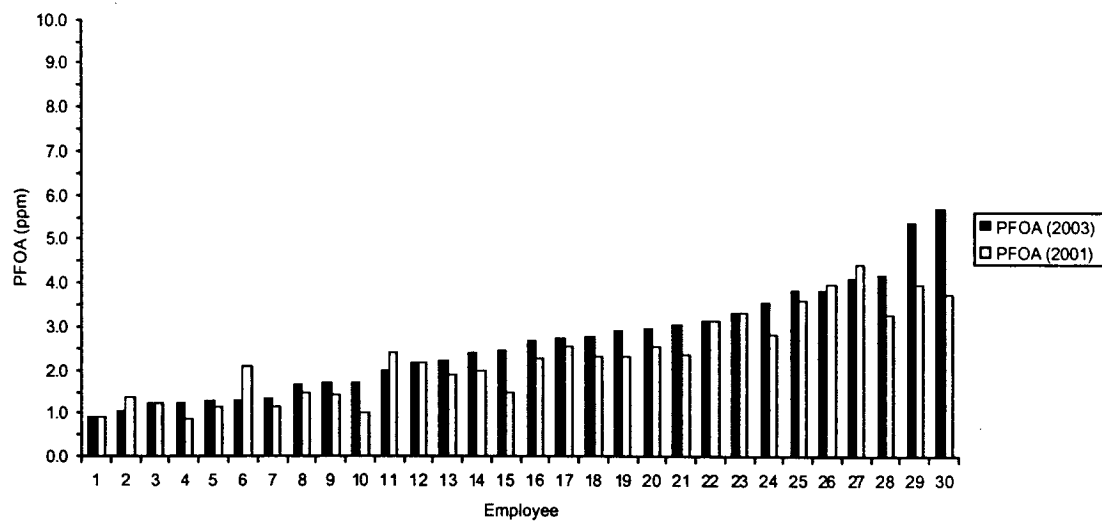


Figure 3. Corresponding Paired Serum PFOS Concentrations for 2003 and 2001 for Antwerp Employees (N = 30) in Same Numerical Order as Displayed in Figure 2.

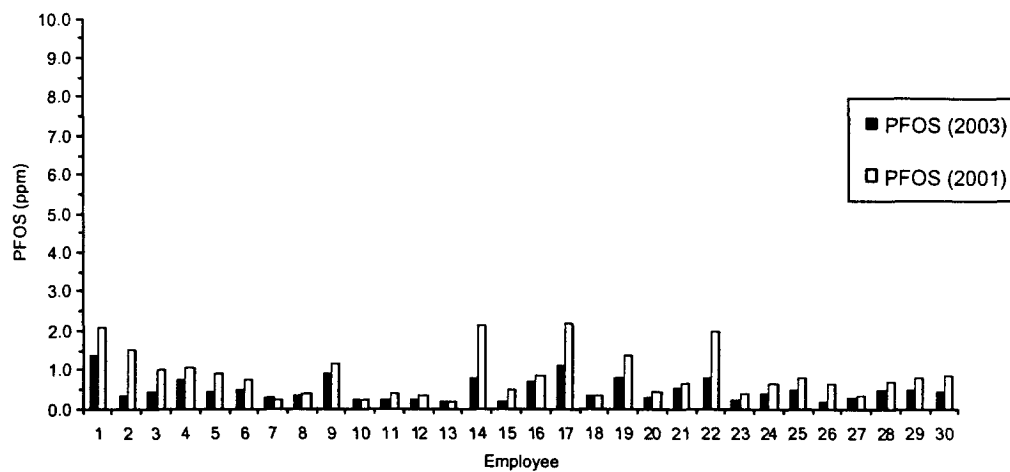


Figure 4. Ascending Distribution of Serum PFOA Concentration in 2003
Compared to Antwerp Employees' (N = 20) 2000 PFOA Serum Concentration

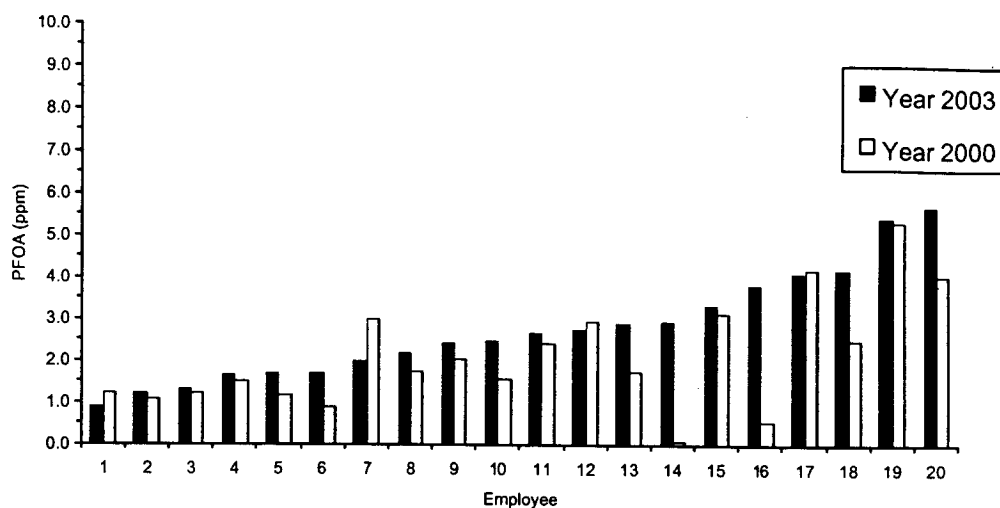


Figure 5. Corresponding Paired Serum PFOS Concentrations for 2003 and 2000 for Antwerp Employees (N = 20) in Same Numerical Order as Displayed in Figure 4

