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March 13, 2003

Stephen L. Johnson
Assistant Administrator
Office Of Prevention, Pesticides And Toxic Substances
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N. W.
Washington, D. C. 20004

Re: **Environmental, Health And Safety Measures**
Relating To Perfluorooctanoic Acid And Its Salts (PFOA)

Dear Assistant Administrator Johnson:

3M Company (3M) understands that your office has been evaluating perfluorooctanoic acid and its salts ("PFOA"), which are perfluorinated, 8 carbon carboxylate surfactants used primarily as fluorinated polymerization aids (FPAs) in the manufacture of fluoropolymers.[1] This letter confirms 3M's intent to continue ongoing environmental, health and safety (EHS) measures relating to PFOA. In particular, this letter documents past EHS measures by 3M to characterize exposure to PFOA; to conduct health and environmental fate and effects research for PFOA; and to reduce PFOA exposure through a production phase-out and other measures. This letter also summarizes 3M's plans for ongoing and future EHS measures to develop additional data characterizing exposure to PFOA; to continue to monitor possible PFOA presence in the environment near 3M's former manufacturing facilities; to characterize possible PFOA exposure pathways from 3M's former manufacturing and commercial activities; and to fund additional health and environmental fate and effects research for PFOA.

I. PERTINENT BACKGROUND

3M production records reflect that PFOA was produced at various facilities from 1969 to 2002 using electrochemical fluorination (ECF) technology. Between 1992 and 2002, 3M's total PFOA production averaged 250,000 pounds per year.

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[1] Chemical Name: Perfluorooctanoic Acid (PFOA). Molecular formula: $C_8 H F_{15} O_2$. CAS Number: Various, including: 335-67-1 (free acid); 3825-26-1 (ammonium salt); 335-95-5 (sodium salt); and 2395-00-8 (potassium salt). The perfluorooctanoate anion has no specific CAS number.

Approximately 97 percent of the PFOA produced by 3M was used by its industrial customers and in its own processes as a fluoropolymer processing aid. The remaining 3 percent totaled roughly 8,000 pounds per year and was used in a medical film coating application and in electronics applications involving printed circuit boards and precision bearings.

Between 1998 and 2002, 3M submitted to EPA serum analyses of the U.S. population and certain U.S. population subgroups. These analyses indicated the presence in individual and pooled human serum samples of the PFOA anion at very low mean levels of 4-6 parts per billion (ppb). Wildlife sampling also occurred during this period and indicated the presence of the PFOA anion only in limited circumstances.

Toxicological and epidemiology studies on PFOA have been sponsored by 3M as well as other members of industry addressing a range of health end-points. These studies are available to the public along with other information through a public docket maintained by EPA OPPTS -- AR-226.

3M does not believe that the PFOA levels measured in workers, the U.S. population or the environment cause adverse effects in humans, but is acting on a voluntary basis to develop additional PFOA health and environmental fate and effects data; to provide additional characterization of potential PFOA routes of exposure; and to agree to undertake additional measures to reduce or prevent PFOA exposure whenever practicable. The details of these EHS commitments by 3M are described in Section II. below.

II. EHS COMMITMENTS BY 3M

A. Past 3M EHS Measures For PFOA

Over the years, 3M has undertaken a wide range of measures to assess the exposure and toxicological profile of PFOA. The elements below describe 3M's major past actions, but are not an exhaustive list of 3M's past EHS measures.

1. 3M has monitored the health of fluorochemical production workers dating back to 1978. More recently, this monitoring program has involved periodically measuring PFOA levels in serum, tracking clinical chemistries and communicating with workers regarding these results; undertaking industrial hygiene measures to monitor and reduce workplace exposures; and conducting medical surveillance, epidemiological and other forms of pertinent study.

2. 3M has both engaged in and supported toxicological research to address whether PFOA has the potential to cause any health effects for a range of end-points, including developmental toxicity, mutagenicity, chronic toxicity, reproductive effects and cancer. These data are available to the public, along with other information, through the EPA-maintained OPPTS AR-226 docket.

3. 3M has performed extensive analytical work to determine PFOA exposure levels in the U.S. population and the environment. For this work, 3M engaged in state-of-the art methods development and refinement to lower limits of detection and quantification. 3M also qualified independent laboratories to apply these methods. Analyses were performed of pooled blood samples from U.S. blood banks as well as of individual blood samples from various population subgroups. A study also examined liver tissue. With respect to environmental monitoring, 3M conducted monitoring in the vicinity of its now former PFOA production facilities; analyzed serum and liver samples from fish, birds and other wildlife for the presence of PFOA; and sponsored a Multi-City Study in which a variety of environmental compartments were analyzed. These data also are available to the public through the OPPTS AR-226 docket.

4. Over the years, 3M also has undertaken steps to limit PFOA exposures in the workplace. These steps have included implementation of industrial hygiene controls at 3M fluorochemical production facilities, including adoption of exposure guidelines. 3M also has taken various actions to reduce environmental releases of PFOA at these facilities, including capture and incineration of PFOA-containing waste streams and the implementation in 1998 of activated carbon systems to improve the removal of PFOA from wastewaters.

5. In 1997, 3M obtained new analytical data on PFOA and perfluorooctane sulfonate (PFOS) serum levels in the general population and promptly shared these data with EPA. Thereafter, 3M shared additional data and exposure information with EPA on perfluorooctanyl chemicals, including PFOA, and cooperated with EPA in evaluating hazard and exposure issues associated with these chemicals.

6. Subsequent to obtaining the new analytical data on PFOA and PFOS serum levels in the general population, 3M decided to phase-out its perfluorooctanyl chemistry substantially by the end of 2000. This phase-out included terminating all PFOA production for commercial sale by the end of 2002. 3M's Dyneon subsidiary[2] continues to manufacture small quantities of PFOA at its facility in Gendorf, Germany for its own internal use as a fluoropolymer manufacturing aid at its two facilities. In this connection, Dyneon has made process changes that reduce the quantity of PFOA required and has developed a "capture for recycle" technology that reduces the need for new PFOA. As described in Section II.C.6. below, Dyneon will be engaging in its own EHS measures in connection with this limited production and use, including further reduction of PFOA use.

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[2] Dyneon engages in the manufacture of fluoropolymers and fluoroelastomers and operates two facilities -- one in the United States and one in Germany. Formerly a joint venture between 3M and Hoechst AG, Dyneon now is a wholly-owned subsidiary of 3M.

B. Characterization Of Other Potential Routes Of Exposure

A qualitative discussion more fully characterizing possible exposure routes related to non-fluoropolymer PFOA uses and discontinued perfluorooctanesulfonyl fluoride (POSF)-based products follows below. This discussion reflects two key points: (i) 3M's commercial PFOA production for non-fluoropolymer uses occurred on a limited basis at a level of only 8000 pounds per year for medical film and electronics applications with low exposure potential; and (ii) POSF-based products did not likely provide a route of measurable PFOA exposure.

1. Production Of PFOA For Non-Fluoropolymer Uses

3M produced limited quantities of PFOA -- approximately 8,000 pounds per year in recent years -- for non-fluoropolymer uses. The principal non-fluoropolymer use occurred in a medical film application where PFOA served as an antistatic additive in coatings sandwiched between multi-layer medical films. No consumer or medical patient exposure would be expected from this application. Worker exposure should have been minimal given that the PFOA sold for this application in recent years was in a 30 percent aqueous solution and the MSDS advised protective measures during handling and use.

A small amount of PFOA -- less than 500 pounds per year -- was derivatized as an ester to form a methacrylate co-polymer coating used in electronics applications to provide a humidity barrier on printed circuit boards and to secure silicone oil on precision bearings, for example, in gyroscopes and telecommunications switching stations. These applications involved PFOA derivatized into a stable polymer, making PFOA exposure to workers, the consumer or the environment highly unlikely.

2. Transformation Of POSF-Based Substances

3M has submitted two biodegradation studies to EPA on N-Et FOSE alcohol.[3] N-Et FOSE alcohol was both a building block intermediate used in the production of many POSF-based products and one of the prevalent fluorochemical residuals found in POSF-based products. The biodegredation studies were performed in accordance with EPA OPPTS Guidelines at 40 C.F.R. 835.3200 – 3210 & -5045. Both studies indicate that PFOS would be generated through the biotic degradation of N-Et-FOSE alcohol, but that PFOA could be formed instead of PFOS only under an abiotic or hydrolytic condition during the last step of the degradation pathway. The diagram below depicts the degradation pathway indicated by these studies.

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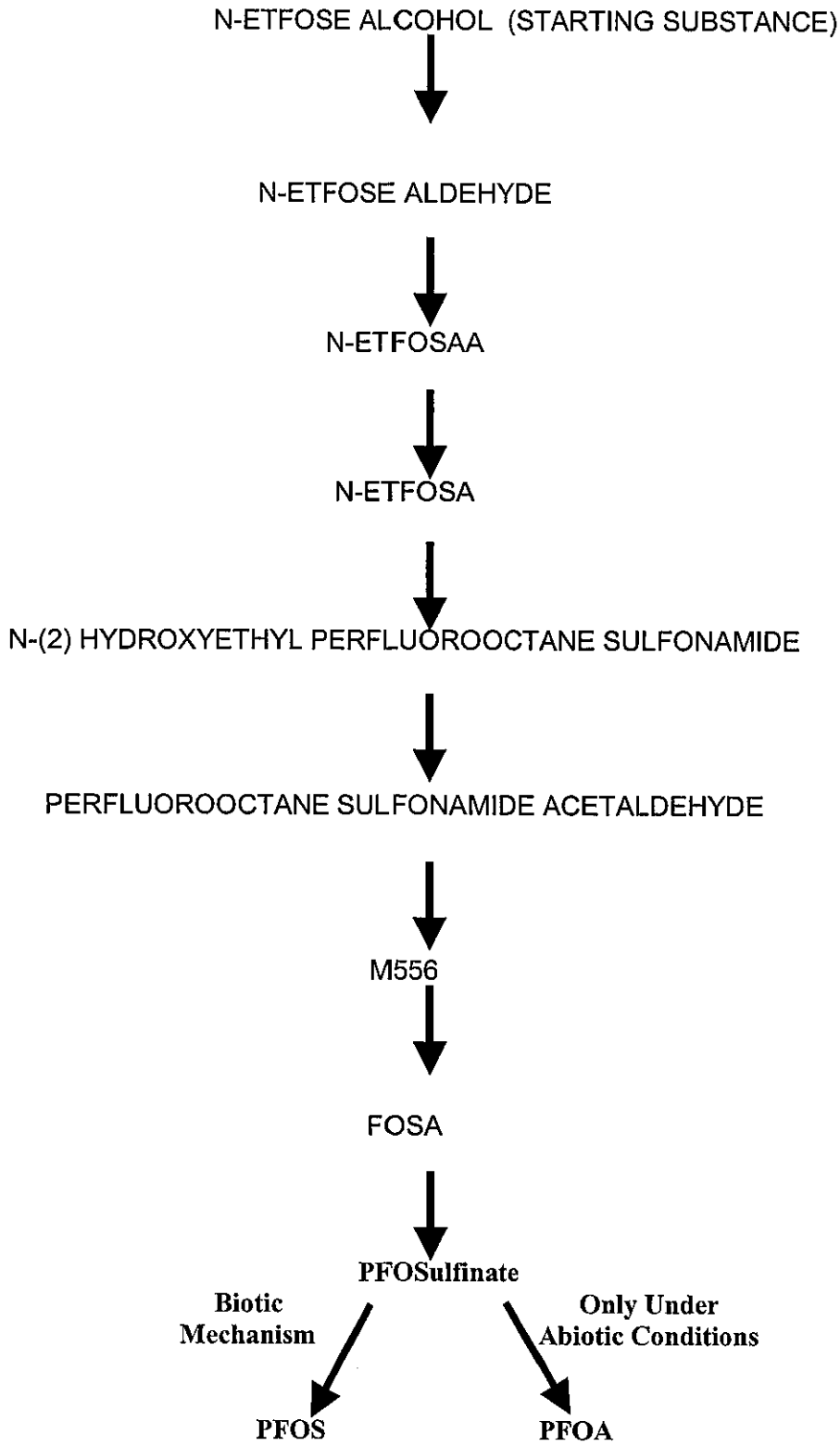
[3] 3M E01-0415 dated February 23, 2001; 3M EOO-2252 dated October 1, 2000, available in OPPTS AR-226 docket.

N-Et FOSE Alcohol Biodegradation Pathway



As the diagram depicts, these studies indicate that under biotic conditions, the N-Et FOSE alcohol will follow a stepwise degradation pathway that results in PFOS as the ultimate degradation product. Prior to the final degradation step to PFOS, the penultimate intermediate degradation step involves degradation to a compound known as perfluorooctane sulfinate. The protocol for these studies requires a degradation control test to be run under abiotic conditions for each step in the pathway. In this control test, the perfluorooctane sulfinate did show some degradation to PFOA. Any such degradation to PFOA, however, did not occur under biotic conditions, but instead only in the abiotic control test mode and only during the last step.

Several factors indicate that PFOA is ***not*** the expected biological degradation end-product of the other fluorochemical residuals present in POSF-based products. *First*, while some degree of abiotic degradation can occur in a biotic system, the particular biodegradation pathway described above suggests that PFOS formation would be the expected degradation route. Hence, even if the other fluorochemical residuals present in POSF-based products were absorbed by humans or wildlife, PFOA is unlikely to be formed as a metabolite. *Second*, to the extent PFOA could be formed in an abiotic environmental compartment, no PFOA uptake from that compartment would be expected because, as studies have shown, PFOA does not bioconcentrate.[4] *Third*, in the highly specialized and limited circumstances where PFOA could form and transfer from an abiotic environmental compartment to water, the PFOA should be immediately diluted due to its water solubility (>100,000 mg/L or 10 percent by weight for ammonium perfluorooctanoate),[5] and hence, should remain present in the water, if at all, at miniscule levels. *Finally*, although studies have been done only on the N-Et FOSE alcohol, this degradation pathway should be representative of the other major building blocks for POSF-based products.[6]

3. PFOA As An Impurity In POSF-Based Products

3M analytical studies of eight POSF-based product samples have identified the presence of PFOA at very low concentrations ranging from 200-1600 ppm as a manufacturing impurity. Based on 1997 production information, the estimated

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4 See Kurume Laboratory, 2001. Bioaccumulation Test of Perfluoroalkylcarboxylic acid (C=7-13), Test No. 51519., Chemicals Evaluation and Research Institute, Japan (Dec. 18, 2001), at 1-26 (the carp exposed to 5 * g/L resulted in a BCF of 3.1, while carp exposed to 50 * g/L showed a BCF of <5.1-9.1); see also Revised Draft Hazard Assessment Of Perfluorooctanoic Acid And Its Salts, U.S. EPA (Nov. 4, 2002), at 1, 14.

5 See Characterization Study of PFOA (Lot #332) Primary Standard – Test Control Reference # TCR-99030-030 Phase: Solubility Determination, available in OPPTS Docket AR-226.

6 The N-Et FOSE alcohol served as the key building block for the vast majority of 3M's POSF-based products. The other key alcohol building block, N-Me FOSE alcohol, would be expected to have a comparable degradation pathway due to its structural similarity to the N-Et FOSE alcohol. Moreover, N-Et FOSE alcohol was a precursor to the other key building block compounds for 3M's POSF-based products, and hence, degradation pathways for these building blocks already are captured by the N-Et FOSE alcohol degradation studies.

annual levels of PFOA residual present in POSF-based products would not have exceeded 6000 pounds. Nearly 95 percent of POSF-based products -- and hence nearly all of the 6000 annual pounds of PFOA residual present in such products – were commercialized into industrial applications.[7] A number of these applications involved use of high molecular weight polymers or other formulated POSF-based products for surface treatment of carpets and fabrics or for coating on paper and packaging. Due to the nature of these applications, only a minute amount of the PFOA residual, at most, would have ended up in the finished article. Moreover, a number of the industrial applications for POSF-based products involved the use of aqueous washing or finishing steps. In view of PFOA's water solubility, a washing or finishing step most likely removed the very small amount of PFOA residual present in such product. Any industrial release of PFOA residual into the environment from these sources would likely have resulted in extremely low concentrations in localized aquatic systems and would not have provided a source of measurable PFOA exposure.

C. Future EHS Measures

In addition to the PFOA production phase-out and the numerous other measures undertaken to date as detailed above, 3M plans to engage in ongoing and future EHS measures itemized below. 3M plans to undertake these measures in an expeditious manner and may undertake additional EHS measures not described in this letter, as warranted, under 3M's existing safety, health and environmental programs.

1. 3M will not resume the manufacture of PFOA for commercial sale.

2. 3M will continue with its medical monitoring efforts for fluorochemical production workers and will provide reports to EPA on a bi-annual basis on the results of this program. These efforts will continue to include monitoring for the presence of PFOA. In addition, 3M will continue to track the mortality experience of the fluorochemical production worker cohort and will submit updated epidemiological study reports to EPA every five years.

3. 3M will continue to monitor in the vicinity of its former PFOA production facilities. This monitoring will include groundwater, surface water and other environmental media and will be part of ongoing requirements and/or voluntary commitments established with local regulatory agencies. 3M will provide an initial summary report to EPA for this monitoring within two years of the date of this letter and periodic additional reports at appropriate intervals thereafter.

4. 3M will work with other members of industry to conduct additional validation of the PFOA serum analytical method and sampling protocol; publish the analytical method in a peer reviewed journal; and continue to qualify independent

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[7] See Fluorochemical Use, Distribution And Release Overview (May 26, 1999), available in OPPTS Docket AR-226.

laboratories to perform the validated method. 3M will support the efforts of the Centers For Disease Control (CDC) and EPA to develop a more complete understanding of the PFOA levels present in the general population and the environment. 3M will continue to assess the appropriateness of undertaking additional research and other actions in coordination with CDC and EPA.

5. 3M will participate in certain human health and environmental fate and effects studies of PFOA. These studies will occur under the auspices of the Association of Plastics Manufacturers of Europe (APME) and will include the following: (i) chronic toxicity in daphnia; (ii) chronic toxicity in trout; (iii) ADE mass balance in rats; (iv) protein binding -- rat/human; (v) physiologically based kinetic modeling; (vi) adsorption/desorption studies; (vii) acute toxicity in daphnia; (viii) acute toxicity in trout; (ix) algal growth; and (x) mechanistic studies of pancreatic tumor induction in rats. The results of these studies, and any additional studies, will be promptly communicated to EPA in the form of final reports. The industry participants will consult with EPA on what additional studies would be beneficial.

6. As discussed above, Dyneon will continue to produce small amounts of PFOA for internal use and will continue to use PFOA in fluoropolymer production. In connection with this production and use, Dyneon will engage in various EHS measures, including:

a. Dyneon will continue to reduce further the now small use at its facility in the United States of PFOA imported from Dyneon's Gendorf, Germany facility.

b. Dyneon has developed and is using a "capture for recycle" technology for PFOA and has made that technology available for license by other PFOA users. This technology, which allows for a recapture and reuse of PFOA, has and will continue to result in a significant reduction of PFOA emissions and production demands for Dyneon.

c. Dyneon's employees in the United States will continue to be part of the 3M program for medical monitoring of fluorochemical production workers and will be included in the above-referenced reports to be submitted by 3M on the results of this program. This program will continue to include monitoring for the presence of PFOA. Dyneon's employees at the Gendorf, Germany facility have been and will continue to be subject to an equivalent program that follows 3M's monitoring protocols.

d. Dyneon's fluoropolymer manufacturing facility in the United States will continue to be part of the above-referenced 3M environmental monitoring program. This monitoring will include groundwater, surface water and other environmental media and will be part of ongoing requirements and/or voluntary commitments established with local regulatory agencies. Periodic reporting of the results of this monitoring program will begin within two years from the date of this letter and occur at appropriate intervals thereafter.

e. Dyneon will commit, as a signatory to the separate letter of intent among PFOA users in the fluoropolymer industry, to perform the exposure assessment and testing specified therein.

In connection with the foregoing EHS measures, 3M recognizes the importance of EPA's recently-issued guidelines pursuant to the Data Quality Act.[8] We will continue -- as we have in the past -- to employ scientific practices, protocols and procedures designed to ensure that data meeting reasonably appropriate benchmarks for objectivity, utility and integrity are developed and provided to the Agency.

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3M appreciates this opportunity to memorialize our prior, ongoing and future EHS measures for PFOA. We look forward to dialogue with EPA regarding the content of this letter.

Very truly yours,

Dr. Larry Wendling (A.F.)

Dr. Larry Wendling
Vice President
Performance Materials Division
3M Company

cc: Charles Auer, Director Office Of Pollution Prevention And Toxics

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8 See Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency; Public Law 106-554; H.R. 5658, § 515(a) (2001); Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, OMB, 67 Fed. Reg. 8452 (2002); see also EPA Order 5360.1A2 "Policy And Program Requirements For Agency-Wide Quality System" (May 5, 2000); EPA Quality Manual For Environmental Programs, 5360A1 (May 5, 2000).