



The
Plastics
Industry
Trade
Association

AR 226 - 1304

Donald K. Duncan
President

26 pp

March 14, 2003

The Honorable Stephen L. Johnson
Assistant Administrator
The United States Environmental Protection Agency, Headquarters
Office of Prevention, Pesticides and Toxic Substances
1200 Pennsylvania Avenue
Room 7101M
Washington, DC 20460

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Dear Mr. Johnson:

On behalf of the Asahi Glass Fluoropolymers USA, Inc.; Daikin America, Inc.; Dyneon LLC; and E. I. du Pont de Nemours and Company, we are transmitting a Letter of Intent describing the initiatives that these companies have taken to assist EPA in its assessment of perfluorooctanoic acid and its salts. This Letter describes in some detail the activities underway to develop information and data needed to assure the continued safe use of ammonium perfluorooctanoate in the manufacture, processing, and use of fluoropolymers

If you have any questions about the Letter of Intent, please contact Lynne R. Harris, of The Society of the Plastics Industry, Inc. (SPI) at 202-974-5233.

Respectfully submitted,

Don Duncan

Enclosure

cc: Charles M. Auer
Margaret N. Schneider

CONTAIN NO CBI

March 14, 2003

Regular Mail

The Honorable Stephen L. Johnson
Assistant Administrator
The United States Environmental Protection Agency, Headquarters
Office of Prevention, Pesticides and Toxic Substances
1200 Pennsylvania Avenue
Room 7101M
Washington, DC 20460

**Re: Voluntary Actions to Evaluate and Control Emissions of Ammonium
Perfluorooctanoate (APFO)**

Dear Mr. Johnson:

Asahi Glass Fluoropolymers USA, Inc.; Daikin America, Inc. (Daikin); E. I. du Pont de Nemours and Company (du Pont), and Dyneon LLC (Dyneon) (the "APFO Users") each use ammonium perfluorooctanoate (APFO)¹ to produce fluoropolymers and fluoroelastomers in the U.S. Fluoropolymers are plastic products while fluoroelastomers are rubber-like products, both of which provide highly desirable and unique properties that make the end-use products created from them useful. All of these companies are members of The Society of the Plastics Industry, Inc. (SPI) Fluoropolymers Manufacturers Group (FMG) and its Fluoropolymers Division (FPD). Together, they and/or their parent companies represent, both globally and in the U.S., most of known use of APFO for production of fluoropolymers.

APFO is essential in making certain fluoropolymers,² which, in turn, are used in many high-performance applications in critical industries such as defense, aerospace, semiconductors, telecommunications, and pollution control. A list of commercial fluoropolymers is provided in Addendum I to this document. Many grades of these fluoropolymers can be made *only* with APFO.

The APFO Users share the goal of the U.S. Environmental Protection Agency (EPA) to understand and assess the toxicity of and exposures to the APFO used by the fluoropolymer industry, and to safeguard human health and the environment. To that end, the APFO Users have made specific commitments to provide additional information and research to EPA. These

¹ The APFO Users use a commercially available form of the compound, technically known as octanoic acid, pentadecafluoro-, ammonium salt, CAS 3825-26-1.

² For purposes of this letter, we will use fluoropolymers to include fluoroelastomers, unless there is a distinction that needs to be made.

commitments are: (1) to reduce emissions of APFO from fluoropolymer and APFO manufacturing facilities; (2) to conduct studies on both finished resins and finished products made from these resins to determine if any exposure to the general population can be related to the fluoropolymer industry; (3) to conduct studies on emissions from fluoropolymer processing facilities to determine the level of current emissions; and (4) to develop additional toxicological data on APFO.

This Letter of Intent includes timetables for completion of various studies and research, including additional studies on the toxicity and environmental fate of the substance. The timetables are the best estimates available at this time. The APFO Users will promptly provide EPA with the information as it is developed so that it can be made available to the public generally.

Addendum II describes the history of APFO use in the fluoropolymer industry, the reasons for the recent interest in APFO, and the extensive activities that the APFO Users in the industry have completed, and continue to conduct, to protect human health and the environment while society retains the substantial benefits of fluoropolymers.

Current Activities of Fluoropolymer Manufacturers

The APFO Users believe that fluoropolymers and products made from them are safe for their intended use. Nevertheless, the companies are examining the use of APFO more closely. Initially, the APFO Users, in conjunction with the FMG, determined that they needed to find out how much APFO was used and how much was emitted to the environment, as well as to re-examine work practices in their own plants. Thus, the FMG prepared a global materials balance including APFO used in manufacturing fluoropolymers.

The information developed from the materials balance was provided to EPA in 2001; it was updated in 2002, and will be revised in the future as described below. The global materials balance was and is based on the best available evidence that the companies have regarding the use of APFO in making fluoropolymers and the fate of these substances in the fluoropolymer industry.

Based on these estimates and the method used, the companies have accounted for essentially all the APFO used in the fluoropolymer manufacturing industry.

As responsible manufacturers, the APFO Users are committed to reducing APFO emissions. Based on that global materials balance, and as described below, FMG members have voluntarily begun to modify their processes to reduce APFO emissions, on a global, individual company-wide basis, by a minimum of 50% for calendar year 2006. This reduction will be compared to baseline data submitted to EPA in September 2002. This initial commitment was based on the best information available to the companies at the time of the decision and what the companies believed could be achieved, even with some difficulty, given the available technology, the characteristics and uses of the surfactants and the nature of processes involved.

Using data collected from the materials balance and such environmental monitoring and other studies as they become available, the companies will continue to use appropriate criteria, including such standards, limits or parameters as the West Virginia air and water screening levels and water quality guidelines, to evaluate operations and emissions.³

To facilitate the commitment to reduce emissions, du Pont has provided, and will continue to provide to FMG companies where needed, its "capture for destruction" technology, license-free. In addition, Dyneon and du Pont each have offered to license their respective company's "capture for recycle" technologies. All of the companies are evaluating the applicability of available technologies to their processes and continue to track APFO emissions. Because of the differences in the manufacturing processes and the kinds of products manufactured, it is not possible to know whether these technologies will be effective, or if they are, what the final reductions will be. Nevertheless, the companies are committed to the minimum 50% reduction and to taking additional steps as described below.

The APFO Users, through the FMG, also continue to support research on the toxicology, ecotoxicology, and environmental fate of APFO, as such research relates to the safe use of APFO as surfactants in the manufacture and use of fluoropolymers. Collectively and individually, the FMG members have worked with customers to help them safely manage the processing of fluoropolymer products, and to help them adopt practices and procedures to control employee exposures. These activities are essential parts of long-standing product stewardship programs and are ongoing, as described below.

In addition, the APFO Users have, and are, committed to working to identify the possible routes, related to the manufacture, processing, and use of fluoropolymers, by which the general population could be exposed to APFO. The APFO Users have begun to examine their products, embarking on the difficult analytical process of determining any residual levels. The first step in this effort was to evaluate methods for analysis of APFO. The method evaluation work is under way, which is necessary to meet EPA's QA/QC criteria and is difficult and time-consuming. As part of that effort, the FMG published in January 2003 *Detecting and Quantifying Low Levels of Fluoropolymer Polymerization Aids – A Guidance Document*. A copy of this document was provided to EPA's technical staff for inclusion in the docket under separate cover.

³ The toxicologists and scientists who participated in the assessment included representatives from government, independent third party experts, and industry. The organizations represented included: West Virginia Department of Environmental Protection; Toxicology Excellence for Risk Assessment, Cincinnati, Ohio; U.S. Environmental Protection Agency, Region III; U.S. Agency for Toxic Substances and Disease Registry; EPA National office in Washington; and EPA's Cincinnati Laboratory.

Further Industry Commitments

A. General Commitment to Product Stewardship Principles and Practices

The APFO Users will continue to follow the principles of product stewardship similar to those described by American Chemistry Council's (ACC) or Synthetic Organic Chemical Manufacturers Association's (SOCMA) Responsible Care® programs in their efforts to support the toxicological research, control occupational exposures in their own facilities, monitor employee health, assist customers in protecting their employees, and meet the general commitment to reduce emissions to the environment.

For example, as has been done in the past, through the semi-annual SPI FPD meetings, an update on information about APFO, including the results of toxicology studies, coordination efforts with EPA, and other activities, will be provided to processor members of the fluoropolymer industry. High on the list of topics will be an emphasis for fluoropolymer users on the need for care in handling and processing the raw fluoropolymer products, and the need to follow recommended procedures to protect their employees. Special attention will be given to address the practices and procedures of those who use dispersions and coatings made from dispersions on the safe handling of products that contain APFO. In addition, as part of their workplace product stewardship efforts described below, the APFO Users, working with the FMG, will continue to update and distribute the manuals and information documents described.

Further industry efforts on product stewardship programs directed to customers will focus on technical support and assistance to fluoropolymer processors to help them keep their occupational safety and health programs current. While APFO Users recognize their responsibilities as suppliers of fluoropolymers, each processor and customer, as an employer, has an independent and non-delegable duty to take reasonable steps to comply with OSHA standards, and where there is a recognized hazard that is not addressed by specific OSHA standards, to assure that their employees are protected from safety and health hazards. Accordingly, the fluoropolymer manufacturer's product stewardship role is to provide the necessary information, assist in the understanding of it and provide support to processors using the fluoropolymers so they can meet their statutory obligations. Specific steps and studies are described below that demonstrate how the APFO Users will meet their obligations under product stewardship principles.

The APFO Users generally will submit information to and work with EPA through the SPI FMG. Such information and studies may be conducted under the auspices of industry groups such as the Association of Plastics Manufacturers in Europe (APME). The APFO Users will share the information we develop with EPA. As described below, the FMG continues to work on additional studies that will provide useful information to assess any potential environmental and health effects of APFO used in fluoropolymers. APFO Users are supportive of EPA's efforts and intend to assure that EPA has adequate information to understand the benefits, and any risks, of APFO use in fluoropolymers.

B. Data Quality

APFO Users recognize the importance of assuring good data quality. EPA's recently issued QA/QC Guidelines⁴ describe EPA's efforts to maximize the quality of environmental information made available to the public in terms of quality, integrity, reliability and validity of the data disseminated. APFO Users will incorporate the guidance contained in EPA's QA/QC guidelines into their research and monitoring programs to assure that sound scientific information is available to EPA and the public.

C. Specific Commitments

1. Supporting EPA Efforts to Involve CDC in Testing Programs

The APFO Users support adding APFO to the CDC NHANES process. To facilitate that step, work is underway to confirm the validity of the analytical method and sampling protocol for analyzing human blood for the presence of APFO, and the results will be shared with CDC. Efforts will be made to have the analytical methodology published in a peer-reviewed journal so it will be widely available. In addition, and in the further interest of adding transparency to the process, there will be support and assistance for one or more independent laboratories to become qualified to perform the validated method.

2. Toxicology Research

Under the auspices of the APME, the following additional studies will be completed on the schedule noted:

Study Description	Anticipated Report Date ⁵
Acute toxicity in daphnia	May 2003
Acute toxicity in trout	May 2003
Algal growth	July 2003
Chronic toxicity in daphnia	June 2003
Chronic toxicity in trout	November 2003
Adsorption/desorption soil studies	June 2003
ADE mass balance in rats	June 2003
Protein binding; rat/human	August 2003

⁴ "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency," announced in 67 F.R. 63657, October 15, 2002. *Quality Assurance for Data Collection*; 5360.1/A2 May 2000.

⁵ Based on commitments from contracting laboratories, we believe these dates can be met. EPA will be advised of any changes in the reporting schedule.

Study Description	Anticipated Report Date ²
Physiologically based kinetic modeling	October 2003
Mechanistic studies of pancreatic tumor induction in rats.	October 2003

Industry plans to conduct an additional study to determine parameters for route-to-route extrapolation (oral to inhalation), and the protocol was discussed with EPA scientists. Timing for the anticipated report date will be communicated when the final bid for the project is accepted.

Copies of the final reports for these studies will be submitted to EPA promptly upon receipt. EPA will be apprised immediately if any substantially new and unanticipated information develops as a result of the research programs consistent with current requirements; the above schedule does not, of course, supersede any statutory reporting obligations.

Following EPA's QA/QC guidelines, the reports will include documentation to allow EPA to evaluate the validity of the studies. This validation will enable EPA to assure that the information provided by the companies can be disseminated to the public consistent with EPA's data quality guidelines. Through the FMG, the APFO Users will promptly submit final reports of these studies to EPA and consult with EPA on what additional studies would be beneficial.

3. Understanding Routes of Exposure

Although there is no known evidence of adverse human health or environmental effects to date related to APFO, the APFO Users agree with EPA that it is useful to examine the potential for human and environmental exposure to APFO to determine where potential exposures may have occurred or currently occur. Such research will include, but may not be limited to (a) sites where APFO is manufactured; (b) sites that use APFO to make fluoropolymers; (c) sites that use fluoropolymer dispersions containing APFO; and (d) articles of commerce containing fluoropolymers, including dry fluoropolymer products and dispersion coated products, that might lead to general population exposure related to the fluoropolymer industry.

D. Specific Product Stewardship Activities by Site

1. Product Stewardship at Sites Where APFO Is Manufactured in the U.S.

Consistent with the principles of Responsible Care®, any APFO User who decides to manufacture APFO for commercial use in the United States (including current manufacturers) will first notify EPA and will review its product stewardship program with EPA covering the provisions listed in Addendum III to this letter, which applies only to APFO manufacturing.

As of the date of this letter, only one company has decided to manufacture APFO in the United States for use in fluoropolymer manufacturing. That company is du Pont, which already has committed to adopting the steps in Addendum III as part of its operating practices. Because

of antitrust considerations, APFO Users are legally barred from seeking to enforce any kind of group sanction against a future U.S. manufacturer that does not adopt Addendum III as part of its operating practices. They also cannot take any steps that might be construed by the U.S. antitrust enforcement agencies as anti-competitive. However, EPA would appear to have adequate authority to assure that future U.S. manufacturers of APFO, if any, follow the provisions outlined in Addendum III and commit to adequate product stewardship.

2. Product Stewardship at Sites in the U.S. That Use APFO To Make Fluoropolymers

As noted above, the APFO Users early on made a specific and substantial voluntary Emissions Reduction Commitment regarding the amounts of APFO emitted from their manufacturing facilities. Based on the baseline data from global materials balance submitted to EPA in September 2002, as described above, APFO Users, as FMG members, have committed to modifying their processes to reduce APFO emissions, on a global, individual company-wide basis, by a minimum of 50% for calendar year 2006. This reduction will be achieved by reducing the use, recycling a greater proportion, or by capturing and destroying it. In addition, at each of the fluoropolymer manufacturing sites listed below, the APFO Users will:

- 1) Develop site-specific plans to assess or model levels of APFO in air and water around their manufacturing sites; development of the plans will begin not later than 30 days after the date of this letter;
- 2) Conduct site-specific air dispersion modeling, using the EPA approved Industrial Source Complex Short Term 3 (ISCST3) model, as described in EPA's Guideline on Air Quality Models (40 C.F.R. Part 51, Appendix W),⁶ and assess the results using the air screening levels established in West Virginia;
- 3) As necessary to implement a site-specific plan, conduct ground and surface water analysis, and assess the results using the water screening levels established in West Virginia; and
- 4) Use the West Virginia screening levels to determine what additional actions, if any, may need to be taken, after reviewing the information with EPA.

These commitments will be undertaken at the following sites:

⁶ http://www.epa.gov/scram001/guidance/guide/appw_01.pdf

- a) du Pont
Washington Works Plant
Rt. 892 South
Washington, WV 26181
- b) Dyneon
1400 State Docks Road
Decatur Alabama
35609-2206
- c) Daikin
905 State Docks Road
Decatur, AL 35601

Six months after this Letter is signed, reports will be submitted by each company for each site on progress made with regard to environmental assessments.

In addition, the APFO Users will:

- 1) Within 30 days of this letter, provide a list of each site in the United States where APFO is used to make fluoropolymers and which fluoropolymers, including CAS numbers, are produced at that site;
- 2) For each listed site, beginning in 2004 for the 2003 calendar year and continuing through the 2008 calendar year, provide EPA with a biennial report, describing total emissions of APFO at each site, on a calendar year basis. The reports will be submitted to EPA within 180 days of the end of each reporting period and will include CAS numbers for the substances reported;
- 3) For each listed site that uses APFO, continue to conduct industrial hygiene monitoring in the workplace of their employees, measuring exposure to APFO and providing results to exposed employees. The results will be used to assure that employee exposures are controlled and to protect employees' health. The companies, as they have in the past, will assure that appropriate protective equipment and proper handling practices are used. They also will continue to provide employees with training on any hazards to which they are exposed, the signs and symptoms of overexposure and methods of proper handling, updating as new information becomes available, as part of their ongoing employee Occupational Safety and Health Administration Hazard Communication Standard programs.

As further evidence of their ongoing commitment, the APFO Users will provide EPA with timely reports of their collective progress in reducing emissions and meeting the target goals so that the information can be made part of the public record. The reports will be based on estimates of annual emissions, derived from available sampling data and supplemented by best estimates when actual data are not available, compared to the original estimates provided to EPA.

The APFO Users long have followed American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) recommendations in assessing their occupational exposures to APFO, and they will continue to do so. As other recommendations become available, the APFO Users will incorporate them into their programs and, as they have in the past, work to ensure that their employees are adequately protected based on the best available scientific evidence.

The APFO Users can provide EPA with details about their individual occupational safety and health and environmental compliance programs. If asked, each APFO User will review its environmental and occupational health data and will describe and provide the rationale of its monitoring programs going forward.

3. Product Stewardship at Sites in the U.S. That Use Fluoropolymer Dispersions Containing APFO

The APFO Users are committed to continuing their Product Stewardship programs for their customers. To assist in assessing the potential routes of exposure at selected sites of their customers, the APFO Users, under the auspices of the FMG, will:

- 1) Engage a third-party consultant to develop a representative material balance for the fate of APFO contained in these dispersions. Similar to the information provided to EPA on fluoropolymer manufacturing, address in the representative material balance how the dispersion is used at the customer site and potential emissions of APFO to the environment;
- 2) Submit the material balance to EPA and work cooperatively to identify and recommend appropriate product stewardship elements to control emissions at customer sites.
- 3) Target completion of the material balance by the end of 2003.

This project is under way and the contractor is being selected. We expect that the results of the materials balance will suggest what actual monitoring may be necessary. After the initial survey is complete, the companies will review the information to determine if further research or monitoring is required, and, if so, will work through SPI to help customers conduct their necessary studies. Among the tasks that need to be completed are: validating air sampling methods applied to customer sites; providing analytical methods; and identifying consultants and laboratories with experience in collecting and analyzing workplace air samples for APFO. The APFO Users will discuss plans for additional work in this area with EPA.

Finally, consistent with the product stewardship principles to which APFO Users firmly adhere and which are discussed above, the APFO Users will continue to update information provided to customers and users of fluoropolymers, make the information widely available and work with customers to assure that the information is disseminated downstream as appropriate. Industry meetings such as the semi-annual FPD meeting and other venues where fluoropolymer

users participate will be used to communicate the need to be knowledgeable about fluoropolymers and APFO, and the need to take the recommended steps to reduce emissions from processor facilities and minimize potential processor employee exposures.

4. Product Stewardship for Articles of Commerce Made with Fluoropolymers

Fluoropolymer products made with APFO are sold in either a dry resin form or as a liquid dispersion. It is the intent of the APFO Users that APFO not be carried through the manufacturing and processing of articles of commerce. To document that this is the case, the APFO Users, under the auspices of the FMG, will:

- 1) Analyze representative articles of commerce containing or made with dry fluoropolymer resins for the presence of APFO and report the results to EPA.
- 2) For products coated or manufactured with liquid dispersions, analyze representative articles of commerce for the presence of APFO and report the results to EPA.
- 3) As appropriate, develop and disseminate information along with recommendations to processors for reducing the potential for exposure to APFO from articles of commerce.
- 4) Target completion of the analysis of articles of commerce by the end of 2003.

These studies will be conducted by contract laboratories or in company laboratories using validated methods. The products selected for analysis will be: (1) those most likely to have widespread consumer use; and (2) a representative sampling of industrial and commercial products.

The articles of commerce being tested will be selected from products made with fluoropolymers supplied by APFO Users. There are some articles of commerce made from imported fluoropolymers that are not produced by APFO Users and also some articles of commerce made outside the U.S. from fluoropolymers not supplied by APFO Users.

Based on preliminary data obtained using preliminary methods, it is our expectation that articles of commerce made from dry fluoropolymers will have no significant amounts of APFO present, and that most coated products will show similar results. An example can be found in the recent submission by du Pont to EPA showing that cookware coated with products made with fluoropolymer resins demonstrated no detectable level of APFO with current methods accepted by the U.S. Food and Drug Administration for analysis of food contact products.

Based on these analyses, the APFO Users will provide EPA with potential exposure source and route information for public dissemination as it is developed. These data will be used to determine whether those sources contribute to potential exposure to the general population and to develop appropriate practices, methods, and measures to reduce and control the emissions of APFO. Again, these will be discussed with EPA as they are being developed.

* * * * *

The APFO Users appreciate the opportunity to work with EPA on this matter and agree that close coordination of our efforts and sharing of information is important. Accordingly, we will continue to communicate with EPA as important relevant information arises and would appreciate similar consideration. As new information becomes available, the APFO Users are committed to work with EPA to take appropriate further actions in light of the information that is developed.

In closing, we would like to emphasize that the fluoropolymer industry is committed to the continued safe manufacture, processing and use of fluoropolymers and to working with EPA.

Respectfully Submitted,

APFO Users, attached

Attachments

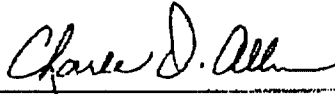
Addendum I: Fluoropolymers and Fluoroelastomers That May Be Made With APFO

Addendum II: Background and Voluntary Activities

Appendix I: Partial List of Studies on APFO in EPA's Docket

Addendum III: Manufacture of APFO

The Honorable Stephen L. Johnson
March 14, 2003
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A handwritten signature in cursive script, reading "Charles D. Allen". The signature is written in black ink and is positioned above a horizontal line.

Name: Charles D. Allen
Title: President
Asahi Glass Fluoropolymers USA, Inc.

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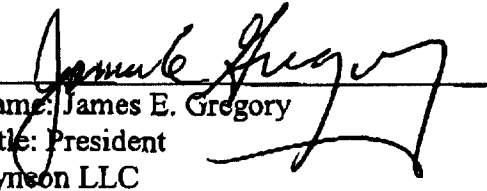


Name Takahito Sakanoue

Title: President

Daikin America, Inc.

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Name: James E. Gregory
Title: President
Dynson LLC

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A handwritten signature in dark ink, appearing to read "R. Angiollo", written over a horizontal line.

Name: Richard J. Angiollo
Title: Vice President & General Manager
E. I. du Pont de Nemours and Company

Addendum I

Fluoropolymers and Fluoroelastomers Which May Be Made With APFO		
Polymer family	CAS Number	Monomers
Fluoropolymers		
PTFE	9002-84-0	TFE
FEP	25067-11-2	TFE, HFP
PFA	26655-00-5	TFE, PPVE
THV	25190-89-0	TFE, HFP, VDF
ETFE	68258-85-5	TFE, E
THE	35560-16-8	TFE, HFP, E
Fluoroelastomers		
Copolymers	9011-17-0	VDF, HFP
Terpolymers	25190-89-0	TFE, HFP, VDF
Base resistant elastomers	54675-89-7, 27029-05-6	TFE, VDF, P TFE, P
Perfluoroelastomers	26425-79-6	TFE, PPVE
CTFE elastomers	9010-75-7	CTFE, VFD
Low temperature elastomers	26425-79-6	TFE, PMVE

Monomers Used in Fluoropolymers		
Acronym	Monomer name	CAS Number
CTFE	Chlorotrifluoroethylene	79-38-9
TFE	Tetrafluoroethylene	116-14-3
HFP	Hexafluoropropylene	116-15-4
VDF	Vinylidene fluoride	75-38-7
PMVE	Perfluoromethyl vinyl ether	1187-93-5
PPVE	Perfluoropropyl vinyl ether	1623-05-8
E	Ethylene	74-85-1
P	Propylene	115-07-1

Addendum II

Background and Voluntary Activities

Background

A. APFO Use in Fluoropolymers

Ammonium perfluorooctanoate, or APFO, is a surfactant that acts as a polymerization aid to make certain base fluoropolymer resins. APFO is currently the most widely used surfactant for fluoropolymer manufacture and is essential in these processes. APFO typically is used in low concentrations (less than 1%) in the fluoropolymer manufacturing process and in a few, very limited industrial applications. Because of its use as a polymerization aid, it is substantially removed in finishing steps in dry fluoropolymer manufacturing. In water-borne dispersions, which are used to make various coatings, it allows application of the dispersion, but it is not intended to be part of the fluoropolymer or the finished, end-use product.

It is critical to understand the role of APFO in the fluoropolymer industry. The surfactant properties of APFO facilitate the *manufacture* of fluoropolymers and fluoroelastomers, but it does not contribute to the performance of the end-use product. Therefore, it is not intended to be – or needed – in the end-use products made with it.

In fact, most of the products made from fluoropolymers require heat treatment that removes or destroys the majority of the APFO in the fluoropolymer resin before the products made with fluoropolymers leave the manufacturing facility or are used. Therefore, fluoropolymer products do not normally present a route of exposure to APFO once they leave the hands of the end-use product manufacturer.

Further, APFO Users have long recognized their obligation to responsible use of chemicals such as APFO in their processes and products and long ago voluntarily committed themselves to establishing and supporting responsible health and environmental practices in the manufacture and use of fluoropolymers. This has been done to minimize the potential effect, if any, these activities have on human health and the environment, and to support the continued safe manufacture and use of fluoropolymers made using APFO. Those commitments continue today, and are exemplified by the additional commitments the APFO Users describe in this letter.

Also important to understand is that, despite more than 30 years of intensive research into alternatives, none has been found, as was presented by du Pont representatives on behalf of The Society of the Plastics Industry, Inc. (SPI) Fluoropolymers Manufacturing Group to the U.S. Environmental Protection Agency (EPA) on April 23, 2001. Driving the research were considerations regarding persistence, the existence of only one supplier, and the need for more effective, cheaper alternatives. Indeed, fluoropolymer manufacturers have tested literally dozens of compounds, and all have been rejected due to technical problems or potential safety concerns that made them unsuitable for such use.

B. The Role of Fluoropolymers in Society

Fluoropolymers are essential to a variety of technologies and products that enhance human life and promote environmental improvements. Ranging from power generation to emission controls on vehicles, to semiconductor chip manufacturing and aerospace applications, fluoropolymers provide superior performance in products that contribute to increased safety in our offices, homes, businesses, and communities.

Fluoropolymers provide unique and critical performance properties in “system critical” applications that protect and benefit people and the environment. Fluoropolymers are among the few plastic materials that can withstand the temperatures inside the engine compartments of aircraft. They also have high resistance to a broad range of fuels, solvents and corrosive chemicals, as well as excellent electrical insulating properties. These unique properties provide critical performance characteristics needed to prevent fire, fluid emission, electrical overloading or similar emergencies in many high-performance applications. And, for virtually all these applications, fluoropolymers are the only materials that meet system performance needs in high temperatures and harsh chemical environments.

C. 50 Years of Experience of Safe APFO Use

APFO has been used safely and without apparent adverse effects on human health for more than 50 years, in part because of the workplace safety programs the APFO Users had in place. This conclusion is supported by epidemiology and other human health studies (contained in EPA’s public record and published in the scientific literature) on employees both at APFO production and fluoropolymer manufacturing facilities.

Multiple studies, the first of which was published in 1980, have examined the health-related experience of employees in the APFO manufacturing process. These studies looked for health effects similar to the effects observed in animal studies. This effort continues even now. No studies of the employees who have direct exposure showed any unusual or unexpected pattern of illnesses or deaths from any disease, including cancer.

Based on this experience, and the ongoing health and safety research they have supported and that has been published over the years, APFO Users do not believe that current levels of exposure to APFO cause adverse effects to human health or the environment.

D. Recent Events Triggering Interest in APFO

In May 2000, 3M announced that it would be “phasing out of the perfluorooctanyl chemistry used to produce certain repellents and surfactant products.” Subsequent to the 3M announcement, EPA broadened their interest in a series of fluorochemicals that they considered to be persistent in the environment. This interest has been heightened recently by the discovery that certain of these fluorochemicals are found at trace levels in the blood of the US population.

Voluntary Activities of APFO Users and Manufacturers

The users and manufacturers of APFO have, both individually and collectively, supported research into the potential effects on human health and the environment, and have adopted in their own workplaces health and safety practices to minimize employee exposure. They have funded research on the toxicology, both for animal and environmental effects and, as noted above, conducted epidemiology studies to be sure that human health has not been affected by the use of APFO. In addition, they have developed control recommendations for the safe use and handling of fluoropolymers and, specifically, for dispersions containing APFO. These recommendations have been disseminated to customers through publications and meetings of the SPI Fluoropolymers Division and the Association of Plastics Manufacturers in Europe (APME), in addition to the information provided individually by the APFO Users through Material Safety Data Sheets (MSDS) and other technical information sources.

The studies the APFO Users and manufacturers have funded were conducted on APFO and a related chemical, perfluorooctanoic acid (PFOA).⁷ These studies are among those that 3M and du Pont have submitted to EPA. The number of research studies on APFO included in EPA's docket is large. A brief list of some of the studies, including studies on human health assessments, is included in Appendix 1 of this Addendum.

To coordinate their efforts to assess and respond to EPA's concerns, the manufacturers of fluoropolymer resins, who are also members of SPI's Fluoropolymers Division, formed the FMG. The mission of the FMG is to promote the continued safe manufacture and use of fluoropolymers made using fluoropolymer polymerization aids such as APFO while establishing and supporting responsible use of fluoropolymer products and promoting environmental stewardship. The APFO Users, working with others in the FMG, will continue to support the safe use of APFO, will work with EPA to understand the information that exists and to develop research programs to fill in the gaps.

The APFO Users, as members of the FMG, first presented information about the FMG's work to EPA in September 2000. Since then, the APFO Users, through the FMG and the APME, have continued to provide information on manufacturing, distribution and use of APFO, as well as the available data on systemic toxicity and environmental fate of APFO. APFO Users have reviewed EPA's preliminary assessment of the potential hazards to human health and the environment associated with exposure to APFO, entitled "Revised Draft Hazard Assessment of Perfluorooctanoic Acid and its Salts," dated November 4, 2002. The FMG has also provided

⁷ While APFO is the product used in fluoropolymers, PFOA is the substance that has been found in some, but not all, the environmental and blood samples that have been tested. PFOA is also the chemical that has usually been tested in animal studies, because APFO dissociates in water into PFOA and ammonium ions. EPA has assigned OPPTS Docket Number AR226 for all submissions on perfluorinated substances. AR226 also contains documents pertaining to other perfluorinated chemical substances. The APFO Users believe that the matters concerning APFO are different from those associated with the other chemical substances included in EPA OPPTS Docket Number AR226.

EPA with a number of new documents and information about the use of APFO in fluoropolymers.

A. Fluoropolymer Manufacturers' Product Stewardship Commitment

The APFO Users specifically concur with and subscribe to the product stewardship principles similar to those described by American Chemistry Council's (ACC) and Synthetic Organic Chemical Manufacturers Association's (SOCMA) Responsible Care® programs. The APFO Users' product stewardship programs incorporate provisions (1) addressing the development and dissemination of health, safety, and environmental information; (2) adopting safe practices to limit risks to the community, customers, and employees from manufacturing and processing of fluoropolymer-based products; (3) establishing proper practices for effective health and safety management; and (4) instituting risk management approaches. These ongoing programs represent a substantial commitment of resources and efforts, and the activities described below are evidence of that commitment.

B. Toxicology Research

A number of the toxicology studies relevant to APFO that have been submitted to EPA, some of which were conducted in the early 1970s, were funded by fluoropolymer industry members, including the users and manufacturers of APFO. More recently, the studies conducted were organized and coordinated by the Toxicology Working Group of the Fluoropolymer Committee of APME. These studies, contained in AR226, examine acute and chronic health effects and include two carcinogenicity studies, a two-generation developmental and reproductive study, and studies of effects on tissues and organs, including in the liver, pancreas and reproductive organs, in laboratory animals.

Other studies have provided information on the physical and chemical characteristics of APFO and its potential effects in a variety of species, including fish, microorganisms and other species. The APFO Users' commitment to support EPA's efforts is demonstrated through the FMG and the APME research programs.

C. Workplace Product Stewardship Activities Directed Toward Protecting Fluoropolymer Manufacturing Employees

As a matter of good industrial hygiene practice, the APFO Users have occupational health and safety programs to protect their employees, including those who handle APFO in fluoropolymer manufacturing. Over the years, as more information has become available, 3M has provided information on APFO to the fluoropolymer manufacturers, along with recommendations for proper handling and use. Among the most significant changes in handling was the decision to sell the substance in a wet form to reduce dusting and thereby employee exposure. Additional precautions to prevent skin contact and otherwise limit exposure include the use of protective clothing, gloves, face shields, and respirators, disposable garments, installation of general mechanical and local exhaust ventilation systems, and other handling practices as recommended in the manufacturer's MSDS. These precautions, the effects of

APFO, and other important information are discussed with employees as part of ongoing Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (HCS) programs and on MSDS and product labels.

All the companies adopted these various practices to keep employee exposures below the current American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) of an eight-hour time-weighted-average (TWA) of 0.01 milligram per cubic meter (mg/m^3). The companies have used industrial hygiene monitoring to document the efficacy of control measures and employee exposures as needed. The companies remain committed to meeting the occupational standards and guidelines recommended by organizations such as ACGIH as they are updated.

D. Existing Product Stewardship Activities Directed Toward Customers

APFO Users have long-standing product stewardship programs that incorporate the principles and practices similar to those of the Responsible Care® program as it applies to obligations to customers. They have worked collectively and individually to provide health, safety and environmental information to customers and distributors. Commensurate with product risk, they select and periodically review customers and distributors to foster proper use, handling, recycling and disposal as well as the transmittal of appropriate information to downstream users. If improper practices involving a product are identified, the APFO Users work with the customer or distributor to improve those practices. Each of the companies evaluates its business relationships in light of these principles.

The APFO Users, with other FMG members, have worked for many years to assure that people who work with fluoropolymers have sufficient information to use them safely. As required under the OSHA HCS, the FMG companies have routinely included information about safe handling of their products on MSDS, including information about toxicity, protective equipment, and safe methods and practices. In addition, the companies have collectively worked to disseminate widely safety and health information using additional methods and documents, going beyond what current law requires.

One of the first collective efforts in this regard was the creation of a *Guide to the Safe Handling of Fluoropolymer Resins* (Safe Handling Guide) in 1992. A 3rd Edition was published in 1998, incorporating the recommendations from all the manufacturers of fluoropolymer resins, and a copy already has been provided to EPA. Those recommendations included chapters on Potential Health Effects, Regulations, Safety Measures, Waste Disposal, and Emergency Measures. Although focused on fluoropolymer resins, the Guide includes information on some ingredients, including surfactants, used in fluoropolymer resins. Health effects of some by-products also were included.

The Chapter on Safety Measures has extensive discussions of steps to take to avoid exposure to hazardous chemicals that might be present when processing fluoropolymers. Specific emphasis was placed on using local exhaust ventilation because of the by-products of thermal degradation, and information was provided on specific processing activities and their

unique associated hazards. Recommendations included required protective clothing and equipment, such as respirators and gloves, as well as other garments to prevent skin contact. Finally, an extensive education effort was conducted through SPI FPD's semi-annual meetings and seminars on the Safe Handling Guide and its updates.

The effort to update the Safe Handling Guide, now in its 3rd Edition, and other documents is an ongoing process that normally involves processor members of the FPD. Information on APFO will be included and highlighted.

In addition, the FMG prepared and published its *Guide to the Safe Handling of Fluoropolymer Dispersions* in October 2001 that describes APFO and related compounds and their use in fluoropolymer dispersions in detail. This document is currently being updated and a revised copy will be provided as soon as it is available.

Appendix 1

Partial List of Studies on APFO in EPA's Docket

Studies funded by APFO Users and manufacturers:

- 1) Fayerweather, "Liver Study of Washington Works Employees Exposed to C8: Results of Blood Biochemistry Testing," January 15, 1981;
- 2) Gortner, E.G. (1981). "Oral Teratology Study of T-2998CoC in Rats." Safety Evaluation Laboratory and Riker Laboratories, Inc. Experiment No. 0681TR0110, December 1981;
- 3) Gortner, E.G. (1982). "Oral Teratology Study of T-3141CoC in Rabbits." Safety Evaluation Laboratory and Riker Laboratories, Inc. Experiment No. 0681TB0398, February 1982;
- 4) Riker (1983). "Two-Year Oral (Diet) Toxicity/carcinogenicity Study of Fluorochemical FC-143 in Rats." Riker Laboratories, Inc., Experiment No. 0281CR0012, May 1983;
- 5) Staples, R.E., Burgess, B.A., and Kerns, W.D. (1984). "The embryo-fetal toxicity and teratogenic potential of ammonium perfluorooctanoate (PFOA) in the rat." *Fundamental and Applied Toxicology*, vol. 4, pp. 429-440;
- 6) York, R.G. (2002). "Oral (Gavage) Two-generation (One Litter per Generation) Reproduction Study of Ammonium Perfluorooctanoic Acid (PFOA) in Rats." Argus Research laboratories, Inc. Protocol Number 418-020, March 26, 2002;

Studies funded by APFO Manufacturers:

- 7) Gilliland, F.D. (1992). "Fluorocarbons and Human Health: Studies in an Occupational Cohort." Doctoral dissertation. Minneapolis (MN), University of Minnesota;
- 8) Gilliland, F.D. and Mandel, J.S. (1993). "Mortality among employees of a perfluorooctanoic acid production plant." *Journal of Occupational Medicine*, vol. 35, pp. 950-954;
- 9) Gilliland, F.D. and Mandel, J.S. (1996). "Serum perfluorooctanoic acid and hepatic enzymes, lipoproteins and cholesterol: a study of occupationally exposed men." *American Journal of Industrial Medicine*, vol. 29, pp. 560-568;
- 10) Olsen, G.W., Gilliland, F.D., Burlew, M.M., Burris, J.M., Mandel, J.S. and Mandel, J.H. (1998). "An epidemiologic investigation of reproductive hormones in men with occupational exposure to perfluorooctanoic acid." *Journal of Occupational and Environmental Medicine*, vol. 40, pp. 614-622;
- 11) Olsen, G.W., Burris, J.M., Burlew, M.M., and Mandel, J.H. (2000). "Plasma cholecystokinin and hepatic enzymes, cholesterol and lipoproteins in ammonium perfluorooctanoate production workers." *Drug and Chemical Toxicology*, vol. 23, pp. 603-620;
- 12) Alexander, B.H. (2001a). "Mortality Study of Workers Employed at the 3M Cottage Grove Facility." Minneapolis (MN), University of Minnesota;
- 13) Alexander, B.H. (2001b). "Mortality Study of Workers Employed at the 3M Decatur Facility." Minneapolis (MN), University of Minnesota;

- 14) Olsen, G.W., Logan, P.W., Simpson, C.A., Burris J.M., Burlew, M.M., Lundberg, J.K., and Mandel, J.H. (2001a). "Descriptive Summary of Serum Fluorochemical Levels among Employee Participants of the Year 2000 Decatur Fluorochemical Medical Surveillance Program." St. Paul (MN), 3M Company. U.S. EPA Docket AR-226-1030a020a;
- 15) Olsen, G.W., Burlew, M.M., Hocking, B.B., Skratt, J.C., Burris J.M., and Mandel, J.H. (2001b). "An Epidemiologic Analysis of Episodes of Care of 3M Decatur Chemical and Film Plant Employees," 1993-1998. St. Paul (MN), 3M Company. U.S. EPA Docket AR-226-1030a02;
- 16) Olsen, G.W., Burris, J.M., Burlew, M.M., and Mandel, J.H. (2003). "Epidemiologic assessment of worker serum perfluorooctanesulfonate (PFOS) and perfluorooctanoic acid (PFOA) concentrations and medical surveillance examinations." Journal of Occupational and Environmental Medicine, in press;

Recent toxicological reviews funded by APFO Users and APME:

- 17) An assessment prepared for the Association of Plastics Manufacturers in Europe and SPI entitled "Genotoxicity, Carcinogenicity, Developmental Effects and Reproductive Effects of Perfluorooctanoate: A Perspective from Available Animal and Human Studies," December 19, 2002; and
- 18) Environmental Health Research Foundation, "Summary and Analysis of Health Data on Perfluorooctanoic Acid (PFOA)," March 5, 2003.

Addendum III

Manufacture of APFO

Responsible manufacturing of APFO requires that the parties undertaking that manufacture meet certain environmental, health and safety standards. Accordingly, when manufacturing APFO for a commercial use in the United States, a responsible manufacturer will first notify EPA, and will review their product stewardship program with EPA covering the provisions listed below. For purposes of this addendum, manufacture means to make or produce for commercial use at a facility in the United States; importation of APFO for use in manufacturing or processing fluoropolymers is not included.

- 1) Limit total annual emissions in the US from each site where manufacturing of APFO occurs, using technology reasonably available that reduces APFO emissions to less than 500 pounds per year (a 99% reduction compared to prior manufacturing technology as reported in the documents contained in EPA's docket); and
- 2) Sell or resell APFO in accordance with ACC or SOCMA good product stewardship codes; and
- 3) Offer voluntary blood testing for employees, conduct industrial hygiene monitoring in the work areas where APFO is made or processed, and, based on the results, take steps to control the exposures to levels at least as low as the ACGIH TLV, by assuring that appropriate protective equipment and safe handling practices are used, and continue to provide and update employee training on safe handling; and
- 4) Monitor groundwater and surface water for APFO in the vicinity of the facility, conduct air modeling studies based on available technology for air monitoring for APFO at the facility; maintain off-site exposure below the West Virginia screening levels; and
- 5) Beginning in the year after production commences, and continuing for five consecutive years following, for the prior calendar year, report to EPA biennially, on a calendar year basis (unless otherwise provided in individual agreements with EPA and state regulatory agencies), within 180 days of the end of the reporting period, annual production volume of APFO, their emissions per facility (air, water, waste), summary reports on groundwater and surface water monitoring results, workplace industrial hygiene monitoring, and summary data on employee blood monitoring results (taking steps to preserve employee confidentiality).