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Perfluorooctanoic Acid (PFOA), Fluorinated Telomers; Request for Comment, Solicitation of Interested Parties for Enforceable Consent Agreement Development, and Notice of Public Meeting

Perfluorooctanoic Acid (PFOA), Fluorinated Telomers; Request for Comment, Solicitation of Interested Parties for Enforceable Consent Agreement Development, and Notice of Public Meeting

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ENVIRONMENTAL PROTECTION AGENCY
[OPPT-2003-0012; FRL-7303-8]

Perfluorooctanoic Acid (PFOA), Fluorinated Telomers; Request for Comment, Solicitation of Interested Parties for Enforceable Consent Agreement Development, and Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).
ACTION: Notice.

SUMMARY: EPA has identified potential human health concerns from exposure to perfluorooctanoic acid (PFOA) and its salts, although there remains considerable scientific uncertainty regarding potential risks. EPA is requesting public comment on pertinent topics of interest, as discussed in this document, and the submission of additional data concerning these chemicals. EPA is also soliciting the identification of interested parties who want to monitor or participate in negotiations on one or more enforceable consent agreements (ECAs) under section 4 of the Toxic Substances Control Act (TSCA) concerning PFOA and fluorinated telomers which may metabolize or degrade to PFOA, and is announcing the first public meeting for these ECA negotiations.

DATES: Comments on this notice must be received on or before May 16, 2003.

Notify EPA in writing on or before May 16, 2003 of your desire to be accorded ``interested party'' status for the purpose of participating in or monitoring the negotiations for development of ECAs concerning PFOA and telomers.

A public meeting has been scheduled to initiate negotiations on an ECA for PFOA and telomers, from 1 p.m. to 5 p.m., on Friday, June 6, 2003.

ADDRESSES: Submit your comments, identified by docket ID number OPPT-2003-0012, online at <http://www.epa.gov/edocket/> (EPA's preferred method), or by mail to EPA Docket Center (7407), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. For additional comment submission methods and detailed instructions, go to Unit I.C. of the SUPPLEMENTARY INFORMATION.

Submit your notification for ``interested party'' status separately from any comments submitted, identified ``Attention: PFOA ECA Notification'' by mail to Brigitte Farren, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. To protect personal information from disclosure to the public, please submit these notifications separately from your comments and do not use any online electronic commenting system to submit this notification.

The public meeting to initiate negotiations on ECAs for PFOA and telomers will be held at the Environmental Protection Agency, EPA East Bldg., Rm. 1153, 1201 Constitution Ave., NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: For general information contact: Barbara Cunningham, Director, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Mary Dominiak, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8104; e-mail address: dominiak.mary@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of particular interest to manufacturers, importers, processors, exporters, distributors, and users of PFOA, fluoropolymers, fluoroelastomers, and telomer chemicals. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Copies of this Document and Other Related Information?

1. Docket. EPA has established an official public docket for this action under docket identification (ID) number OPPT-2003-0012. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. Additional information concerning the topics discussed in this notice can be found in Administrative Record (AR)-226: PFOS, PFOA,

Telomers, and Related Chemicals, which was established by the Agency in 2000 to receive information on various fluorinated chemicals, including PFOA. These materials are also available in the EPA Docket Center. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566-1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566-0280.

2. Electronic access. You may access this Federal Register document electronically through the EPA Internet under the ``Federal Register'' listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ``search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other

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information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand

delivery/courier. (Please note, however, that to protect personal information from disclosure to the public, you should not follow the instructions in this section to submit your notification for ``interested party'' status. Such notification should be submitted separately from any comments on this document using the specific instructions provided under ADDRESSES. Do not use any online electronic commenting system to submit this notification.) To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ``late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. Electronically. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. EPA Dockets. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, and follow the online instructions for submitting comments. Once in the system, select ``search,'' and then key in docket ID number OPPT-2003-0012. The system is an ``anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. E-mail. Comments may be sent by e-mail to oppt.ncic@epa.gov, Attention: Docket ID Number OPPT-2003-0012. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ``anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. Disk or CD ROM. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. By mail. Send your comments to: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. By hand delivery or courier. Deliver your comments to: OPPT Document Control Office (DCO) in EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number OPPT-2003-0012. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930.

D. How Should I Submit CBI To the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI,

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please consult the technical person listed under FOR FURTHER INFORMATION CONTACT.

E. What Should I Consider as I Prepare My Comments for EPA?

We invite you to provide your views on the various options we propose, new approaches we have not considered, the potential impacts of the various options (including possible unintended consequences), and any data or information that you would like the Agency to consider during the development of the final action. You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the notice or collection activity.
7. Make sure to submit your comments by the deadline in this notice.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and Federal Register citation.

II. What Action is the Agency Taking?

EPA has prepared a preliminary risk assessment (Ref. 1) on perfluorooctanoic acid (PFOA) (Octanoic acid, pentadecafluoro-; Chemical Abstracts Service Registry Number (CAS No.) 335-67-1) and its salts, predominantly ammonium perfluorooctanoate (APFO) (Octanoic acid, pentadecafluoro-, ammonium salt (CAS No. 3825-26-1)). This preliminary assessment indicates potential nationwide human exposure to low levels of PFOA. Based on certain animal studies, there could be a potential risk of developmental and other adverse effects associated with these exposures in humans. However, this assessment also reflects substantial

uncertainty about the interpretation of the risk. EPA has identified areas where additional information could be very helpful in allowing the Agency to develop a more accurate assessment of the potential risks posed by PFOA and the other compounds addressed in this notice, and to identify what voluntary or regulatory mitigation or other actions, if any, would be appropriate. EPA is making this preliminary assessment public in order to identify the Agency's concerns, to indicate areas where additional information or investigation would be useful, and to request the submission of data addressing these issues.

EPA is also soliciting the identification of parties who would be interested in monitoring or participating in negotiations for the development of one or more ECAs under section 4 of TSCA on PFOA and on fluorinated telomers (hereafter ``telomers'') which may metabolize or degrade to PFOA. The intent of the ECAs would be to develop additional information, particularly environmental fate and transport information, to enhance understanding of the sources of PFOA in the environment and the pathways by which human exposure to PFOA is occurring.

III. Background

In 1999, EPA began an investigation after receiving data on perfluorooctyl sulfonate (PFOS) indicating that PFOS was persistent, unexpectedly toxic, and bioaccumulative. These data also showed that PFOS had been found in very low concentrations in the blood of the general population and in wildlife around the world. 3M Company (3M), the sole manufacturer of PFOS in the United States and the principal manufacturer worldwide, announced in May 2000 that it was discontinuing its perfluorooctanyl chemistries, including PFOS. EPA followed the voluntary 3M phaseout with regulatory action under TSCA section 5 to limit any future manufacture or importation of PFOS before EPA has had an opportunity to review activities and risks associated with the proposed manufacture or importation (Ref. 2).

In June 2000, EPA indicated that it was expanding its investigation of PFOS to encompass other fluorochemicals, including PFOA, in order to determine whether these other fluorochemicals might present concerns similar to those found with PFOS. EPA was concerned in part because 3M had also found PFOA in human blood during the studies on PFOS (Ref. 3).

In September 2002, the Director of OPPT initiated a priority review on PFOA because the developmental toxicity data, the carcinogenicity data, and the blood monitoring data presented in an interim revised hazard assessment raised the possibility that PFOA might meet the criteria for consideration under TSCA section 4(f) (Refs. 4 and 5). When the priority review commenced, EPA anticipated completing the review within a few months. However, as explained in this notice, there remain substantial uncertainties associated with the preliminary risk assessment. EPA believes these uncertainties may be reduced through acquisition of the information described in this notice. EPA is therefore continuing the priority review in order to acquire this information and better inform the Agency's decisionmaking.

A. PFOA Sources and Uses

PFOA and its salts are fully fluorinated organic compounds that can be produced synthetically and formed through the degradation or metabolism of certain other manmade fluorochemical products. PFOA is a synthetic chemical and is not naturally occurring. Consequently, all PFOA in the environment is attributable to human activity.

PFOA is used primarily to produce its salts, which are used as essential processing aids in the production of fluoropolymers and fluoroelastomers. Although they are made using PFOA, finished fluoropolymer and fluoroelastomer products are not expected to contain

PFOA. In recent years, less than 600 metric tons per year of PFOA and its salts have been manufactured or imported in the United States (Ref. 6). The major fluoropolymers manufactured using PFOA salts are polytetrafluoroethylene (PTFE) and polyvinylidene fluoride (PVDF). PTFE has hundreds of uses in many industrial and consumer products, including soil, stain, grease, and water resistant coatings on textiles and carpet; uses in the automotive, mechanical, aerospace, chemical, electrical, medical, and building/construction industries; personal care products; and non-stick coatings on cookware. PVDF is used primarily in three major industrial sectors: Electrical/electronics, building/construction, and chemical processing.

PFOA can be commercially manufactured by two major alternative processes: The Simons Electro-Chemical Fluorination (ECF) process, and a telomerization process. Releases from manufacturing processes are one source of PFOA in the environment. Historically, most U.S. production was by 3M using the ECF process. 3M discontinued its manufacture of PFOA between 2000 and 2002, and other domestic producers are using the telomerization process exclusively.

In the ECF process, an electric current is passed through a solution of anhydrous hydrogen fluoride and an organic feedstock of octanoic acid or a derivative. The ECF process replaces the

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carbon-hydrogen bonds on molecules of the organic feedstock with carbon-fluorine bonds. Perfluorination occurs when all the carbon-hydrogen bonds are replaced with carbon-fluorine ones. The ECF process yields between 30-45% straight chain (normal) perfluorooctanonyl fluoride (PFOF), along with a variable mixture of byproducts and impurities. The output of the ECF process consists of a complex combination of chemical substances with varying molecular weights, including higher and lower straight-chain homologues; branched-chain perfluoroalkyl fluorides of various chain lengths; straight-chain, branched, and cyclic perfluoroalkanes and ethers; and other byproducts. After disposal or recovery of some of the byproducts and impurities, the acid fluoride is base hydrolyzed in batch reactors to yield PFOA. The PFOA salts are synthesized by base neutralization of the acid to the salt in a separate reactor.

In the telomerization process, tetrafluoroethylene is reacted with other fluorine-bearing chemicals to yield fluorinated intermediates which are readily converted into PFOA. This process yields predominantly straight-chain acids with an even number of carbon atoms. Distillation can be used to obtain pure components. Commercial products manufactured through the telomerization process, sometimes known as telomers, are generally mixtures of perfluorinated compounds with even carbon numbers, although the process can also produce compounds with odd carbon numbers.

In addition to releases from the deliberate manufacture of PFOA through either the ECF or telomerization processes, and from the use of PFOA and its salts in the manufacture and processing of fluoropolymers and fluoroelastomers, PFOA may have entered the environment through other sources. 3M has indicated that PFOA may have been present as a trace contaminant in some of the fluorochemical products which it discontinued manufacturing between 2000 and 2002 (Ref. 7). Because these products are no longer being manufactured, they will likely not be a significant potential future source of PFOA.

EPA has also received data which indicate that the 8-2 telomer alcohol (1-Decanol, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluoro- (CAS No. 678-39-7)) although not itself made with PFOA, can be metabolized by living organisms or biodegrade under environmental conditions to produce PFOA (Refs. 8 and 9). Other telomer

chemicals have not been tested to determine whether they may also metabolize or degrade to form PFOA. Telomers are used widely in a range of commercial products, including some that are directly released into the environment, such as fire fighting foams, as well as soil, stain, and grease resistant coatings on carpets, textiles, paper, and leather. The extent to which these telomer-containing products might degrade to release PFOA is unknown. However, anecdotal evidence of the atmospheric presence of telomer alcohols in a multi-city North American survey suggests that telomers may be one source of environmental PFOA (Ref. 10). Additional fate information is necessary to determine whether and the extent to which telomer product degradation may be a source of PFOA.

EPA is not currently aware of any other potential sources of PFOA in the environment. EPA specifically requests comment on this issue, and the submission of any data identifying or characterizing PFOA sources. EPA is especially interested in the thermal stability and oxidative degradation products of materials containing PFOA or telomer chemicals which are incinerated.

B. Hazard and Exposure

EPA has conducted a detailed review of all available hazard and exposure information on PFOA. This review is available in the Agency's Revised Draft Hazard Assessment on PFOA and Its Salts (Ref. 11). This draft hazard assessment has not been formally peer reviewed, but has been reviewed internally by the EPA Office of Research and Development (ORD).

PFOA is persistent in the environment. It does not hydrolyze, photolyze, or biodegrade under environmental conditions. Based on recent human biomonitoring data provided by industry, which found PFOA in the blood of workers and the general population in all geographic regions of the United States, exposure to PFOA is potentially nationwide, although the routes of exposure for the general population are unknown.

Several epidemiological studies on the effects of PFOA in humans have been conducted on workers. An association with PFOA exposure and prostate cancer was reported in one study; however, this result was not observed in an update to the study in which the exposure categories were modified. A non-statistically significant increase in the levels of the hormone estradiol in workers with high serum PFOA levels (>30 parts per million (ppm)) was also reported, but none of the other hormone levels analyzed indicated any adverse effects.

APFO is the most widely used salt of PFOA, and most animal toxicity studies have been conducted with APFO. An extensive array of animal toxicity studies have been conducted in rodents and monkeys. These studies have shown that APFO exposure can result in a variety of toxic effects in animals including liver toxicity, developmental toxicity, and immunotoxicity. In addition, rodent bioassays have shown that chronic APFO exposure is associated with a variety of tumor types. The mechanisms of APFO tumorigenesis are not clearly understood. At this time, EPA is evaluating the scientific evidence and has not reached any conclusions on the potential significance to humans of the rodent cancer data.

There are marked gender differences in the elimination of PFOA in rats. In addition, there are substantial differences in the half-life of PFOA in rats, monkeys, and humans. The gender and species differences are not completely understood and therefore the extent of potential risks to humans is uncertain.

C. Preliminary Risk Assessment

Because TSCA section 4(f) is focused narrowly on the specific toxicity endpoints of cancer, birth defects, and gene mutation, the preliminary risk assessment prepared as part of this priority review focused on the potential risks for developmental toxicity in humans. EPA did not include cancer risk in this preliminary assessment due to questions concerning the potential significance to humans of the rodent cancer data. Because data indicate that PFOA is not mutagenic, concern for gene mutation was not an issue for this preliminary assessment.

The preliminary risk assessment used a margin of exposure (MOE) approach (Ref. 1). For many risk assessments, the MOE is calculated as the ratio of the administered dose from the animal toxicology study to the estimated human exposure level. The human exposure is estimated from a variety of potential exposure scenarios, each of which requires a variety of assumptions.

A more accurate estimate of the MOE can be derived if measures of internal dose are available for humans and the animal model. In this preliminary risk assessment, serum levels of PFOA, which are a measure of internal dose, were available for some administered dose levels in the rat 2-generation reproductive toxicology study and from human biomonitoring studies. Thus, internal dose was used for the

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calculation of MOEs in this assessment. The actual values of the MOEs derived must be viewed with caution, however, due to the differences in kinetics between humans and rodents. The range of MOEs in the preliminary assessment encompasses some values that would indicate potential concern and other values that would indicate a low level of concern. Due to the uncertainties in the assessment, and the possibility that the additional information discussed in this notice might reduce those uncertainties, the Agency has not attempted further interpretation of these MOEs at this time. The interpretation of the significance of the MOEs for ascertaining potential levels of concern will necessitate a better understanding of the appropriate dose metric in rats, and the relationship of the dose metric to the human serum levels.

As this priority review of PFOA progresses, EPA will continue to develop the characterization of hazard and potential risk associated with exposure to PFOA. Because the scientific interpretation issues in this case are particularly complex, given the unusual properties and behavior of PFOA and the absence of data on exposure pathways and levels, EPA anticipates that a more comprehensive risk analysis will be taken to the Agency's Science Advisory Board for review and comment in fall 2003. The preliminary risk assessment described in this notice has not been formally peer reviewed, but has gone through internal review by multiple EPA offices, including ORD, the Office of Science Coordination and Policy (OSCP), the Office of Pesticide Programs (OPP), and the Office of Policy, Economics, and Innovation (OPEI). The preliminary risk assessment has also been the subject of an external letter peer review.

D. Uncertainties and Data Needs

Although EPA has concerns with respect to the potential nationwide presence of PFOA in blood and with the potential for developmental and other effects suggested by animal studies, there are significant uncertainties in the Agency's quantitative assessment of the risks of PFOA. In addition, the uncertainties discussed in this unit with respect to the identification of the pathway or pathways that result in human exposure to PFOA (air, water, food, etc.), and the uncertainties associated with how PFOA gets into those pathways (including the

products or processes that are responsible for the presence of PFOA in the environment) make it difficult to determine what, if any, particular risk mitigation measures would be appropriate. The Agency believes that the additional information identified in this notice would better inform this priority review and Agency decisionmaking with respect to PFOA.

The sources of PFOA in the environment, as described in Unit II.A., are not fully defined or understood. Historically, direct PFOA releases during the manufacture of PFOA and its use in the manufacture and processing of fluoropolymers and fluoroelastomers have been quantified at some sites. Industry has identified and implemented voluntary control technologies to reduce releases, as well as to improve PFOA recovery for recycling or destruction, as described in Unit II.E. The effectiveness of these programs could be assessed, possibly through the ECA process described in Unit V., by monitoring PFOA levels at the respective facilities and determining if the release reduction and waste management programs are reducing the PFOA levels in the media surrounding the affected facilities. PFOA exposures and releases to the environment may also come from the distribution of PFOA in aqueous dispersions of fluoropolymers used by processors to apply coatings to metals and textiles, a topic which industry is also attempting to resolve.

In addition, the question of the potential contribution to PFOA levels from telomer manufacture and from telomer product degradation remains. The universe of specific telomer chemicals that may ultimately degrade or metabolize to PFOA has not been fully defined. Preliminary data suggest that only higher perfluorinated homologues (chemicals with carbon chain lengths of eight and higher) would be converted into PFOA via normal environmental pathways. The 8-2 telomer alcohol has been shown to biodegrade and metabolize to form PFOA, but other telomer chemicals, including telomer iodides and telomer-derived polymers, have not yet been tested. Determining possible telomer product sources of PFOA may be particularly difficult because these fluorochemicals are typically used in products in very low concentrations, indicating that any individual source contribution by specific products could be very small, widely distributed, and difficult to detect. For example, products contaminated with volatile, unreacted telomer alcohol residuals could potentially release those residuals into the environment where they could be subject to biodegradation.

The exposure routes leading to the presence of PFOA in human blood are not known. The nationwide presence of PFOA in human blood, contrasted with the limited geographic locations of fluorochemical plants making or using the chemical, suggests that there must be additional sources of PFOA in the environment, and exposures beyond those attributable to direct releases from industrial facilities. But whether these exposures are due to PFOA in the air, the water, on dusts or sediments, in dietary sources, or through some combination of routes is currently unknown. Data evaluating the environmental presence of PFOA in water are very limited and site-specific. Data on the presence of PFOA in air or soil are not currently available. Data on the presence of PFOA in wildlife suggest that animals are not as likely as humans to have PFOA in their blood, and that PFOA is not found as widely in animals as PFOS. Whether these differences may be due to different exposure pathways or to differences in how the chemicals are processed or retained by animals and humans is unknown. The technical difficulties of detecting and accurately measuring the chemical in all these various media, particularly in the low concentrations that EPA would anticipate, are considerable.

The preliminary risk assessment on potential developmental toxicity was based on a comparison of serum levels in the 2-generation rat reproductive study with those found in the human population. However,

there are considerable species differences in the kinetics of PFOA. Interpretation of the significance of the MOEs for ascertaining potential levels of concern will necessitate a better understanding of the appropriate dose metric in rats, and the relationship of the dose metric to the human serum levels.

Finally, there are some uncertainties regarding the use of the human biomonitoring data. Although the available data include a range of populations with various demographics in many States and all geographic areas of the country, there may be some populations that are not represented. Because it is unknown how the human exposures are occurring, proximity to a manufacturing facility may or may not be a factor in exposure. However, populations living near these facilities were not sampled. Therefore, it is possible that PFOA serum levels may be underestimated for certain portions of the U.S. population. The children's sample was derived from blood collected in 1994/1995; therefore, it may not reflect the current status of PFOA in children's blood.

Voluntary activities by industry are underway as described in Unit II.E. to help address some of these uncertainties

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and data gaps. For example, pharmacokinetics studies examining the biological processing of PFOA in rats are expected to be completed in the summer and fall of 2003. These studies may help to reduce the uncertainty in the estimation of risk to humans. In addition, EPA has submitted a nomination to the Centers for Disease Control and Prevention (CDC) to include PFOS, PFOA, and certain related fluorochemicals in the next National Health and Nutrition Examination Survey (NHANES). This would provide a national baseline of PFOA exposure, both to indicate whether current data are representative of the U.S. population and to offer a gauge with which to measure the effectiveness of actions to reduce exposures.

EPA will continue to develop and clarify issues relating to hazard, exposure, and risk as the priority review continues and the Agency receives additional information that allows further resolution of the uncertainties identified in this unit.

Additional data beyond EPA's current activities and the voluntary efforts undertaken by the industry may be necessary to resolve the existing uncertainties and fill remaining data gaps, including gaps not yet identified. EPA requests comment on these issues, and particularly requests that comments include the submission of any additional data that may help to fill these gaps. Certain specific information requests are identified in Unit IV.

E. Ongoing Voluntary Activities

In 2000, EPA opened a non-regulatory public docket file, Administrative Record AR-226, for information on PFOS, PFOA, telomers, and related fluorinated chemicals, and began to express its concerns to the global fluorochemical industry (Ref. 3). In response, the industry began providing information to the Agency, all of which has been placed into AR-226. Two industry groups, the Fluoropolymer Manufacturing Group (FMG) and the Telomer Research Program (TRP), formed and began pursuing voluntary collective actions to address issues associated with PFOA and the telomers. 3M continued its ongoing research efforts despite having discontinued the manufacture of both PFOS and PFOA. Much of the information reflected in the EPA's revised draft hazard assessment and preliminary risk assessment on PFOA was provided through these voluntary activities on the part of industry.

In March 2003, EPA received letters from 3M, FMG, and TRP

documenting their ongoing voluntary programs and outlining their plans for continuing research and product stewardship activities (Refs. 7, 12, and 13). These letters have been placed in the public docket for this notice and can be accessed as described in Unit I.B.2. The letters contain substantial additional information concerning the specifics of the voluntary industry actions beyond what is presented in this notice.

In its letter, 3M indicated that it would not resume the manufacture of PFOA for commercial sale; that it would continue its medical monitoring efforts for workers and provide biannual reports to EPA and update its epidemiological study reports to EPA every 5 years; and that it will continue monitoring groundwater, surface water, and other environmental media and provide a summary report to EPA within 2 years. 3M also stated that it would work with other members of industry to conduct additional validation of PFOA analytical methods and sampling protocols and to participate in human health and environmental fate and effects studies of PFOA. 3M also indicated that the facilities and employees of its subsidiary, Dyneon LLC, would continue to be part of the 3M monitoring program.

The members of the FMG--Asahi Glass Fluoropolymers USA, Inc.; Daikin America, Inc.; E.I. duPont de Nemours & Company; and Dyneon LLC--indicated that they and their parent companies represent most of the known use of APFO for the production of fluoropolymers both in the United States and worldwide. Their letter includes commitments to reduce emissions of APFO from fluoropolymer and APFO manufacturing facilities on a global, individual company-wide basis by a minimum of 50% by 2006; to conduct studies on both finished polymers and finished products from these polymers to determine if any exposure to the general population can be related to the fluoropolymer industry; to conduct studies on emissions from fluoropolymer processing facilities to determine the level of current emissions; and to develop additional toxicological data on APFO. The companies noted that they are participating in activities through the Association of Plastics Manufacturers in Europe (APME) to conduct pharmacokinetics studies in rats and develop a pharmacokinetic model, and would share those data with EPA as they are developed, beginning in spring 2003. The companies indicated that they would continue to follow principles of product stewardship similar to those described in the Responsible Care[reg] programs of the American Chemistry Council and the Synthetic Organic Chemical Manufacturers Association in their efforts to support 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. The companies stated that they will continue to use appropriate criteria, including such standards as the interim air and water screening levels and water quality guidelines recently adopted in West Virginia, to evaluate operations and emissions (Refs. 14 and 15). The letter includes a schedule for the completion of various studies already underway.

The members of the TRP--AGA Chemicals (Asahi Glass); Clariant GmbH; Daikin America, Inc.; and E.I. duPont de Nemours & Company--indicated that they comprise the major telomer producers, and that they are evaluating telomer products sold in the United States to determine whether they contribute to significant human or environmental exposure to PFOA. They noted that their evaluation has six key components: Analysis of products and articles; analysis of ``aged'' products and ``in use'' articles; characterization of potential release of PFOA from telomer-based product manufacture; characterization of potential release of PFOA from telomer-treated article manufacture; analysis of possible biodegradation of telomer-based polymeric products; and evaluation of the ultimate fate and disposal routes for telomer-treated articles in the United States. The letter includes lists and schedules

for these various evaluation components, as well as for the submission of additional information to the Agency.

EPA appreciates the industry response to the Agency's concerns regarding PFOA and the telomers, and looks forward to continued cooperation on assessment and management activities. EPA invites the participation of additional interested persons in these efforts. EPA considers that the timely submission of the information which industry has already committed to provide will be essential to developing a better and more complete understanding of the potential risks of PFOA. However, in light of the concerns identified to date, the Agency will continue its ongoing expeditious review.

While the voluntary industry activities as described in the letters will provide substantial additional information, EPA considers it likely that

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issues will remain even after these activities are complete, and that the results of some of these programs may well identify additional questions that will need to be answered. EPA requests comment on these issues.

IV. Specific Requests for Comments, Data, and Information

EPA specifically requests comments, data, and information on the following topics.

A. Use and Production Volume Information

What are the specific chemical identities (by Ninth Collective Index name and CAS No., if available) of the telomer chemicals, including polymers derived from these telomers, and of the fluoropolymers and fluoroelastomers made with PFOA or related chemicals, currently in commerce? In what volumes and at what locations are these chemicals manufactured or imported? How and in what volumes are these chemicals used? What are the benefits of these chemicals and products in their specific uses, and what alternatives to these chemicals may be available for specific uses?

B. Exposure Information

How are products containing the chemicals identified in Unit IV.A. used? How are these products disposed of? What environmental releases occur at manufacturing and processing facilities where these chemicals are used? What data are available on worker exposures to these chemicals? What data are available on exposures to the general population? What data are available on measured levels of these chemicals in humans and the environment, in all environmental media? What data are available on the biodegradation of these chemicals, on releases of these chemicals from consumer and industrial products, and on their breakdown during product biodegradation, incineration, and other disposal practices?

C. Monitoring and Related Information

EPA specifically requests that any persons who have in their possession existing human or environmental monitoring data indicating or assessing the presence of PFOA and related fluorochemicals in humans, in wildlife, or in any environmental media, including studies conducted in other countries, provide those data to the Agency in response to the publication of this notice to enhance the understanding

of PFOA presence in the environment and of the pathways leading to exposures. EPA includes in this request any existing data not otherwise provided to EPA concerning the toxicity, pharmacokinetics, and half-life of PFOA in organisms.

D. Additional Data

Are there other pieces of information not addressed in Unit IV. A., B., and C., that would help EPA more accurately assess the risks of these chemicals and determine appropriate further action, if warranted?

V. Enforceable Consent Agreement Development

EPA is interested in developing one or more ECAs under TSCA section 4 and 40 CFR part 790 for PFOA and telomers that focus on identifying environmental fate and transport information, as well as other relevant information to enhance understanding of the sources of PFOA in the environment and the pathways by which human exposure to PFOA is occurring. The objective of the ECA process is to conclude one or more ECAs that will set in place an industry-sponsored testing program that will address a number of EPA's current data needs for PFOA and telomers. EPA expects that industry will meet the voluntary testing commitments made in their letters of intent, as discussed in Unit III.E. Therefore, EPA anticipates that the ECA process will focus generally on testing issues beyond or supplemental to those contained in the industry letters of intent.

A. Solicitation of Interested Parties

EPA is soliciting interested parties to monitor or participate in negotiations on ECAs for PFOA and telomers. As discussed in Unit III.E., 3M; AGA Chemicals; Asahi Glass Fluoropolymers USA, Inc.; Clariant GmbH; Daikin America, Inc.; Dyneon LLC; and E.I. duPont de Nemours & Company, have been pursuing voluntary collective actions to address issues associated with PFOA and telomers and have been keeping EPA informed of these activities. Any person who desires treatment as an ``interested party'' during the development of the ECAs must respond in writing to this notice on or before May 16, 2003 following the instructions in Unit I., and must specifically request that they be given ``interested party'' status. These interested parties will not incur any obligations by being so designated. Negotiations will be conducted in one or more meetings, all of which will be open to the public. EPA will contact all interested parties who have expressed a desire to participate in or monitor the ECA negotiations and advise them of all meeting dates. EPA will also notify the public of such meeting dates in the electronic public docket for this action. The negotiation time schedule for PFOA and telomers will be established at the first negotiation meeting. It is EPA's current intent to move quickly to attempt to finalize any ECAs, if possible. If an ECA is not established in principle within a reasonable time-frame, negotiations will be terminated, and any unmet data needs may be pursued via a test rule promulgated under TSCA section 4. If the data generated from the ECA do not meet the Agency's needs, EPA reserves the right to proceed with rulemaking to obtain the needed data. EPA also reserves the right to announce and convene subsequent ECA negotiations for additional data, if the testing from voluntary activities, the initial ECA, or from a test rule identify additional data gaps which must be filled.

B. ECA Process and Public Participation in Negotiations

EPA will provide the public with an opportunity to comment on and

participate in the development of any ECAs on PFOA and telomers to ensure that the views of interested parties are taken into account during the ECA process. This process is described generally in this unit, and is more fully addressed in 40 CFR part 790.

Individuals and groups who respond to this notice by May 16, 2003 and request treatment as interested parties will have the status of interested parties. All negotiating meetings for the development of this ECA will be open to the public and minutes of each meeting will be prepared by EPA and placed in the official public docket for this action. The Agency will advise interested parties and the public of meeting dates and make available meeting minutes, testing proposals, background documents, and other relevant materials exchanged at or prepared for negotiating meetings. Where tentative agreement is reached on an acceptable testing program, a draft ECA will be made available for comment by interested parties and, if necessary, EPA will hold a public meeting to discuss any comments that have been received and determine whether revisions to the ECA are appropriate. EPA will not reimburse costs incurred by non-EPA participants in this ECA negotiation process.

Enforceable consent agreements will only be concluded where an agreement can be obtained, which is satisfactory to the Agency, manufacturers or processors who are potential test sponsors, and other interested parties, concerning the need for and scope of testing. In the

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absence of an ECA, EPA reserves the right to proceed with rulemaking.

More specifically, EPA will not enter into an ECA if either the Agency and affected manufacturers or processors cannot reach an agreement on the provisions of the ECA, or the draft ECA is considered inadequate by other interested parties who have submitted timely objections to the draft ECA. However, EPA may reject these objections if the Agency concludes that:

1. They are not made in good faith;
2. They are untimely;
3. They are not related to the adequacy of the proposed testing program or other features of the ECA that may affect EPA's ability to fulfill the goals and purposes of TSCA; or
4. They are not accompanied by a specific explanation of the grounds on which the draft ECA is considered objectionable.

EPA will prepare an explanation of the basis for each ECA. That document will summarize the agreement (including the needed data development), explain the objectives of the data collection/development activity, and outline the chemicals' use and exposure characteristics. That document, which will also announce the availability of the final ECA, will be published in the Federal Register. Upon the successful completion of an ECA, export notification under TSCA section 12(b) would be required for all signatories to the ECA who export or intend to export the chemicals subject to the ECA. A separate action would be published in the Federal Register following the announcement of the ECA to apply the export notification requirement to others by adding the ECA chemicals to the list of chemicals subject to testing consent orders at 40 CFR 799.5000.

VI. References

These references have been placed in the official docket that was established under docket ID number OPPT-2003-0012 for this action as indicated in Unit I.B.2. Reference documents identified with an Administrative Record number (AR226-XXXX) are available in the public version of the official docket maintained in the OPPT Docket. Copies of

these documents may be obtained as described in Unit I.B.2.

1. USEPA. Preliminary Risk Assessment of the Developmental Toxicity Associated with Exposure to Perfluorooctanoic Acid (PFOA) and its Salts. OPPT, Risk Assessment Division. Washington, DC. April 10, 2003.

2. Federal Register. (65 FR 62319, October 18, 2000) (FRL-6745-5); (67 FR 11008; March 11, 2002) (FRL-6823-6); (67 FR 11014, March 11, 2002) (FRL-6823-7); (67 FR 72854, December 9, 2002) (FRL-7279-1).

3. (AR226-0639) PFOS Presentation to CMA. Auer, Charles M., USEPA. Washington, DC. June 19, 2000.

4. (AR226-1127) Revision of PFOA Hazard Assessment and Next Steps. Memorandum from Charles M. Auer to Oscar Hernandez, Mary Ellen Weber, and Ward Penberthy. USEPA. Washington, DC. September 27, 2002.

5. Section 4(f) of TSCA (15 U.S.C. 2603 (4)).

6. (AR226-0620) Sulfonated Perfluorochemicals in the Environment: Sources, Dispersion, Fate, and Effects. 3M. St. Paul, MN. March 1, 2000.

7. Environmental, Health And Safety Measures Relating to Perfluorooctanoic Acid and Its Salts (PFOA). Letter from Dr. Larry Wendling, 3M, to Stephen L. Johnson, USEPA. 3M. St. Paul, MN. March 13, 2003.

8. Characterization of Fluorinated Metabolites by a Gas Chromatographic-Helium Microwave Plasma Detector; The Biotransformation of 1H, 1H, 2H, 2H-Perfluorodecanol to Perfluorooctanoate. Hagen, Donald F.; Belisle, John; Johnson, James D.; and Venkateswarlu, P. Analytical Biochemistry. 118, 336-343 (1981).

9. (AR226-1149). Revision 1, Biodegradation Screen Study for Telomer-Type Alcohols. Lange, Cleston C. Pace Analytical Services, Minneapolis, MN. November 6, 2002.

10. Mabury, Scott. Annual Report of Activities for Telomer Research Program Grant to University of Toronto. University of Toronto, Toronto, Canada. September 2002.

11. (AR226-1136) Revised Draft Hazard Assessment of Perfluorooctanoic Acid and Its Salts. USEPA, OPPT, Risk Assessment Division. Washington, DC. November 4, 2002.

12. Voluntary Actions to Evaluate and Control Emissions of Ammonium Perfluorooctanoate (APFO). Letter from Charles D. Allen, Asahi Glass Fluoropolymers USA, Inc.; Takahiko Sakanoue, Daikin America, Inc.; James E. Gregory, Dyneon LLC.; and Richard J. Angiullo, E.I. duPont de Nemours & Company, to Stephen L. Johnson, USEPA. March 14, 2003.

13. Letter of Intent for the Telomer Research Program from H. Okuno, AGA Chemicals, Inc.; Hans Ludwig Panke and Reinhard Jung, Clariant GmbH; Takahiko Sakanoue, Daikin America, Inc.; and Stephen H. Korzeniowski, E.I. duPont de Nemours & Company, to Stephen L. Johnson, USEPA. March 14, 2003.

14. Order on Consent between E.I. duPont de Nemours & Company and USEPA, Region III and Region V. Philadelphia, PA. March 12, 2002.

15. West Virginia Department of Environmental Protection. Final Ammonium Perfluorooctanoate (C8) Assessment of Toxicity Team (CATT) Report. Charleston, WV. August 2002.

List of Subjects

Environmental protection, Chemicals, Hazardous substances.

Dated: April 14, 2003.

Stephen L. Johnson,
Assistant Administrator for Prevention, Pesticides and Toxic
Substances.

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