

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