

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® 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