



Perfluorochemicals & EPA

Presentation to MDH PFC Workshop

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Overview

- Current Status Summary
- Background: Perfluorochemicals (PFCs)
- History of Investigation
- Actions Taken
- Ongoing Research
- International Activities
- Next Steps
- Information Resources



Current Status Summary

- EPA has no information indicating that the current levels of PFCs found in human blood in the general U.S. population are producing any adverse health effects in people
- EPA and others are conducting important studies that will significantly improve our understanding of these chemicals within the next few years



Current Status Summary

- While risk assessment activities continue, EPA and others have taken prudent steps to reduce releases of PFCs to the environment, and to scrutinize new chemicals under development
- Because EPA is still conducting risk assessment, the Agency has not made regulatory risk determinations, and is not in a position to make recommendations on regulatory action



Current Status Summary

- Even though no effects have been seen at the blood levels in the general U.S. population, EPA is still investigating these chemicals because:
 - They remain in the environment and some can remain in people for a long time
 - For some of these chemicals, there's a narrow margin between the dose that causes mild effects and a dose that causes severe effects in animals
 - While we don't know what the adverse effect level would be in people, we believe it makes sense to limit future releases of these chemicals



Background

- What are PFCs?
 - Man-made chemicals with unique properties that make them valuable in many uses
 - Characterized by persistence in the environment
 - Some PFCs have demonstrated unusual toxicity in animal studies
 - Some PFCs may remain in the body for years
 - PFCs have been found in the environment and in human blood; how they got there isn't known



Background

- Examples of PFCs: PFOS
 - Perfluorooctane sulfonate
 - Discontinued by 3M between 2000-2002
 - Was used in soil, stain, oil, and grease-resistant coatings on carpets, textiles, paper, leather
 - Was used as a surfactant in fire fighting foams, high tech coatings, performance fluids
 - Still used only in very limited quantities in aviation hydraulic fluids, semiconductor manufacturing, and photographic imaging



Background

- Examples of PFCs: PFOA
 - Perfluorooctanoic acid
 - Not used intentionally in any product
 - Used to manufacture *fluoropolymers*, which include non-stick coatings on cookware; waterproof, breathable fabric membranes; heat and chemical-resistant cables and tubing; others
 - May result from breakdown of fluorinated *telomers*, chemicals used in many of the same functions as PFOS used to be



Background

- Examples of PFCs: PFBS, PFBA
 - PFBS: Perfluorobutane sulfonate
 - Related to PFOS, but appears less toxic in animal studies, not retained long in the body
 - PFBA: Perfluorobutyric acid
 - Related to PFOA, but appears less toxic in animal studies, not retained long in the body
- Many other PFCs exist, and are being studied



History of Investigation

- EPA's current inquiry began in late 1999: 3M submitted data on PFOS indicating unexpected toxicity in a reproductive study in rats, together with data on widespread presence in human blood and environment and long half-life in humans
- EPA expanded inquiry to similar PFCs including PFOA, telomers, and related chemicals in 2000 because of concerns for this class of chemicals



History of Investigation

- EPA, Industry, and academia began numerous new studies on multiple PFCs in 2000, following questions raised by EPA
 - Studies identified more questions, more work
- Industry undertook voluntary actions
 - 3M initiated voluntary production phaseout of PFOS, PFOA in 2000, completed before 2003
 - Companies began to assess and reduce PFC emissions from manufacturing facilities



Actions Taken: PFOS

- EPA issued Significant New Use Rules (SNURs) in 2000 and 2002 to restrict the return of 88 PFOS-related chemicals phased out by 3M to the U.S. market
 - SNURs allow only three specific, technically essential low volume, low exposure, low release uses to continue
- EPA proposed a SNUR to control the 183 related chemicals still on the Inventory in 2006; final rule will publish in 2007



Actions Taken: PFOA

- EPA began an enforceable consent agreement (ECA) negotiation process in 2003 to obtain data on the sources of PFOA in the environment and the pathways leading to exposures
 - Signed two ECAs for incineration testing to determine whether incinerating telomer and fluoropolymer products could be a source
 - Signed two MOUs for monitoring near fluoropolymer facilities



Actions Taken: PFOA

- Discussions in the ECA process led to the creation of independent testing programs by EPA and industry to assess:
 - The potential of telomers to degrade to PFOA in the environment
 - Whether fluoropolymer and telomer products could release PFOA as they age in use, potentially leading to exposures
- All testing and monitoring initiated through ECA process are still underway



Actions Taken: PFOA

- 2010/15 PFOA Stewardship Program
 - January 2006, EPA Administrator invited eight major companies to commit to:
 - Reduce facility emissions and product content of PFOA and related chemicals by 95% by 2010 from a year 2000 baseline; and
 - Work toward eliminating facility emissions and product content of these chemicals by 2015
 - All companies committed by March 2006, submitted baseline year data October 2006



Actions Taken: PFOA

- 2010/15 PFOA Stewardship Program
 - Companies will submit annual reports on progress toward goals each October
 - Companies report on both US and global operations
 - Companies, EPA, and others to work toward commonly accepted lab methods and standards to ensure comparability in results by first goal year of 2010



Actions Taken: PFOA

- EPA Risk Assessment
 - 1/05, EPA submitted draft PFOA Risk Assessment to Science Advisory Board
 - Assessment did not include risk numbers; sought review of scientific approaches being used
 - 5/06, SAB Report generally endorsed EPA's risk assessment approach, recommended including additional endpoints and conducting cancer risk assessments; noted uncertainties
 - Studies addressing SAB comments and other issues are currently underway
 - When assessment complete, will be submitted to SAB again; premature to draw conclusions on risk now



Actions Taken: PFOA

- In 11/06, EPA Regions 3 and 5 modified an existing Consent Order with DuPont to lower the site-specific action level for PFOA in drinking water to 0.50 ppb near Parkersburg, WV
 - Site-specific: affects only this community
 - Local water supplies contained 2-15 ppb PFOA; blood levels in local residents averaged about 350 ppb, much higher than the 5 ppb national average
 - Local exposure study suggested drinking water was the primary source of community exposure
 - New site-specific action level replaced interim 150 ppb level set by WV years earlier and used in initial Consent Order; no longer considered protective given current data



Actions Taken: New Chemicals

- EPA incorporated information on PFOS, PFOA into new chemical reviews for related materials and substitute compounds
 - Reviews typically consider decomposition products, fate, transport, bioaccumulation potential, toxicity, use patterns, potential exposures and releases
 - Consent Orders under TSCA §5(e) specify additional testing, other controls where necessary on new chemicals that make it through review
- New and Existing Chemical Programs coordinate for consistency in approach, data



Ongoing Research

- Government, Industry, and Academic research programs are underway to help provide missing information, especially:
 - Sources and pathways of exposure
 - Toxicology and pharmacokinetics
- Researchers include CDC, NTP, EPA, Industry, others
- Data will contribute to risk assessment process



Ongoing Research - CDC

- EPA requested in 2003 that CDC include PFOS, PFOA, other related chemicals in the National Health and Nutrition Examination Survey (NHANES); initial data will appear in the 2007 *National Report on Exposure to Chemicals in the Environment*
 - CDC will provide baseline national human blood levels, yardstick for measuring success of attempts to reduce future exposure to perfluorinated compounds
 - CDC published results of analysis of samples from 2001-2 in 4/06; and from 1999-2000 in 3/07



Ongoing Research - NTP

- In response to EPA's 2003 request, the National Toxicology Program (NTP) initiated a class study on related perfluorinated acids, including possible PFOA and PFOS substitutes, in late 2004: initial preliminary data possible in 2008/10 timeframe
 - NTP to fill in missing toxicity, pharmacokinetics, bioaccumulation data; help assess how related chemicals compare with PFOA, PFOS; assess how carbon chain length affects toxicity, biopersistence



Ongoing Research - EPA

- EPA's Office of Research and Development has PFC research underway at multiple EPA labs
- EPA ORD is conducting research in several areas, including:
 - Telomer biodegradation research
 - Toxicology and pharmacokinetics
 - Analytical techniques development
 - Aged article analysis



Ongoing Research - EPA

- Telomer Biodegradation Research
 - Outgrowth of PFOA ECA process
 - Assess potential for telomers to break down over time in the environment to release PFOA
 - Studies in soil and sludge
 - Studies will take 1 to 2 years to complete and publish



Ongoing Research - EPA

- Toxicology and Pharmacokinetics
 - Studies address questions raised in risk assessment process
 - Study topics include:
 - Developmental toxicity (modes of action; effects of exposure on reproductive tissues)
 - Immunotoxicity
 - PFOA-induced liver tumors and hepatotoxicity
 - Pharmacokinetic modeling



Ongoing Research - EPA

- Analytical Techniques Development
 - PFCs are difficult chemicals to analyze; require special equipment and handling for accuracy
 - Analytical work ties in with biodegradation studies; includes:
 - Analysis of perfluorinated compounds in environmental and biological matrices
 - Methods development for detection in soil



Ongoing Research - EPA

- Aged Article Analysis
 - Decision to test emerged from PFOA ECA discussions: determine whether telomer and fluoropolymer articles could release PFOA as they age, contributing to exposures. Testing will:
 - Determine the content of PFOA and its homologues (C4 to C12) in new consumer products
 - Evaluate PFOA releases from consumer products by accelerated aging tests
 - Evaluate PFOA releases from consumer products under close-to-realistic exposure conditions
 - Two to three year study, now underway



Ongoing Research – Non-Fed

- NIEHS funded a community exposure study in Little Hocking, OH, where the local water supply contains 2-15 ppb levels of PFOA; discovered significantly elevated PFOA levels in residents, no correlation with any health effects. The study is continuing.
- A major blood sampling and health screening study is underway in OH/WV as part of a class action lawsuit settlement by DuPont, to determine whether any correlation exists between elevated levels of PFOA in blood and adverse human health effects.



International Activities

- The US has shared data and issues on PFOS, PFOA, PFCs in global forums, and multiple international activities are underway:
 - OECD activities include a survey on production and use of PFOS, PFOA, and related chemicals; a hazard assessment on PFOA; and a November 2006 PFOA Workshop to identify ongoing activities and unmet data needs
 - Sweden nominated PFOS for inclusion in the Stockholm Convention and LRTAP POPs protocol; a review process is underway



Next Steps

- PFOA Stewardship Program and related voluntary activities will continue to reduce emissions and potential exposures to PFOA and related chemicals
- Ongoing research is expected to increase understanding over the next few years; major publications are expected in 2007-8
- Research will feed into risk assessment process to direct further action as appropriate
- EPA sharing information with States, others



Information Resources

- PFOS, PFOA-related electronic dockets at www.regulations.gov:
 - EPA-HQ-OPPT-2003-0012 (PFOA ECA Process)
 - EPA-HQ-OPPT-2002-0043 (PFOS SNURs)
 - EPA-HQ-OPPT-2005-0015 (Follow-up PFAS SNUR)
 - EPA-HQ-OPPT-2003-0071 (FP Incineration)
 - EPA-HQ-OPPT-2004-0001 (Telomer Incineration)
 - EPA-HQ-OPPT-2004-0112 (3M MOU)
 - EPA-HQ-OPPT-2004-0113 (DuPont MOU)
 - EPA-HQ-OPPT-2002-0051 (Polymer Exemption)
 - EPA-HQ-OPPT-2006-0621 (Stewardship Program)
- EPA website: www.epa.gov/oppt/pfoa/



Information Resources

- Non-regulatory AR-226 data repository of information on PFCs currently available on 20+ CD-ROM media from EPA OPPT Docket Office,
oppt.ncic@epa.gov
- Project Coordinator:
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