

U.S. Regulatory Actions and Risk Management Activities on Perfluorinated Chemicals

Ana Corado

U.S. Environmental Protection Agency



Outline

- Background on Regulation and Risk Management
 - Regulation of PFOS
 - 2010/15 PFOA Stewardship Program
 - New Chemicals Review of Alternatives for PFOA and Related Chemicals
 - Amendment of Polymer Exemption Rule
 - International Efforts
- Current Activities
 - Summary of the Long-Chain Perfluorinated Chemicals Action Plan
 - Actions under TSCA to adequately address unreasonable risk from LCPFCs
- Information Sources



Overview

- EPA is investigating PFCs because
 - They are found world-wide in the environment, in wildlife, and in humans
 - They are persistent in the environment and some can remain in people for years
 - Some PFCs cause developmental, systemic, and other adverse effects in laboratory animals
 - For some PFCs, there's a narrow margin between the dose that causes mild effects and a dose that causes severe effects in animals
- Mitigate exposures at the source
 - PFAS Significant New Use Rules
 - 2010/15 PFOA Stewardship Program
 - LCPFCs Action Plan
- Manage alternatives
 - New Chemicals Program



Regulation of PFOS

- US industry undertook voluntary actions to phase out production of PFOS between 2000 to 2002
- EPA issued two Significant New Use Rules (SNURs) under the Toxic Substance Control Act (TSCA) in 2002 to restrict the return of 88 PFOS-related chemicals phased out by 3M, the sole US manufacturer
 - SNURs allow only three specific, technically essential low volume, low exposure, low release uses to continue: photographic/imaging industry, semiconductor industry, aviation industry; also allowed use as an intermediate to produce other chemical substances to be used solely for the uses listed
- Final SNUR for 183 PFAS chemicals was published in 2007
 - The SNUR continues to apply the 4 excluded uses from the previous SNURs and provides for two new exclusions for ongoing uses: seven chemicals are allowed for use as an etchant, and one chemical is allowed for metal plating and finishing uses
- More information: <http://www.epa.gov/oppt/pfoa/pubs/pfas.html>



2010/15 PFOA Stewardship Program

- In January 2006, EPA invited eight major companies in the fluoropolymer and fluorotelomer industries to commit to a voluntary program with global goals
- Goals
 - Commit to achieve, no later than 2010, 95% reduction in *both* facility emissions to all media *and* product content of PFOA, PFOA precursor chemicals, and related higher homologue chemicals, measured from a year 2000 baseline
 - Commit to working toward elimination of PFOA, PFOA precursors, and related higher homologue chemicals from emissions and products by 2015
- Participating companies
 - Arkema, Asahi, BASF, Clariant, Daikin, DuPont, 3M/Dyneon, Solvay Solexis
 - Report annual progress in terms of both U.S. and global operations
- More information: <http://www.epa.gov/oppt/pfoa/pubs/stewardship/index.html>



New Chemical Review of Alternatives for PFOA and Related Chemicals

- EPA is reviewing substitutes for PFOA, PFOS and other long-chain perfluorinated substances as part of its review process for new chemicals
 - EPA established the New Chemicals Program under TSCA to help manage the potential risk from chemicals new to the marketplace
- EPA's review of alternatives of perfluorinated chemical substances has been ongoing since 2000 and is consistent with the approaches to alternatives encouraged under the Stewardship Program
 - Over 150 alternatives of various types have been received and reviewed
- EPA reviews the new substances against the range of toxicity, fate and bioaccumulation issues that have caused past concerns with perfluorinated substances, as well as any issues that may be raised by new chemistries
- More information: <http://www.epa.gov/oppt/pfoa/pubs/altnewchems.html>



Amendment of Polymer Exemption Rule

- Polymer exemption was originally established in 1984 and modified in 1995
 - Exempts eligible polymers from having to go through the full new chemical premanufacture notice (PMN) and review process
 - Statutory basis for exemption is that eligible polymers “will not present” an unreasonable risk to health, environment
- Final rule (75 FR 4295) published on January 27, 2010
 - EPA can no longer presume or conclude that these polymers “will not present” an unreasonable risk
 - Amends the polymer exemption rule to exclude from eligibility for the exemption polymers containing certain perfluoroalkyl moieties; polymers containing these substances will need to go through the PMN review process
 - Rule can be accessed at <http://edocket.access.gpo.gov/2010/pdf/2010-1477.pdf>
- January 27, 2012
 - Manufacture of these polymers will no longer be authorized under the polymer exemption rule



International Efforts

- Stockholm Convention on Persistent Organic Pollutants (POPs)
 - In May 2009, PFOS, its salts, and perfluorooctane sulfonyl fluoride (PFOSF) were added to Annex B, subjecting them to restrictions on production and use
- Strategic Approach to International Chemicals Management (SAICM)
 - In May 2009, during the International Conference on Chemicals Management (ICCM2), delegates agreed to consider the development of stewardship programs and regulatory approaches to reduce emissions and content of PFAC and PFAS chemicals in products and to work toward their elimination, where feasible
- Organisation for Economic Co-operation and Development's (OECD)
 - 2010 *Survey of Product Content and Environmental Release Information on PFCs*:
http://www.oecd.org/document/58/0,3746,en_2649_34375_2384378_1_1_1_1,00.html
 - OECD Web Portal on PFCs:
http://www.oecd.org/site/0,3407,en_21571361_44787844_1_1_1_1_1,00.html
- More information: <http://epa.gov/oppt/pfoa/pubs/related.html>



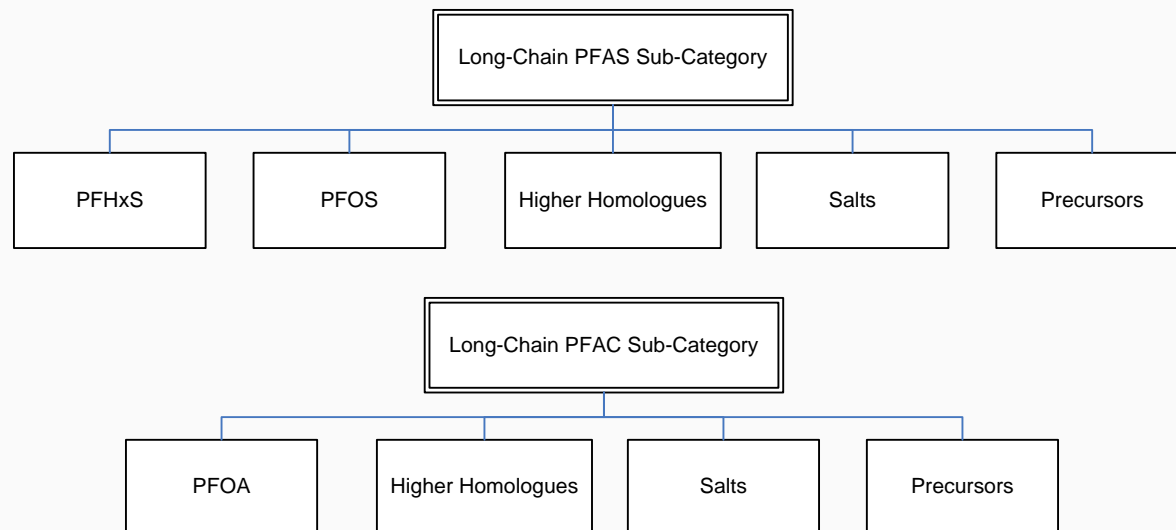
Long-Chain Perfluorinated Chemicals (LCPFCs) Action Plan

- In December 2009, EPA published an Action Plan on LCPFCs
 - Given the concerns with LCPFCs, it can reasonably be anticipated that continued exposure could increase body burdens to levels that would result in adverse outcomes
 - TSCA section 6 provides EPA the authority to ban or restrict the manufacture, processing, and use of these chemicals
 - More information:
<http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/pfcs.html>



Long-Chain Perfluorinated Chemicals Addressed in the Action Plan

- Perfluoroalkyl sulfonates (PFAS) and Perfluoroalkyl carboxylates (PFAC)





Possible Scenarios of Concern with PFCs

- Long-chain PFAS chemicals
 - Direct releases to the environment from U.S. facilities as a result of few existing uses
 - Direct releases to the environment from non-U.S. facilities, resulting in transboundary environmental transport to U.S.
 - Articles containing PFAS chemicals could release PFCs, significantly increasing the magnitude and duration of exposure to humans and the environment to these chemicals
- Long-chain PFAC chemicals
 - Direct releases to the environment from U.S. facilities not participating in PFOA Stewardship Program
 - Direct releases to the environment from non-U.S. facilities not participating in PFOA Stewardship Program, resulting in transboundary environmental transport to U.S.
 - Articles, including imports, releasing PFAC as a result of their residual content in fluorotelomer-based products and/or as the fluorotelomers-based polymers in articles biodegrade



TSCA Section 6 Rulemaking for LCPFCs

- EPA intends to propose a TSCA section 6 rule in 2012 to adequately address unreasonable risk from LCPFCs
 - Expand beyond existing SNURS to address PFAS-containing articles
 - Expand the reach of the 2010/15 PFOA Stewardship Program beyond the eight participating companies and further address exposure via PFAC-containing articles
- Initiated detailed assessments to evaluate whether EPA can make the TSCA section 6 "presents or will present an unreasonable risk" findings
- If these more detailed assessments indicate that a different approach to risk management is appropriate, EPA will consider additional approaches



Next Steps

- Publish a proposed rule in 2012 with actions under TSCA to adequately address unreasonable risk from LCPFCs
- Continue the 2010/15 PFOA Stewardship Program
- Continue to evaluate alternatives in the New Chemicals Program
- Work cooperatively with other countries on this global issue



Information Sources

- EPA website: www.epa.gov/oppt/pfoa
- 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-HQ-OPPT-2010-0145 (Action Plan)
- 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 Coordinators:
 - Katherine Sleasman; 202-564-7716; sleasman.katherine@epa.gov
 - Toni Krasnic; 202-564-0984; krasnic.toni@epa.gov