

Long-Chain Perfluorinated Chemicals: Risk Reduction Approaches

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Risk Reduction Approaches to PFCs

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Overview

- Background
- Concerns with PFCs
- Regulation of PFOS and LCPFAS
- Amendment of Polymer Exemption Rule
- 2010/15 PFOA Stewardship Program
- Regulation of PFOA and LCPFAC
- New Chemical Review of Alternatives
- Office of Water Lifetime Health Advisories
- Summary



EPA's Interest in Perfluorinated Chemicals (PFCs)

- Investigating PFCs since late 1990s
- Persistent and Bioaccumulative
 - PFCs found world-wide in the environment, in wildlife, and in humans
 - Bioaccumulation potential, as evidenced by greater concentrations of long-chain perfluorinated chemicals (LCPFCs) in higher trophic-level organisms
 - Long half-life in humans (years)
- Toxicity
 - Reproductive, developmental, and systemic effects in laboratory animals
 - *2005-2013 C8 Health Project*. The C8 Science Panel concluded that there is a “probable link” between perfluorooctanoic acid (PFOA) and diagnosed high cholesterol, kidney cancer, testicular cancer, thyroid disease, pregnancy-induced hypertension/preeclampsia, and ulcerative colitis;
www.c8sciencepanel.org



LCPFC Risk Management

TSCA TOOLS

Voluntary
Agreements

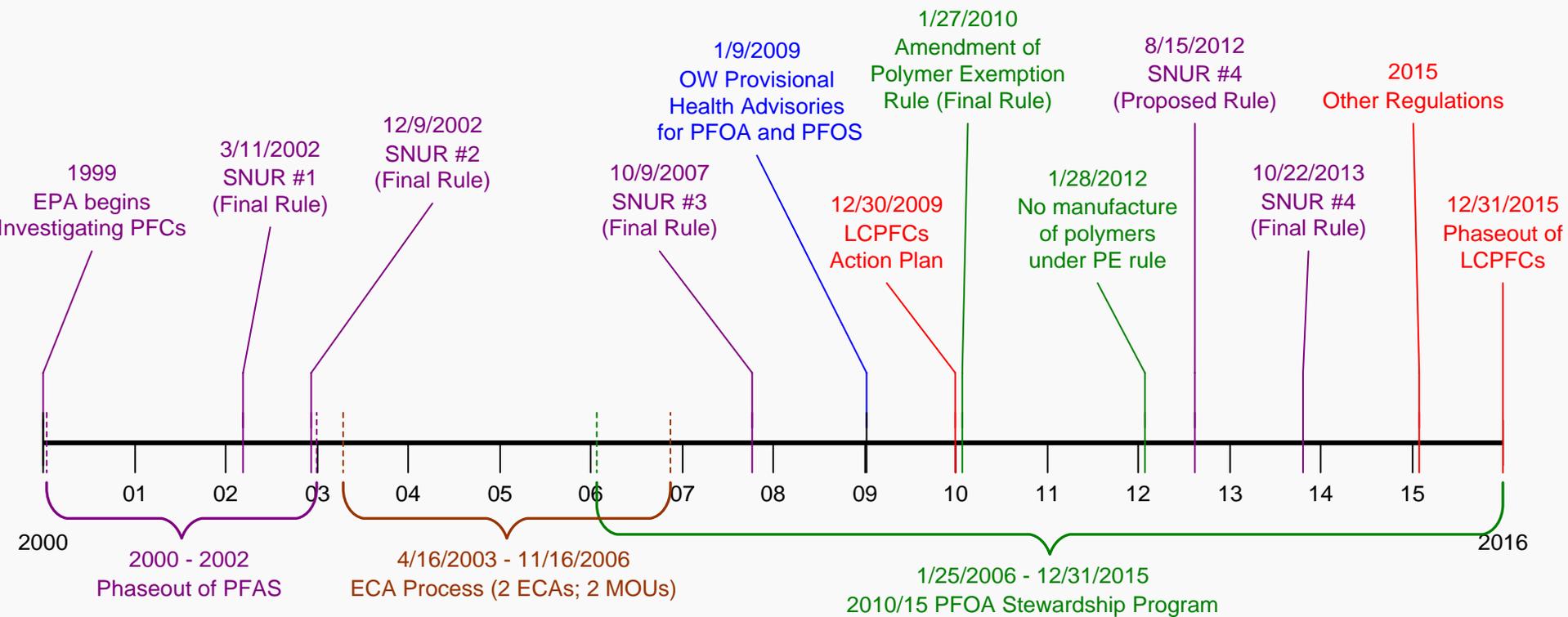
Regulatory

2010/15 PFOA
Stewardship
Program

Significant New
Use Rules
(SNURs)

Manage
Alternatives - New
Chemicals
Program

Consider a
Section 6 Rule for
Managing Risks





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>



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 no longer be authorized under the polymer exemption rule



2010/15 PFOA Stewardship Program

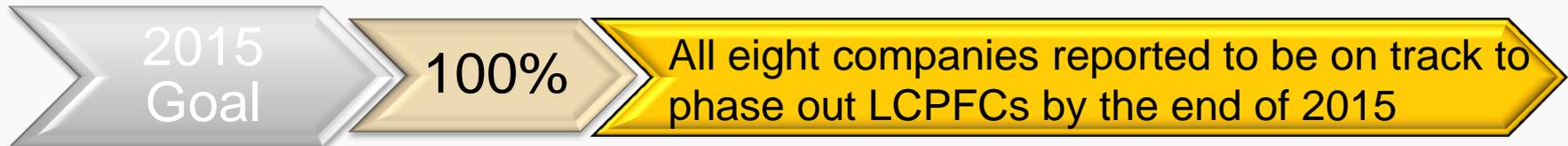
GOALS:

- Launched in 2006
- 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
- Commit to working toward elimination of these chemicals by end of 2015

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- | | |
|--|------------------|
| ➤ 3M/Dyneon | ➤ Clariant |
| ➤ Arkema | ➤ Daikin |
| ➤ Asahi | ➤ DuPont |
| ➤ BASF Corporation (successor to Ciba) | ➤ Solvay Solexis |
-



2011 Progress Reports PFOA Stewardship Program



More info: <http://epa.gov/oppt/pfoa/pubs/stewardship/index.html>



PFAS and LCPFAC Carpet SNUR

- Final rule published on October 22, 2013
 - Rule effective December 23, 2013
- PFAS Chemical Substances
 - Seven PFAS chemicals submitted for PMN but never entered commerce
 - Designate (for all listed PFAS chemical substances) processing as a significant new use
- Long-Chain Perfluoroalkyl Carboxylate (LCPFAC) Chemical Substances
 - Designates manufacturing (including importing) and processing for use as part of carpets or for treating carpet (e.g., for use in the carpet aftercare market) as a significant new use, except for use of two chemical substances as a surfactant in carpet cleaning products
 - Makes an exemption inapplicable to persons who import or process the LCPAC chemical substances as part of an article
 - Category definition
 - Processing of articles not included
- More info
 - <http://www.gpo.gov/fdsys/pkg/FR-2013-10-22/html/2013-24651.htm>



Significant New Use Rules (SNURs): Post-Phaseout Under Development

- EPA anticipates proposing a SNUR in 2014/2015 to support the voluntary phaseout of LCPFAC chemicals as part of the 2010/15 PFOA Stewardship Program
- Proposed SNUR would likely:
 - Designate manufacturing, import, or processing of all LCPFACs meeting category definition for any use as significant new use, except ongoing uses, after 12/31/2015



New Chemical Review of Alternatives

- EPA is reviewing substitutes for LCPFCs as part of its review process for new chemicals under EPA's New Chemical Program
 - Ongoing since 2000
 - Consistent with the approaches to alternatives encouraged under the PFOA Stewardship Program
 - Over 150 alternatives of various types have been received and reviewed by EPA
- Full toxicity and fate testing programs on new chemicals
 - EPA reviews the new substances against the range of issues that have caused past concerns with PFCs, as well as any issues that may be raised by new chemistries
 - Reviews typically consider decomposition products, fate, transport, bioaccumulation potential, toxicity, use patterns, potential exposures and releases
- More information at <http://epa.gov/oppt/pfoa/pubs/altnewchems.html>



TSCA Section 6

- LCPFC Action Plan published in December 2009
- EPA will consider rulemaking on LCPFCs under the Toxic Substance Control Act (TSCA) section 6
 - Provides authority for EPA to ban or restrict the manufacture (import), processing, and use of chemicals
 - Requires a "presents or will present an unreasonable risk" finding
 - Further assessment will inform EPA's approach to risk management
- EPA will consider additional approaches to risk management, as appropriate



EPA Office of Water (OW)

- OW initiated external peer review of perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS) human health effects documents
 - EPA will use the revised documents to derive lifetime health advisories for PFOA and PFOS in drinking water
 - Once finalized, the lifetime health advisories will supersede EPA's provisional health advisories issued in 2009
 - 0.4 micrograms per liter for PFOA
 - 0.2 micrograms per liter for PFOS
 - Health advisories serve as guidance only and are not enforceable
- More Info
 - <http://water.epa.gov/drink/standards/hascience.cfm>



Summary

- Target to publish proposed rule(s) in 2014/2015 under TSCA to adequately address risk from LCPFCs
- Continue with 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-2002-0043 (PFOS SNURs)
 - EPA-HQ-OPPT-2002-0051 (Polymer Exemption)
 - EPA-HQ-OPPT-2003-0012 (PFOA ECA Process)
 - 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-2005-0015 (Follow-up PFAS SNUR)
 - EPA-HQ-OPPT-2006-0621 (Stewardship Program)
 - EPA-HQ-OPPT-2010-0145 (Action Plan)
 - EPA-HQ-OPPT-2012-0268 (Carpet SNUR)
- 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
- Additional Information:
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