New Chemical Review of Alternatives for PFOA and Related Chemicals in U.S.

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Overview

Review of Alternatives: Background & Statistics

Strategy: Integrated Approach

Data Needs on Alternatives

Example of Integrated Testing

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Summary

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Review of Alternatives: Background & Statistics

- 2010/15 PFOA Stewardship Program
  - Major driver for companies to reduce residuals in products and to switch from C8 products to safer alternatives
- EPA is reviewing substitutes for PFOA, PFOS, and other long-chain perfluorinated substances (LCPFCs) as part of its review process for new chemicals under EPA's New Chemicals Program
- Over 150 alternatives of various types have been received and reviewed by EPA
  - Many products are perfluorinated with C4 or C6 perfluoroalkyl constituents
  - Companies prefer these as drop-in replacements

Strategy: Integrated Approach

- EPA believes a strategic integrated approach to testing is needed to speed development of the data needed to understand the issues/concerns with the various types of alternatives

- EPA believes this can be done scientifically without necessarily testing every alternative chemical for every endpoint

- Accordingly, EPA has developed a matrix of data needs for each type of alternative
  - Matrix is being filled by testing required in Consent Orders with costs being distributed across companies based on market share and the value of products

Data Needs on Alternatives

- EPA incorporated information on PFOS and PFOA into review on new alternatives

- To enable EPA to understand the risks of the new alternatives, EPA believes it needs an authoritative understanding of hazards and fate as outlined below
  - Health and metabolism
    - Subchronic, chronic, reproductive, developmental, oncogenicity, pharmacokinetics, hepatotoxicity and other systemic effects, lung toxicity (if spray application by consumers is possible), and metabolism
  - Ecotoxicity
    - Avian reproductive, fish early life stage
  - Environmental fate
    - Biodegradation (water, soil, and/or sewage), photolysis, hydrolysis
  - Half-life in animals
  - Human biomonitoring or epidemiological data to augment animal data, when possible

Example of Integrated Testing

Example PFC Alternative	Health and Metabolism	Ecotoxicity	Environmental Fate
A	X (many on list)	Avian reproductive	X (many on list)
B	X (many on list)	Fish early life stage	
C			X (many on list)
D	X (some on list)	Avian reproductive	X (some on list)

- Testing could be required on the notified substance and/or on the degradant. Testing would include, depending on what testing has been completed on the substance or analogous substances, one or more of the following:
  - Health and Metabolism – subchronic, chronic, reproductive, developmental, oncogenicity, pharmacokinetics, metabolism;
  - Ecotoxicity – avian reproductive, fish early life stage
  - Environmental fate – biodegradation (water, soil, and/or sewage), photolysis, hydrolysis

Results to Date

- Data on the C4 sulfonate and the C6 acid have shown different pharmacokinetics (shorter half-life) and lower toxicity than PFOA and PFOS
- EPA has issued Consent Orders that require testing which, taken together, will characterize the effects of the substances and their degradants
- For fate data, EPA has and will continue to categorize chemicals based on polymer content and the likelihood that chemical composition will affect degradation (e.g., solubility and reactivity)
- EPA expects that the value of all testing will be more than $30 million

Summary

- Great example of interplay between new and existing chemicals
  - Concerns with existing chemicals led to substitution by alternative chemicals through the 2010/15 PFOA Stewardship Program
- Integrated testing approach made it easier and faster to fill the data needs
  - U.S. EPA is getting data from multi-year, multi-million tests which one company alone would not be able to provide
- A comprehensive program, which considers both existing and new chemicals, greatly facilitates the transition from problem chemicals to safer alternatives

Information Resources

- Perfluorinated chemicals
  - Toni Krasnic, U.S. EPA; 202-564-0984; krasnic.toni@epa.gov
  - Katherine Sleasman, U.S. EPA; 202-564-7716; sleasman.katherine@epa.gov
- Alternative chemicals
  - New Chemical Review of Alternatives for PFOA and Related Chemicals by U.S. EPA is available at http://epa.gov/oppt/pfoa/pubs/altnewchems.htm
  - Rose Allison; U.S. EPA; 202-564-8970; allison.rose@epa.gov