Nanotechnology and the Toxic Substances Control Act

Jim Willis
Director, Chemical Control Division
Office of Pollution Prevention and Toxics, EPA

Overview

- Public Meeting
- Science Policy Council Workgroup
- TSCA as a possible “Toolkit”

Public Meeting

- Announced on May 10 (70 FR 24574)
- Will be held on 23 June from 9 AM to 5 PM
- Venue – Washington Plaza, 10 Thomas Circle, NW, Washington DC
- Opportunity to collect views of all stakeholders
- Requests to provide oral comments must be submitted by June 9

General Issues

- Scope and purpose of a voluntary pilot program for nanoscale materials that are existing chemical substances
- The kinds of information relevant to the evaluation of potential risks from exposure to nanoscale materials
- Chemical characterization and nomenclature of nanoscale materials for regulatory purposes
- Identification of interested stakeholders

Specific Issues

- Feasibility and value of a voluntary pilot program
- Scope and design of a voluntary pilot program
- Information that would be useful in the evaluation of effects on human health and the environment resulting from exposure
- Size, dimensions and shapes of chemical substances that should be considered nanoscale materials
- Types of information (e.g., unique and novel properties) that would be useful to a voluntary pilot program
- Manufacturing processes for nanoscale materials and how they might relate to product identities

About the meeting

- Structure will become clearer when we know how many participants and who wishes to make statements
- The Agency does not have a preconceived notion about what it wants as a result
- We hope:
  - To see a convergence of views (even if only in the broadest sense)
  - That we don't see irreconcilable differences
- Comments (etc.) will be in docket OPPT-2004-0122
- Following the meeting we hope to provide a synthesis, hopefully in the form of a proposal

SPC Nanotechnology Framework Committee

- The Science Policy Council's charge to the committee is to develop a framework document that addresses all aspects of nanotechnology that are relevant to EPA, such as science and research needs, regulatory and policy implications, statutory authorities, and communication approaches
- Co-chaired by ORD (Jeff Morris) and OPPT (Jim Willis)
- All offices and most regions actively involved

SPC – Draft Outline of Eventual Product

- NNI Strategy Workgroup
- EPA Research Strategy and Coordination
- Risk Assessment
  - Physical-Chemical Properties and Characterization
  - Health and Ecological Effects
  - Human Exposures During Manufacture and Use
  - Environmental Release, Fate, and Transport
- Statutes, Regulations, Policies, Media-Specific Issues
- Risk Management
- Converging Technologies
- P2: Pollution Prevention and Life Cycle Analysis
- P3: Sustainability and Society
- Public Communications

SPC – Schedule

• SPC Mandate	December 2004
• Initial Workgroup meetings	February-April 2005
• Draft products submitted by workgroups	June 2005
• Workshop to develop draft document	Early Sept. 2005
• Draft for SPC Steering Committee review	Late Sept. 2005
• Peer review draft to SPC for approval	October 2005
• External peer review	November 2005
• Final review and approval by SPC	December 2005
• Publication as an SPC document	January 2006

TSCA as a possible "Toolkit"

- Form Follows Function
  - It will be important to first determine what to do with respect to nanotech, then find the appropriate tool or mix of tools to achieve success
- Some elements of TSCA are already in play, e.g., section 5 for new chemicals and section 8(e) for substantial risk
- Our regulations, as drafted, did not anticipate nanotechnology
- Nanotechnology will evolve from "dumb" to "smart"
- EPA has a long, and good, track record of applying a variety and mix of approaches towards problem solving, sometimes including a blend of voluntary and regulatory approaches
- Paperwork Reduction Act (etc.) requirements

Examples of TSCA Tools

- Voluntary programs (e.g., HPV, 33/50)
- “Blended”programs (e.g., PFOA)
- Section 8(a) – production, use and exposure data reporting
- Section 8(d) – health and safety data reporting
- Section 4 – testing
- Enforceable Consent Agreements – testing
- Section 5 – manufacturing and processing notices
  - 5(a)(1) – new chemicals
  - 5(a)(2) – significant new uses
- Section 6 – control

Summary

- Possible stepwise process
  - Agreement on what the program goals should entail
  - Agreement on what tools/combinations are appropriate
  - Agreement on how and when to get there
  - Is there an interim, pilot program that helps us “learn by doing” and bridges the gap and what does that program look like?
- Public meeting is the first step
- Relationships to other EPA and US governmental programs