

EPA's Management of Chemicals under Existing TSCA Authorities

Presented by

Michael Boucher

McKenna Long & Aldridge LLP, Washington DC

February 19, 2013, 1:00-2:00 PM, Tokyo, Japan

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Background

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- Existing chemical substances are those listed on the TSCA Inventory
- EPA's Existing Chemicals Program includes a variety of actions under multiple TSCA authorities
- EPA's alleged failure to regulate existing chemicals is the main reason given for amending TSCA

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- Stakeholders remain in broad agreement on principles
 - EPA: <http://www.epa.gov/oppt/existingchemicals/pubs/principles.html>
 - Am. Chem. Council: <http://www.americanchemistry.com/Policy/Chemical-Safety/TSCA/10-Principles-for-Modernizing-TSCA.pdf>
 - Consumer Specialty Prod. Ass'n/Am. Cleaning Inst./Grocery Mfr. Ass'n: http://www.cleaninginstitute.org/assets/1/workflow_staging/AssetManager/284.PDF
 - Safer Chemicals, Healthy Families: <http://www.saferchemicals.org/about/platform-for-reform.html>
- But there is disagreement about specifics

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- In 2010, two bills introduced in Congress
 - One in Senate, one in House of Representatives
 - Widely discussed but went nowhere
- In 2011, one bill re-introduced in Senate
 - Allegedly revised to win industry support
 - Reported out of Environment and Public Works Committee in 2012, along party lines, but did not progress further before 112th Congress ended

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- In 113th Congress, each political party will introduce a bill in the Senate this year
- The House of Representatives will wait for the Senate to produce compromise legislation
- But any compromise legislation will take time
- Meanwhile, EPA has been increasing its use of existing TSCA authorities
 - Contradicts critics' story that TSCA "does not work"

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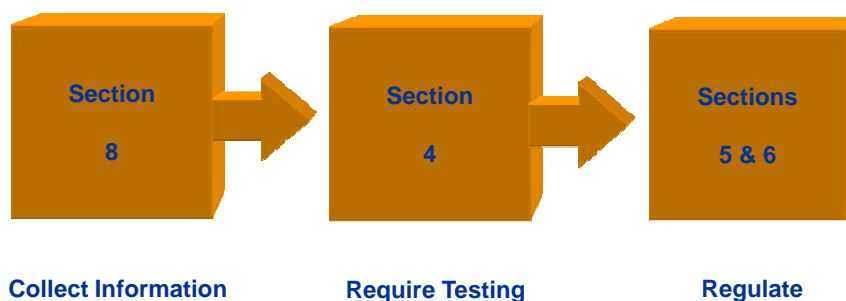
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Data Form the Basis for Regulatory Action



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TSCA Authorities

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- To gather information
 - Section 8(a) chemical-specific information rules
 - Section 8(a) Preliminary Assessment Information Rule (“PAIR”)
 - Section 8(a) Chemical Data Reporting (“CDR”) Rule (formerly, the Inventory Update Rule or “IUR”)
 - Section 8(c) recordkeeping of allegations of significant adverse reactions
 - Section 8(d) reporting of unpublished health and safety studies
 - Section 8(e) reporting of substantial risk information

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TSCA Authorities

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- To require testing
 - Section 4 test rules
 - Section 4 Enforceable Consent Agreements
 - Section 4 Voluntary Testing Agreements
- To regulate
 - Section 5(a) Significant New Use Rules (“SNURs”)
 - Section 5(b)(4) “chemicals of concern” list (new)
 - Section 6 rules to prohibit or limit import, manufacture, processing, distribution, use, or disposal

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TSCA Authorities

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- Other/miscellaneous
 - Section 9 requires EPA to consider other laws
 - Environmental laws administered by EPA
 - Laws administered by other U.S. federal agencies
 - Section 12(b) requires filing of export notices
 - Section 13 requires filing of import certifications
 - Section 21 allows citizens to petition for issuance, repeal, or revision of rules and orders under sections 4, 5(e), 6, and 8

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TSCA § 6

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- Broad authority to regulate existing substances that present “unreasonable risk of harm to health or the environment”
- But EPA has promulgated only a handful of regulations under section 6
- Critics cite unworkable procedures and standards
- But EPA also has been slow to use TSCA § 4
- And industry has voluntarily withdrawn many substances and uses (e.g., asbestos)

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TSCA § 6 Procedures and Standards

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- EPA must demonstrate “unreasonable risk of harm to human health or environment”
 - Difficult to do with insufficient section 8 exposure/use data or section 4 hazard data
- EPA must publish a risk/benefit analysis
 - Human health effects and magnitude of human exposure
 - Environmental effects and magnitude of environmental exposure
 - Benefits of uses and availability of substitutes
 - “Reasonably ascertainable” economic consequences of rule to national economy, small business, technological innovation, the environment, and public health

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- EPA must follow informal rulemaking procedures under the Administrative Procedure Act
 - Publish proposed rule in the *Federal Register*
 - Take written comments from the public
 - Provide an opportunity for an informal hearing
 - If there are disputes of material fact, EPA may allow interested parties to cross-examine witnesses and offer rebuttal witnesses
 - Promulgate a final rule with unreasonable risk findings
 - Must specify an effective date that is as soon as feasible
- EPA must use its other laws, where more efficient

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TSCA § 6 Rules

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- Polychlorinated biphenyls (“PCBs”)
 - A special case, because section 6(e) of TSCA required EPA to promulgate rules for PCBs
 - Big rulemaking: all of 40 C.F.R. part 761
 - TSCA’s PCB program is old but still consumes significant EPA resources
 - PCBs also remain an enforcement priority at EPA

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- Asbestos (40 C.F.R. part 763)
 - 1982 asbestos in schools rules, replaced by 1987 Asbestos Hazardous Emergency Response Act (i.e., Title II) rules
 - 1987 asbestos abatement project rules
 - 1989 asbestos product ban (famous case)
 - Shows potentially broad scope of section 6 rules
 - Started with a section 21 petition
 - EPA did not refer to OSHA under section 9
 - Most of rule set aside by Fifth Circuit Court of Appeals in 1991

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- Ban on lead- and zinc-containing fishing sinkers was proposed under section 6 in 1994 but never finalized
- Section 21 petition filed on Aug. 3, 2010 to ban lead shot, bullets, and fishing sinkers under section 6
 - EPA denied petition as to lead ammunition on Aug. 27, 2010, citing exclusion in TSCA § 3(2)(B)(v)
 - EPA denied petition as to lead sinkers on Nov. 4, 2010, citing no showing of need for rule to address an “unreasonable risk” in light of U.S. state and local activities
 - Petitioners sued EPA on Nov. 23, 2010
 - On Sept. 29, 2011, the court dismissed as untimely the claim against EPA regarding lead ammunition

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- Section 21 petition filed on Nov. 17, 2011 to ban fishing tackle containing lead under section 6
 - EPA denied petition on Feb. 14, 2012, citing U.S. state and local actions and prevalence of non-lead alternatives in the marketplace
- New section 21 petition filed on Mar. 13, 2012 to regulate bullets and shot containing lead under section 6
 - On Apr. 9, 2012, EPA declared petition repeat of prior one from 2010 and inadequate for the same reasons

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- Chlorofluorocarbons
- Tetrachlorodibenzo-*p*-dioxin
- Metalworking fluids
- Hexavalent chromium

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EPA's Existing Chemicals Program Areas

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- Collecting and assessing information on chemicals
- Increasing transparency and public access to information
- Nanoscale materials

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Chemical-Specific Actions

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- PCBs (§ 6(e))
- Asbestos (§ 6 and Title II)
- Lead (Title IV)
 - Lead paint rules in 40 C.F.R. part 745
- Formaldehyde
 - Congress directed EPA to promulgate rules by Jan. 1, 2013 to implement the Formaldehyde Standards for Composite Wood Products Act (new Title VI of TSCA)
 - No rules yet, and EPA plans to conduct Small Business Advocacy Review Panel

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Chemical-Specific Actions

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- Mercury
 - 2007 SNUR - use in convenience light switches, anti-lock brake system switches, and active ride control system switches in certain motor vehicles
 - 2010 SNUR - use in flow meters, natural gas manometers, and pyrometers
 - May 30, 2012 SNUR - use in barometers, manometers, hygrometers, and psychrometers
- Glymes
 - July 14, 2011 proposed SNUR for 14 glymes

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Chemical-Specific Actions

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- Unsponsored HPV chemicals
 - Section 4 test rule for first group (2006)
 - Section 4 test rule for second group (2011)
 - Section 4 test rule for third group (2011)
 - Proposed section 4 test rule and SNUR for fourth group (2011)
 - 23 chemicals met exposure finding for test rule
 - 22 chemicals did not and will fall under the SNUR
 - Section 8(a)/8(d) rules (2006, 2007)

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Chemical Action Plans

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- From 2009 through 2011, EPA published Chemical Action Plans (“CAPs”)
 - Summarize available hazard, exposure, and use information on chemicals
 - Outline risks that each chemical may present
 - Identify the specific steps that EPA is taking to address such risks
- Process for selecting chemicals for CAPs was unclear
- In February 2012, EPA replaced CAPs with Work Plan Chemicals

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Chemical Action Plans

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- CAPs issued by EPA
 - Benzidine dyes
 - Bisphenol A
 - Hexabromocyclodecane
 - Methylene diphenyl diisocyanate
 - Nonylphenol and nonylphenol ethoxylates
 - Perfluorinated chemicals
 - Penta, octa, and decabromodiphenyl ethers in products
 - Phthalates
 - Short-chain chlorinated paraffins
 - Toluene diisocyanate

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Example: CAP for Phthalates

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- Section 5(b)(4) rule to add eight phthalates to “chemical of concern” list
- Emergency Planning and Community Right-to-Know Act § 313 rule to add six phthalates to Toxic Release Inventory
- Section 6 rule following Consumer Product Safety Commission, Food and Drug Administration, and Integrated Risk Information System assessments
- On March 20, 2012, EPA proposed a SNUR covering most uses of di-n-pentyl phthalate based on IUR data showing no current “use”
- EPA began DfE assessment in August 2011

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Work Plan Chemicals

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- In August 2011, EPA developed a two-step process to identify potential chemicals for near-term review and assessment under TSCA
- Based on comments, EPA modified the original two-step process in February 2012

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Work Plan Chemicals

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- In Step 1, EPA searched a specific set of data sources for chemicals with one or more characteristics
 - Potentially of concern to children's health (for example, because of reproductive or developmental effects)
 - Neurotoxic effects
 - Persistent, bioaccumulative, and toxic ("PBT")
 - Probable or known carcinogens
 - Used in children's products
 - Detected in biomonitoring programs
- EPA identified 1,235 chemicals in Step 1, excluded chemicals outside of TSCA or not feasible to include, and ended up with 345 candidates

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Work Plans Chemicals

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- In Step 2, EPA assigned chemicals from Step 1 a hazard score, an exposure score, and a persistence/ bioaccumulation score
 - Hazard score (of 1-3) based on highest scoring human health or environmental toxicity endpoint
 - Exposure score (of 1-3) normalized from rankings based on use type, general population and environmental exposure, and TRI or surrogate release data
 - Persistence/bioaccumulation score (of 1-3) normalized from separate scores for persistence and bioaccumulation

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- Chemicals that could receive all three scores in Step 2 were normalized and prioritized as high (score 7-9), moderate (score 5-6), and low (score 3-4) priority
- Chemicals that received no score for hazard in Step 2 or no score for exposure but moderate or high scores for hazard or for persistence/bioaccumulation were designated as candidates for information gathering
- EPA identified 83 high-priority Work Plan Chemicals in Step 2
 - Will be candidates for risk assessment in the next few years

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Work Plan Chemicals

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- EPA planned to assess seven chemicals in 2012
 - Antimony and antimony Compounds*
 - HHCB (1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta[g]-2-benzopyran)*
 - Long-chain chlorinated paraffins
 - Medium-chain chlorinated paraffins
 - Methylene chloride*
 - N-Methylpyrrolidone*
 - Trichloroethylene*
- On Jan. 4, 2013, EPA published first five draft risk assessments(*) for public comment

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Work Plan Chemicals

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- On June 1, 2012, EPA identified an additional 18 chemicals to be assessed in 2013 and 2014
- CDR Rule data will be used to assess all 83 chemicals but was only one factor in creating the list itself
- In addition, EPA has asked industry to share REACH data on the 83 high-priority chemicals

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EPA's Existing Chemicals Program Areas

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- Collecting and assessing information on chemicals ←
- Increasing transparency and public access to information
- Nanoscale materials

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Collecting/Assessing Information

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- Work Plan Chemicals will keep EPA fully occupied at current funding and staffing levels
- But publication and analysis of CDR Rule reporting (Feb. 1 to June 30, 2012) also is a priority
 - EPA will use data to screen chemicals to refine data needs and identify candidate chemicals for risk assessment and reduction

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Collecting/Assessing Information

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- And EPA will continue to fill data gaps on HPV chemicals
 - In latest proposed test rule, EPA is seeking comments on future approaches to testing
 - Whether production volume should drive testing
 - Whether other exposure or hazard factors should be included
 - Whether SIDS remains the best approach
 - How computational toxicology should be used
 - EPA was still developing and publishing hazard characterizations as of December 2012

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Increasing Public Access

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- Increasing public access to chemical information
 - Chemical Data Access Tool to find health and safety data submitted to EPA
 - CDR Rule will increase available screening-level, exposure-related information
 - Chemicals and facilities added to Envirofacts Database
 - TSCA Inventory is now free on the Internet

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Increasing Transparency

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- Tightening confidential business information (“CBI”) policy
 - Ensuring that CBI claims are necessary and consistent with TSCA
 - Jan. 1 and May 27, 2010 policies on CBI claims for chemical identities in health and safety studies
 - Feb. 10, Mar. 24, and June 8, 2011 actions to “declassify” chemical identities claimed as CBI
 - As of Nov. 28, 2011, EPA had made public 577 formerly confidential chemical identities and more than 1,000 previously unavailable health and safety studies

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Increasing Transparency

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- Tightening CBI policy
 - EPA also has challenged industry to reduce CBI claims voluntarily
 - For 2012, EPA asked companies to review and “declassify” where possible CBI claims in submissions made under section 8(e) during the section 8(e) Compliance Audit Program (i.e., from 1991 to 1994) and from May 2001 to January 2010

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- Increasing transparency and public access to chemical information
- Nanoscale materials ←

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Nanotechnology under TSCA

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EPA informally uses the three-part definition of National Nanotechnology Initiative:

- Size: length scale of approximately 1 – 100 nm in at least one dimension
- Properties: creating structures with *novel* properties and functions due to size
- Control: ability to control on the atomic scale

Nanoscale materials often are “different physical forms” (structures) of macroscale counterparts

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Nanoscale Materials: How Small?

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- Nanometer = 1 billionth of a meter (“nm”)
- Regulatory focus = 1-100 nm
- Comparisons

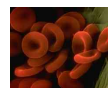


Ant
~ 5 mm

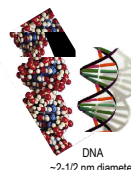


Carbon
buckyball
~1 nm
diameter

Ant	~	5,000,000 nm
Dust mite	~	200,000 nm
Human hair	~	60,000 nm
Blood cell	~	7,000 nm
Virus	~	50 nm
DNA (diameter)	~	2.5 nm
Carbon nanotube	~	1.5 nm
Fullerene	~	1 nm



Red blood cells
(~7-8 μm)



DNA
~2-1/2 nm diameter

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TSCA Inventory Status of Nanoscale Materials – General Approach (2008)

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- Particular molecular identity differences that do not matter
 - Particle size (different physical form)
 - Physical/chemical properties due to particle size
- Particular molecular identity differences that do matter
 - Molecular formulas (number of atoms), e.g., ethane (C_2H_6) and propane (C_3H_8)
 - Atom connectivities, e.g., structural/positional isomers (n-butane and isobutene)
 - Spatial arrangements of atoms, e.g., isomers ((Z)-2-butene and (E)-2-butene)
 - Crystal lattices, e.g., forms of titanium dioxide (anatase/tetragonally and brookite/orthorhombically)
 - Allotropes of the same element, e.g., graphite and diamond
 - Isotopes of the same element

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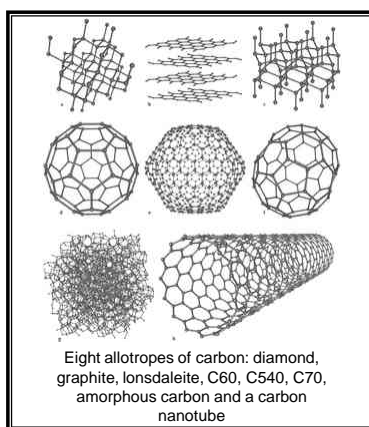
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Allotropes of Carbon

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From Wikipedia, http://en.wikipedia.org/wiki/Allotropes_of_carbon

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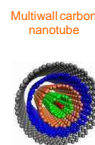
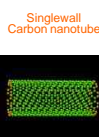
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Carbon Nanotubes (“CNTs”)

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- Carbon, graphite, and diamond are different carbon allotropes but also are existing chemicals
- New carbon nanoforms: existing or new chemical substances?
 - Fullerenes = new chemical substances
 - SW/MW CNTs = new chemical substances
- October 31, 2008 *Federal Register* notice
 - Most carbon nanotubes are “new chemicals”



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Control of New Nanoscale Materials

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- Since 2005, EPA has received and reviewed over 100 premanufacture notices (“PMNs”)
- EPA has permitted limited manufacture under section 5(e) order and SNURs
- EPA has controlled and limit exposures by
 - Limiting the uses of new nanoscale materials
 - Requiring personal protective equipment
 - Limiting environmental releases
 - Requiring health and environmental effects testing
- EPA also has allowed manufacture under PMN exemptions, e.g., Low Volume Exemption (“LVE”), but only when exposures could be tightly controlled

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Control of Existing Nanoscale Materials

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- What EPA is proposing to do
 - Section 8 rule to gather information on production volumes, methods of manufacture and processing, exposures and releases, and available health and safety data
 - Section 4 test rule for certain nanoscale materials known to be in commerce
 - SNUR for nanoscale materials based on existing (Inventory-listed) macroscale substances
- But “end of 2010” deadline is long past

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