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Applicability of U.S. Environmental Laws to Assess,
Prevent, and Control Risks of Nanotechnology: TSCA

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TSCA -- Overview

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- Enacted nearly 30 years ago, TSCA is the central law governing industrial chemicals
- TSCA authorizes EPA to screen and regulate “new” and “existing” chemicals
- EPA’s authority over chemical substances must be exercised in a manner “not to impede unduly or create unnecessary economic barriers to technological innovation”
- TSCA was intended to fill a regulatory gap (prevent introduction of new chemicals that pose risk) and reflects a preference that other laws be used to control chemical risks when possible and appropriate

Other Federal Chemical Control Laws

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- Federal Insecticide, Fungicide, and Rodenticide Act -- Regulates new pesticides, reregisters older ones
- Federal Food, Drug, and Cosmetics Act -- Regulates pharmaceuticals, food additives, materials that come in contact with food, and cosmetics

Chemicals in Commerce

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- EPA maintains under TSCA Section 8(b) an information Inventory that enables EPA to identify chemicals in commerce
- Initial Inventory in 1979 contained information on 61,000 “existing” chemicals
- Information on chemicals listed on Inventory is updated every four years, last updated in 2002, and will be updated again in 2006

Existing Chemicals -- TSCA Section 6

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- TSCA Section 6 authorizes EPA to prohibit/limit the manufacture, import, processing, distribution in commerce, use, or disposal of a chemical if there is a reasonable basis to conclude the chemical presents or will present an **unreasonable risk of injury to health or the environment**
- “Unreasonable risk” determinations require EPA to consider risks and benefits, availability of substitutes, reasonably ascertainable economic consequences of regulating the chemical after considering the effects of regulation on the economy, small business, technological innovation, the environment, and public health. TSCA requires the “least burdensome” regulatory measure to provide adequate protection
- Chemicals now regulated -- Halogenated aromatic compounds (PCBs and dioxins); metals (lead and mercury); fibers (asbestos, refractory ceramic fibers, and products contaminated with asbestos/fibers)

Issues with TSCA Section 6

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- Unreasonable risk findings require “substantial evidence” through Section 6(a) rulemaking
- Burden of proof on EPA is heavier than required under APA (not arbitrary and capricious) (*Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991))
- Elements of proof as to available substitutes, economic viability, least burdensome alternative, etc., are difficult to prove
- Economic showing is difficult to quantify
- Judicial precedent on proposed bans is adverse to EPA; less burdensome pathways have not been used or challenged

Issues with TSCA Section 6 (cont'd)

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- TSCA itself encourages use of other statutory authority
- Identifying and quantifying risks and benefits of nanomaterials is uniquely challenging given nascent stage of commercial development and absence of track record of performance
- Classification of “new” versus “existing” nanomaterial consisting of a chemical substance is unclear
- Relevance of the definition of chemical substance (particular molecular identity) is questionable with respect to nanomaterials

Existing Chemicals -- TSCA Section 5

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- Section 5 -- Authorizes EPA to develop Significant New Use Rules (SNUR).
- “New Use” can be interpreted very broadly, arguably including the first time a chemical is manufactured at the nanoscale. EPA could take the position nanomaterials consisting of existing chemicals (those listed on Inventory) are “new uses”
- EPA must consider projected volume of the chemical, extent to which “use changes the type or form of exposure to human beings to a chemical,” extent to which use increases magnitude of exposure, manner and methods of manufacturing, processing, distribution in commerce, and disposal

Existing Chemicals -- TSCA Section 5 (cont'd)

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- Once a SNUR is in place, a Significant New Use Notice (SNUN) must be submitted by entities that intend to manufacture SNUR-designated chemicals in a manner restricted by the SNUR
 - SNUNs operate much like Premanufacture Notices (PMN)
 - SNUNs enable EPA to evaluate new uses to assess whether new data or limitations on production, use, distribution, or disposal need to be imposed

Issues with TSCA Section 5

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- Implications derived from distinction between new vs. existing chemicals based on size are unclear
- Not clear in all cases nanoscale materials reflect hazard and exposure profile of bulk counterpart material
- Not clear the nanoscale material is a “new use” of an existing chemical or a “new chemical” in that the nanoscale material may or may not reflect toxicity profile and fate tendencies of listed chemical; if new chemical, what regulatory pathway for conversion to PMN?
- Rulemaking requires OMB approval
- Rulemaking takes time, resources, with uncertain results

Existing Chemicals TSCA -- Section 4 Chemical Testing

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- TSCA Section 4(a) authorizes EPA to require manufacturers and/or processors of chemical substances to develop new data on health and environmental effects that are needed to assess potential risks from chemicals, provided certain statutory findings are made
- Findings are:
 - The manufacture, distribution, use, disposal practices may present an unreasonable risk of injury [Section 4(a)(1)(A)(i)] *or*
 - The chemical may be produced in substantial quantities and it enters or may be anticipated to enter the environment in substantial quantities or there may be significant or substantial human exposure to the substance [Section 4(a)(1)(B)(i)] *and*
 - There are insufficient data to assess the effects of the manufacture, distribution, etc. of such activities *and* testing is necessary to develop such data

Issues with TSCA Section 4 Test Rules

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- TSCA Section 4 rules have been subject to much litigation
- Promulgating Section 4 test rules take years
- “A” findings would require more available data and it is unlikely EPA could sustain its legal burden in a rulemaking; “B” findings are based on production volume, a metric of questionable relevance to nanomaterials
- Facilities that manufacture less than 500 kg a year, or manufacture only for R&D purposes, are typically exempt unless a final rule specifies otherwise, potentially excluding many manufacturers of nanoscale materials
- Processors typically are not subject to Section 4 test rules unless the risks under review arise from processing, thus excluding risks arising from the processing of nanomaterials unless EPA had specific reason to believe risk arose from processing facilities, which is unlikely based on data limitations

Existing Chemicals -- TSCA Section 12(b) Authority

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- TSCA Section 12(b) requires exporters to notify EPA, in writing, if they export, or intend to export, chemical substances or mixtures that are subject to certain TSCA rules or orders. The chemical substances that are subject to export notification are those for which EPA has issued:
 - Final TSCA Section 4 test rules and Enforceable Consent Agreements;
 - Data required under Section 5(b);
 - Order issued under Section 5;
 - Proposed or final rules issued under Sections 5 or 6; or
 - Actions pending or relief granted under Sections 5 or 7
- EPA, in turn, notifies those foreign governments of hazards that may be associated with a chemical substance or mixture absent requirements in the importing country

Issues Associated with TSCA Section 12(b) Export Notifications

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- To trigger a TSCA Section 12(b) export notification, there must be a final Section 4 rule or a proposed or final Section 5, 6, or 7 rule. If these underlying rules are not in place, as is the case for nanomaterials, there are no Section 12(b) requirements
- Absent export notification, nanomaterials could be exported for use, distribution, processing, or disposal to anywhere in the world with no way of tracking its movement

New Chemicals -- TSCA Section 5

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- Chemicals not listed on the TSCA Inventory are presumptive “new” chemicals
- TSCA Section 5 authorizes EPA to review activities associated with the manufacture, processing, use, distribution in commerce, and disposal of any new chemical substance before it enters commerce and requires PMN reporting
- Exemptions from PMN requirements fall into two categories:
 - Self-executing exemptions; and
 - Exemptions requiring EPA approval

New Chemicals -- TSCA Section 5 Self-Executing Exemptions

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- Chemicals satisfying a self-executing exemption may be manufactured without first submitting a PMN, provided the manufacturer complies with recordkeeping or other requirements for that exemption
- Self-executing exemptions include:
 - Substances that are not manufactured or imported for a separate commercial purpose (*i.e.*, impurities, byproducts, non-isolated intermediates);
 - Research and Development (R&D) substances; and
 - Polymers

New Chemicals -- TSCA Section 5 EPA- Approval Exemptions

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- Other exemptions from PMN requirements require EPA approval. In these instances, a manufacturer or importer must submit, and EPA must approve, an exemption application before a company may commence the manufacture or import of the new chemical substance
- Exemptions requiring EPA approval include:
 - Low Volume Exemption (LVE);
 - Low Release and Low Exposure Exemption (LoREX); and
 - Test Marketing Exemption (TME)

Issues with TSCA Section 5 PMN Exemptions

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- For substances that satisfy the criteria for a LVE, LoREX, or TME, EPA conducts an expedited 30-day review (for LVEs and LoREXs) or an expedited 45-day review (for TMEs) compared to the more robust 90-day (or longer) PMN review
- Due to the very nature of nanomaterials, any exemption based on volume alone may not be an appropriate metric for establishing eligibility for exemption status
- In that the polymer exemption is premised on the belief that high molecular weight polymers are low risk, molecular weight may not be an appropriate metric for nanomaterials

New Chemicals -- TSCA Section 5 PMN

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- If a chemical is not listed on the TSCA Inventory and not otherwise exempt, a PMN must be submitted and approved by EPA prior to commercial manufacture or import
 - The PMN Form seeks information on the submitter's identity, the chemical substance's identity, production volume, uses, exposures, and environmental fate
 - Section 5 does not require testing of new chemical substances for potential toxic effects. EPA's PMN review (and Section 5(e) regulatory actions) are often conducted in the absence of data

Issues with TSCA Section 5 PMN Requirements

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- EPA's TSCA exposure models are not designed for nanoscale materials; unclear how EPA will review PMNs for nanomaterials in the absence of appropriate models and other assessment criteria
 - New Chemicals Program in OPPT uses a series of models to estimate toxicity, ecotoxicity, and environmental fate characteristics
 - Human Health and Environmental Hazards: OncoLogic, ECOSAR, PBT Profiler
 - Environmental Fate: AOPWIN, HYDROWIN, BIOWIN, BCFWIN, STPWIN, LEV3EPI
 - Initial inquiry has identified the following limitations:
 - Typical input is CAS Registry Number or SMILES (simplified molecular input line entry system) notation. EPA relies on structure activity relationship analysis to bridge from known data
 - Organic chemicals only, with molecular weights up to 1000

Issues with TSCA Section 5 PMN Requirements (cont'd)

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- Questionable whether these models can be used for nanomaterials. Although it may be possible to override the models, input measured physical-chemical data for nanomaterials would be needed to obtain useful output from most of the models
- Burden of proof on the PMN submitter; unclear what the standard is with respect to a showing of no unreasonable risk with respect to nanoscale materials
- While no test data are required to be submitted, unclear on what EPA would base its review and approval of a PMN for a new nanoscale substance
- It is arguable whether some nanomaterials could be considered listed on the Inventory because they fall within a broader category (*i.e.*, carbon) and thus exempt from the PMN requirements

TSCA Section 9 Authority -- Relationship to Other Federal Laws

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- TSCA Section 9 sets forth TSCA's relationship to other laws by stating that if EPA determines that an unreasonable chemical risk may be prevented or sufficiently reduced by action under a federal law not administered by EPA, it must refer information on the chemical's risk to the agency administering the other law
- EPA has a memorandum of understanding (MOU) with OSHA and CPSC regarding the "working relationship" and process under which formal referrals will be made. *See* http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=MOU&p_id=232 (EPA-OSHA MOU)

TSCA Section 9 Authority -- Relationship to Other Federal Laws (cont'd)

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- Section 9(d) also directs EPA to consult and coordinate with other federal agencies and other EPA program offices “for the purpose of achieving the maximum enforcement of [TSCA] while imposing the least burdens of duplicative requirements on those subject to [TSCA]”