

OECD Workshop on the Safety of  
Manufactured Nanomaterials  
December 7-9, 2005

Parallel Breakout Session D  
Regulatory Frameworks

Nanomaterials:  
A Comparative Look at Regulatory  
Frameworks

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# Topics

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- Background
- Toxic Substances Control Act (TSCA) -- Key statutory provisions providing opportunities for regulatory intervention
- Illustrative comparisons with selected other chemical control programs
- Other governance mechanisms
- Summary/conclusions

# Background

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- The OECD held a special session on nanotechnology at its June 2005 meeting
- Agreed to hold a workshop in December 2005 in Washington, D.C., covering:
  - Definitions, nomenclature, and characterization (properties, uses, fate);
  - Environmental effects (hazard identification, hazard and exposure assessment methods);
  - Human health effects (hazard identification, hazard and exposure assessment methods); and
  - **Regulatory frameworks (in the industrial chemicals sector)**

## Background (cont'd)

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- Workshop output will contribute generally to the global responsible development of nanotechnology
- Workshop output will be presented at the 39th meeting of the Chemicals Committee in February 2006

# TSCA

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- Promulgated in 1976
- Provides the U.S. Environmental Protection Agency (EPA) with broad authority to address potential risks posed by the manufacturing, processing, use, and disposal of chemical substances
- Includes 82,000 registered chemicals
  - 62,000 were in commerce and listed on the TSCA Inventory of existing chemicals
  - Approximately 700 “new” chemicals introduced each year

# New Chemicals: Pre-Manufacture Notice (PMN)

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- 90-day notice prior to market
- Notifiers must provide EPA with information on:
  - Volumes;
  - Intended uses;
  - Potential exposure/release levels;
  - Disposal/byproducts; and
  - Test data in possession of notifier

## PMN (cont'd)

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- EPA predicts exposure/toxicity using screening models to estimate toxicity, ecotoxicity, and environmental fate characteristics, including Quantitative Structure Activity Relationships (QSAR) (Ecological Structure Activity Relationships (ECOSAR), PBT Profiler, etc.)
- Approximately 80 percent of new chemicals are screened out and require no further review if EPA concludes that:
  - The chemical has low toxicity to human health and environment; and
  - Use, exposure, and release pose limited risks to human health and environment

# EPA PMN Review Options

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- Take no further action
- Impose restrictions on manufacturing, processing, use, distribution, and/or disposal pending data development
- Deny the manufacturer of the chemical pending data development

# Significant New Use Rule (SNUR)

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- TSCA authorizes EPA to determine that the use of a chemical constitutes a “significant new use”
- Once a SNUR is issued, a Significant New Use Notice (SNUN) must be submitted by entities that intend to manufacture a SNUR-designated chemical
- SNUNs operate much like PMNs
- Of the 32,000 chemicals submitted for review, EPA has used this for approximately 1,000 chemicals

# TSCA Exemptions From PMN

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- Two types of exemptions: self-executing and those requiring EPA approval
- 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

# TSCA Exemptions (cont'd)

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- EPA approval exemptions include:
  - Low Volume Exemption (LVE);
  - Low Release and Low Exposure Exemption (LoREX);  
and
  - Test Marketing Exemption (TME)

# 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
- Statutory findings have been difficult to make and sustain

## 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” findings require “substantial evidence” -- tough burden of proof (heavier than arbitrary and capricious)

# Selected Comparisons of Chemical Substance Inventory Listing Exemptions

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JURISDICTION	ARTICLE EXEMPTION	POLYMER EXEMPTION	LOW VOLUME EXEMPTION
United States	Self executing; no need to notify EPA. TSCA has specific definitions for article exemption. 40 C.F.R. § 710.3.	Self-executing if qualifying criteria are satisfied; no need to notify EPA. TSCA only requires companies to submit an annual report on the number of exempt polymers in the beginning of each year.	Need prior EPA approval (30-day EPA review period). 10,000 kg/annual limit.
European Union (EU)/European Commission (EC)	Yes. Various member countries have different views and interpretations on what constitutes an “article” or what is not considered an “article.”	Polymers are considered notified if all of the monomers and reactants used to make the polymers are notified consistent with the OECD definitions. Otherwise, full notification is required.	Notification required from 10 kg but a modest “base set” from 1 tonne.

# Selected Comparisons of Chemical Substance Inventory Listing Exemptions (cont'd)

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JURISDICTION	ARTICLE EXEMPTION	POLYMER EXEMPTION	LOW VOLUME EXEMPTION
Japan	Silent on the article exemption.	No polymer exemption per se. Treats polymers the same as chemicals, but imposes diminished requirements on qualified polymers.	Renewable annually. 1,000 kg/annual limit.
Australia	Similar to the U.S.	Similar to the EU provisions.	Need prior approval (to be renewed every three years). 100 kg/annual limit.
Canada	Similar to U.S.; article exemption provision with definitive language on the definition of "article."	No polymer exemption per se. Reduced data requirements if monomers and reactants are on the Domestic Substances List (DSL) or Non-Domestic Substances List (NDSL).	Below 20 kg per annum if not on NDSL. Below 1,000 kg/yr or 5,000 kg cumulative if listed on NDSL.

# Comparisons of New Chemical Substance Inventory Listing Requirements

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JURISDICTION	TRIGGER	DATA SUBMISSION REQUIREMENTS	USE OF QSAR RISK METHODOLOGIES
United States	Reporting of new chemicals under TSCA.	No requirement to test under PMN provisions. Health and safety data relating to a new chemical substance's health or environmental effects that are in a submitter's possession or control must be submitted with the PMN.	Yes -- EPA assesses chemical structural similarity to chemicals for which data are available -- structure-activity relationship (SAR) -- to predict toxicity.
European Union/ European Commission	Various EU legislations regarding chemical substances, preparations, and products that involve data reporting, priority setting, risk evaluation, labeling, and classification requirements.	Yes -- there are varying data requirements that are volume-based.	Limited use of QSARs for new and existing chemicals. Under REACH, it is anticipated that QSARs will be used more extensively.

# Comparisons of New Chemical Substance Inventory Listing Requirements (cont'd)

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JURISDICTION	TRIGGER	DATA SUBMISSION REQUIREMENTS	USE OF QSAR RISK METHODOLOGIES
Japan	Law concerning the evaluation of chemical substances and regulations require volume-based notification and data submission.	Yes -- data required are volume-driven: up to 1 ton, notification only; more than 1 ton and less than 10 tons, biodegradability and bioaccumulation data; and 10 tons or over, data above plus toxicity tests (repeated dose 28-day oral toxicity study, bacterial reverse mutation test, <i>in vitro</i> mammalian chromosome aberration test, and ecotoxicological assessment.	Alternative methodologies ( <i>i.e.</i> , QSAR, SAR, analog data) can be used on a case-by-case basis. There is no formal policy. Companies need to negotiate with authorities.
Australia	New chemicals, data requirements and assessments are volume/hazard driven. <100 kg/yr no notification/restrictions if no "unreasonable risk."	Yes -- data requirements depending on type of substance (including biodegradation, bioavailability, animal and <i>in vitro</i> toxicological and ecological studies). Additional requirements for polymers.	Alternative methodologies ( <i>i.e.</i> , QSAR, SAR, analog data) can be used on a case-by-case basis. There is no formal policy. Companies need to negotiate with authorities. There are formal procedures to request waivers from study requirements.
Canada	Under the Canadian Environmental Protection Act, new chemicals are reviewed against current volume triggers. Volume triggers are higher if the substance is listed on the NDSL.	Yes -- depending on supply volume: <20 kg/yr -- exempt from notification >20 to <1,000 kg/yr -- limited data requirements ≥1,000 to 10,000 kg/yr -- more stringent data requirements ≥10,000 to ≥50,000 kg/yr -- most stringent data requirements.	Alternative methodologies ( <i>i.e.</i> , QSAR, SAR, analog data) can be used on a case-by-case basis. There is no formal policy. Companies need to negotiate with authorities. There are formal procedures to request waivers from study requirements.

# Other Governance Mechanisms

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- Voluntary initiatives
- Standards
- Other

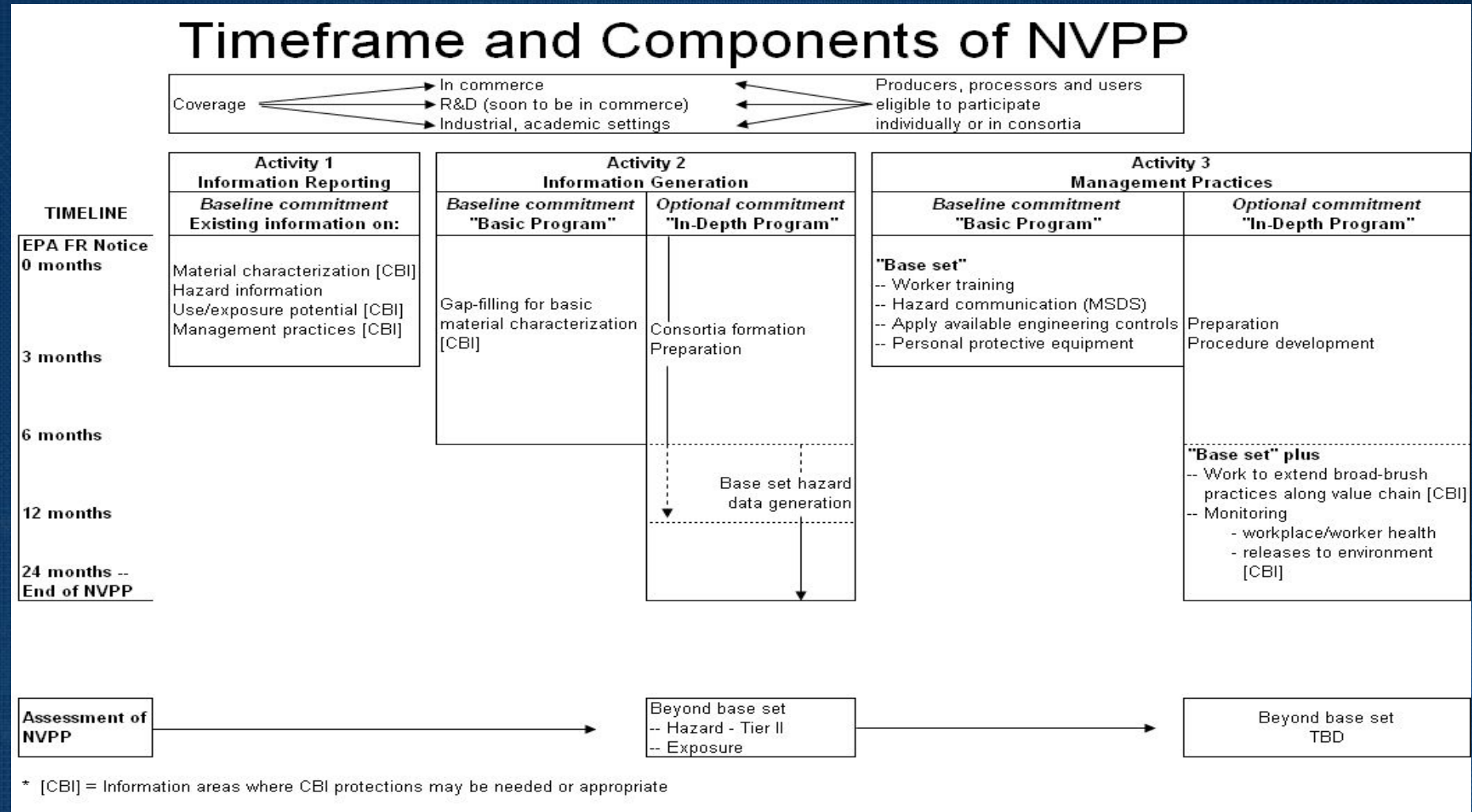
# Nanomaterials Voluntary Program

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- The National Pollution Prevention and Toxics Advisory Committee (NPPTAC) (advisory group) offered to EPA on November 22, 2005, a framework for an approach to a voluntary program for existing engineered nanoscale materials
- Intended to compliment the approval to new nanoscale chemicals required under TSCA

# Nanomaterials Voluntary Program (cont'd)

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\* Source: EPA web

# Standard-Setting Initiatives

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- ASTM E56 Committee -- working on several standards:
  - Subcommittee E56.01 -- Terminology and Nomenclature
  - Subcommittee E56.03 -- Environmental and Occupational Health and Safety
  - Subcommittee E56.04 -- International Law and Intellectual Property
  - Subcommittee E56.05 -- Liaison and International Cooperation
  - Subcommittee E56.06 -- Risk Management and Product Stewardship

## Standard-Setting Initiatives (cont'd)

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- ISO/TC 229 Nanotechnologies -- Standardization in the field of nanotechnologies, with specific tasks being classification, terminology and nomenclature, basic metrology, characterization, including calibration and certification, risk and environmental issues
- Inaugural ISO/TC 229 met in the UK on November 9, 2005

## Standard-Setting Initiatives (cont'd)

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- IEEE Standards Association P1650, Standard Test Methods for Measurement of Electrical Properties of Carbon Nanotubes
- IEEE is working on a Nanotechnology Roadmap, addressing the methods, devices, and specifications needed to start nanotechnology methods and processes so data are reported uniformly and results are comparable

# Other Approaches

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- Information disclosure
- ?

# Conclusion

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- Responsible development of nanotechnology will likely require a combination of regulatory, voluntary, standard-setting, and perhaps other governance mechanisms
- International collaboration is essential
- OECD participation is critically important