

Nanochemicals and Navigating the Regulatory Patchwork

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NANOMATERIALS IN COMMERCE

- DIVERSITY OF INDUSTRIES
- DIVERSITY OF NANOMATERIALS
- DIVERSITY OF COMPANIES

REGULATORY STRUCTURE

- United States
 - Product-Based Regulation, Not Process Based
 - Evaluating Risks and Controlling Risks
 - Data Gap and Uncertainty
 - Federal vs. State Regulations
- European Union
 - Precautionary Principle
 - European Council vs. Member States

US FEDERAL AGENICES

- Environmental Protection Agency
- Food and Drug Administration
- Occupational Safety and Health Administration
- Consumer Product Safety Commission

SPEAKERS

- Vanessa Edwards
 - REACH
 - Cosmetic Directive
- Ed Sangster
 - Green Chemistry Initiative
 - Department of Toxic Substances Control Data Call-In

SPEAKERS

- Allison Starmann
 - Toxic Substances Control Act
 - Nanoscale Materials Stewardship Program
 - FIFRA and Nanopesticides
- Bill Gulledge
 - FDA
 - Cosmetic Regulation
 - OSHA and CPSC

EU and Nanoregulation

Vanessa Edwards

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New EU Regulation on Cosmetic Products

- “An insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm”
- Notification to Commission of any cosmetic product containing nanomaterials to include:
 - Identification of nanomaterial
 - Specification including size of nanoparticles, physical and chemical properties
 - Estimated quantity of nanomaterial to be placed on market per year
 - Toxicological profile and safety data
 - Reasonably foreseeable exposure conditions
- Labelling – all ingredients present in form of nanomaterials to be clearly indicated in list of ingredients, followed by “(nano)”

Proposed New Regulation

“any intentionally produced material that has one or more dimensions of the order of 100 nm or less or is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic to the nanoscale. [These] include: (i) those related to the large specific surface area of the materials considered; and/or (ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material”

REACH

- EU Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals
- “TSCA with teeth”
- All substances to be registered – “No data, no market”
- Many substances already on market may be pre-registered
- Duty to provide information down the supply chain
- Use of some substances will be authorised/restricted
- No specific provision for nanosubstances

Registration Deadlines

- Deadlines for registration depend on tonnage manufactured/imported and degree of hazard
 - 30 November 2010:
 - 1000 tonnes p.a.
 - 100 tonnes p.a. + very toxic to aquatic organisms
 - 1 tonne p.a. + CMR category 1 or 2
 - 31 May 2013:
 - 100 tonnes p.a.
 - 31 May 2018:
 - 1 tonne p.a.
- Tonnage triggers apply to total volume of substance, whether in nano or bulk form

REACH and Nanosubstances - Issues

- Substance identification
- Registration dossier
- Chemical safety assessment
- Communication of information
- Evaluation, authorisation and restriction

Substance Identification

- “One substance, one registration”
- Identification normally by chemical composition
 - “Some substances which can be so identified need to be further specified by additional identifiers to get their own substance identification, for example if the properties of the substance differ significantly for reasons other than their chemical composition.”
- “The current state of development is not mature enough to include guidance on the identification of substances in the nanoform in this TGD”

Substance Identification - Carbon

- Carbon and graphite originally exempt from registration as “sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties”
- Exemption removed “due to the fact that the concerned Einecs and/or CAS numbers are used to identify forms of carbon or graphite at the nano-scale, which do not meet the criteria for [this exemption]”

Registration

- Registrant must provide information about:
 - Identified use(s) and uses advised against
 - Any hazard classification and resulting hazard label
 - Guidance on safe use
 - Information on exposure
- Where such information would be different for the nanoform as opposed to the bulk substance, it would have to be supplied
- Once substance registered, registrant under duty to update registration if there are any changes to information provided, which may be triggered by introduction of new nanoform

Registration – Nanosubstance Examples

- Many nano parent substances (e.g. silver, carbon, zinc oxide, silica, titanium dioxide, gold, aluminium) have been pre-registered with planned registrations in 2010
- Five specific pre-registrations of nanomaterials as such
 - Nanosilver
 - Carbon nanotubes
 - Unspecified
 - Single-walled
 - Multi-walled
 - A phthalocyanine-fullerene compound
 - Two main groups of nanomaterials which will not be registered:
 - Those based on polymers (exempt from registration)
 - Those manufactured/imported at less than 1 tonne p.a.
- No specific nano-substance yet registered in own right

Chemical Safety Assessment

- CSA required for substances manufactured or imported above 10 tonnes p.a.
- If hazard assessment → classification:
 - Exposure assessment
 - Risk characterisation
- ECHA Guidance: assessment should consider exposure to nanoparticles (< 100 nm) where relevant

Chemical Safety Assessment - Carbon

- Carbon black pre-registered and now registered
- CSA did not include Exposure Assessment on ground that carbon black not classified as hazardous in EU
- “Differentiation for carbon black between nano-material and bulk/conventional material is not necessary” because carbon black is nano-structured material (Carbon Black REACH Consortium)

Communication of Information - Substances

- Suppliers of hazardous substances must communicate information down the supply chain
- New information on hazardous properties and any information calling into question the appropriateness of the risk management measures in the SDS must be passed up the supply chain

Communication of Information - Articles

- Suppliers of articles containing a Substance of Very High Concern above 0.1% w/w must provide sufficient information to allow safe use including at least the name of the substance to:
 - Recipients
 - Consumers, on request, free of charge and within 45 days of the request
- Applies regardless of annual volume
- Applies as soon as SVHC in candidate list

Evaluation, Authorisation and Restriction

- Evaluation
 - Dossier evaluation
 - Substance evaluation
- Authorisation and Restriction
 - Regardless of quantity
 - Must be evidence of harm to environment or health

Classification

- CLP Regulation complements REACH
- Classification
 - “When evaluating the available information for the purpose of classification, the manufacturers, importers and downstream users shall consider the forms or physical states in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used”
 - Substances, including nanomaterials, meeting the classification criteria as hazardous must be notified to ECHA by 3 January 2011

Future Developments

- REACH CA Group on Nano
- Review of scope of REACH – 1 June 2012
- SCENIHR definition of “nanomaterials”
- 2009 Commission consultancy report recommended voluntary EU-level scheme pending legislation for mandatory reporting
- RIP-oN 1, 2 and 3
- Commission 2009 review of all relevant legislation to ensure safety for all applications of nanomaterials with potential health, environmental or safety impacts over their life cycle – completion 2011

California: Green Chemistry, Call Ins, and Nanotech

Ed Sangster

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“Green Chemistry”

- Comprehensive strategy designed to foster:
 - Development of information on the hazards posed by chemicals
 - Ways to reduce exposure to dangerous substances
 - Approaches that encourage cleaner and less polluting industrial processes
 - Approaches that “encourage manufacturers to take greater responsibility for the products they produce.”
- DTSC May 1, 2007 press release announcing the initiative:
 - “Fundamentally change how government and business work together to deal with waste before it is generated.”
 - “Similar to measures adopted by European Union and Canadian government to encourage greater manufacturer responsibility.”

12 Principles of Green Chemistry

- **Prevent waste:** Design chemical syntheses to prevent waste, leaving no waste to treat or clean up.
- **Design safer chemicals and products:** Design chemical products to be fully effective, yet have little or no toxicity.
- **Design less hazardous chemical syntheses:** Design syntheses to use and generate substances with little or no toxicity to humans and the environment.
- **Use renewable feedstocks:** Use raw materials and feedstocks that are renewable rather than depleting. Renewable feedstocks are often made from agricultural products or are the wastes of other processes; depleting feedstocks are made from fossil fuels (petroleum, natural gas, or coal) or are mined.
- **Use catalysts, not stoichiometric reagents:** Minimize waste by using. Catalysts are used in small amounts and can carry out a single reaction many times. They are preferable to reagents, which are used in excess and work only once.
- **Avoid chemical derivatives:** Avoid using or any temporary modifications if possible. Derivatives use additional reagents and generate waste.
- **Maximize atom economy:** Design syntheses so that the final product contains the maximum proportion of the starting materials. There should be few, if any, wasted atoms.
- **Use safer solvents and reaction conditions:** Avoid using solvents, separation agents, or other auxiliary chemicals. If these chemicals are necessary, use less harmful or dangerous chemicals.
- **Increase energy efficiency:** Run chemical reactions at background or room temperature and pressure whenever possible.
- **Design chemicals and products to degrade after use:** Design chemical products to break down to innocuous substances after use so that they do not accumulate in the environment.
- **Analyze in real time to prevent pollution:** Include in-process real-time monitoring and control during syntheses to minimize or eliminate the formation of byproducts.
- **Minimize the potential for accidents:** Design chemicals and their forms (solid, liquid, or gas) to minimize the potential for chemical accidents including explosions, fires, and releases to the environment.

December 2008 DTSC “Final Report”

- Expand pollution prevention
- Develop Green Chemistry workforce education
- Create an online product ingredient network
- Create an online toxics clearinghouse
- Accelerate the quest for safer products
- Move towards a “Cradle-to-Cradle” economy

Quest for Safer Products

- AB 1879
 - Gives DTSC the power to identify, evaluate and ban potentially harmful chemicals
 - Identify and prioritize chemicals of concern in consumer products
 - Study impacts of chemical over life cycle
 - January 2011 deadline to adopt process for identifying chemicals of concern

DTSC Interest in Nanotech as Part of Green Chemistry

- Five symposia hosted by DTSC regarding nanotechnology since late 2007
- Positive environmental uses (e.g., possible PCE remediation)
- Recent paper by EPA scientists: “Despite the potentially high performance and low cost of nanoremediation, more research is needed to understand and prevent any potential adverse environmental impacts, particularly studies on full-scale ecosystem-wide impacts. To date, little research has been done.”
- DTSC sees nanotechnology as the new “plastic” because it will show up in many industrial applications and consumer products
 - But, negative ramifications are believed to be poorly understood
- Previous failures to anticipate consequences
- Public fears of the unknown

Frequently Stated Concerns

- Nanomaterial may behave differently
- Some nanomaterials may pose health risks
- Risks of exposure not clearly understood
- Do new nanomaterials present new safety and health hazards?
 - Occupational hazards
 - Consumer hazards
 - Long term environmental consequences
- Example: 2008 study suggests long carbon nanotubes could be as harmful as asbestos if inhaled in sufficient quantities.

Green Chemistry Regulatory Process as it Affects Nanotechnology

- Identification of nanomaterials of concern to DTSC
- New materials?
- Formal and informal collection of information
- Risk assessment
- Life cycle management

“Data Call In”

- AB 289 (Health & Safety Code Section 57018-57020)
- Allows DTSC to request information regarding analytical test methods, fate and transport in the environment, and other relevant information from manufacturers of certain chemicals of concern
- Requires a manufacturer to provide the state agency with the additional information requested for the specified chemical within one year.
- Information that can be requested
 - (A) An analytical test method for that chemical, or for metabolites and degradation products from that chemical, that are biologically relevant in the matrix specified by the state agency.
 - (B) The octanol-water partition coefficient and bioconcentration factor for humans for that chemical.
 - (C) Other relevant information on the fate and transport of that chemical in the environment.

Call in for Nanotech

- First “call in”: Carbon nanotubes
 - DTSC justification
 - in use commercially and because data on analytical methods, toxicity, physicochemical properties, and fate and transport are largely unavailable.
 - Nineteen companies responded January 2010
 - Enforcement threatened against several companies who did not respond

Impact of Call Ins and Informal Data Collection on Green Chemistry

- Data collection is first step in regulatory process
- Anticipate increasing regulatory interest
 - Research regarding impacts
 - Studies to be required
 - Life cycle regulation
 - Manufacture, use and disposal issues

Where is Nanotech in the Green Chemistry Regulatory Process?



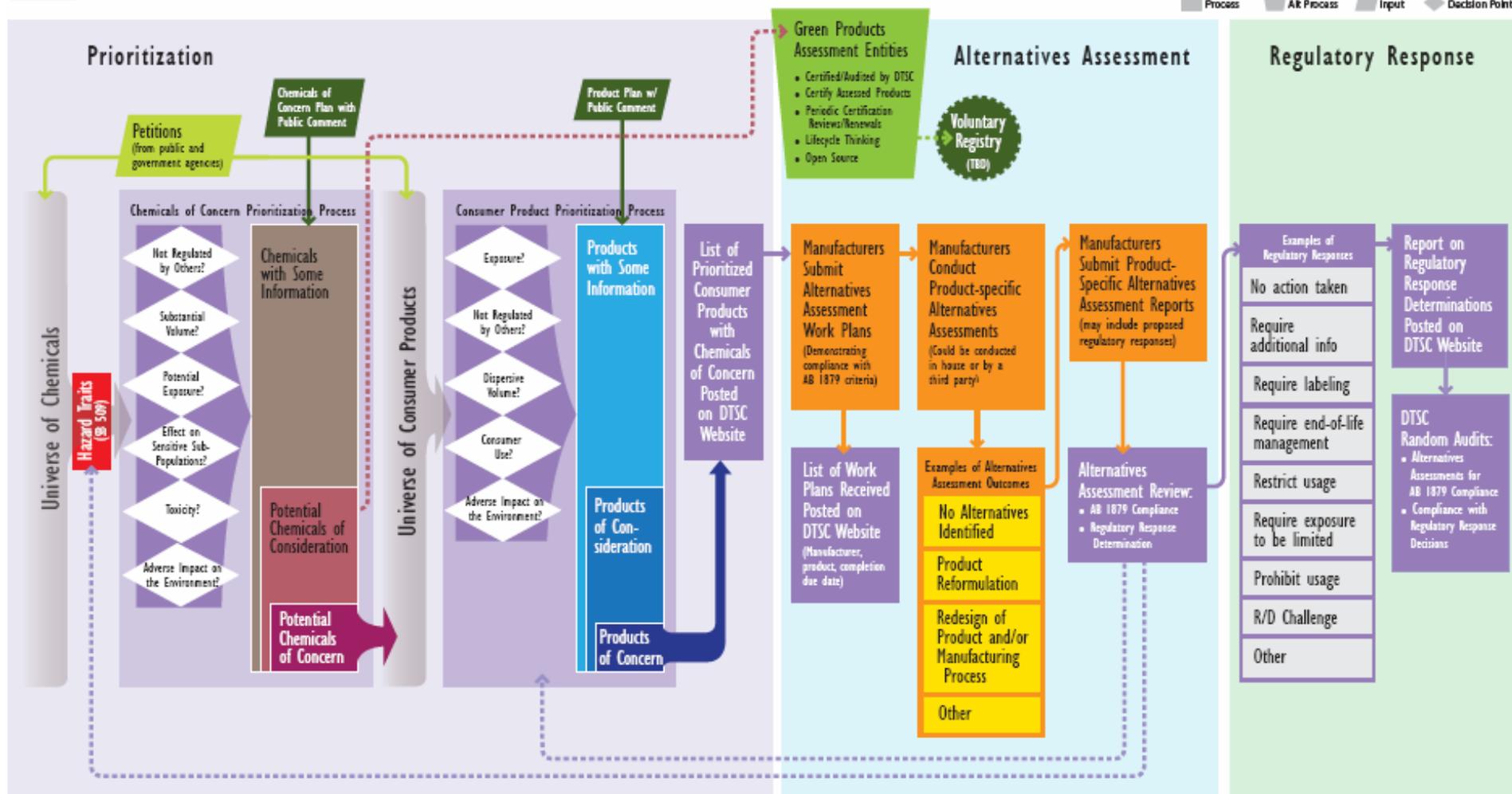
Regulations for Safer Products

AB 1879 (FEUER) / SB 509 (SIMITIAN)
CONCEPTUAL FLOW CHART

DRAFT
(FEBRUARY 23, 2010)



Process Alt Process Input Decision Point



Federal Regulation of Nanotech

EPA Regulatory Activities





EPA Regulatory Activities

- Toxic Substances Control Act
- Nanoscale Materials Stewardship Program
- FIFRA and Nanopesticides



TSCA Framework

- § 4 – Test Rule
- § 5 – PMN, SNUR
- § 6 – Regulation of manufacture, use, labeling, recordkeeping, and disposal
- § 7 - Seizure
- § 8 – Chemical Inventory and Data Requirements



“New” or “Existing”?

- TSCA Inventory Status of Nanoscale Substances – General Approach, January 23, 2008
 - Particular Molecular Identity
- SNURs
 - Carbon Nanotubes
 - Nanoscale Materials



Nanoscale Materials Stewardship Program

- Final NMSP – announced January 2008
 - Basic Program
 - Existing data (hazard, use, potential exposures, material characterization, and risk management practices) on engineered nanoscale materials
 - In-Depth Program
 - Testing Program



Nanoscale Materials Stewardship Program

- NMSP Interim Report
 - January 2009
 - 29 companies, 128 materials
 - Basic Program
 - In-depth Program
- Non-CBI Company Submissions available on EPA's website
- Program Concluded December 2009





Nanoscale Materials Stewardship Program

EPA stated:

Although the NMSP provided EPA with useful information regarding a limited number of nanoscale materials in commerce, a significant number of the environmental health and safety data gaps remain. To address these gaps and prevent potential risks that may be posed by nanoscale materials, EPA is taking action on existing nanoscale materials under the Toxic Substances Control Act.





FIFRA

FIFRA regulates manufacture, distribution, sale, and use of pesticide products, including nanomaterials

- Active Ingredients
- Inert Ingredients

FIFRA Activities regarding nanomaterials

- Nanosilver Pesticides
- FIFRA §6(a)(2) interpretation



Regulations for Manufactured Nanomaterials- U.S.

- Food and Drug Administration- food, food contact materials, drugs, medical devices, cosmetics (guidance for nanomaterials)
- Environmental Protection Agency- new and existing chemical substances under TSCA, FIFRA and other environmental laws
- Occupational Safety and Health Administration
- Consumer Product Safety Commission



Food and Drug Administration

- Food, Drug, and Cosmetic Act- no specific mention of nanomaterials
- Case-by-case regulation focusing on pre-market approval- extensive data requirements
- General guidance for products containing nanomaterials- sector documents being drafted
- Early consultation encouraged



FDA Scope of Nanomaterial Regulation

- Food and Food Contact Materials
- Cosmetics (no pre-market authorization)
- Drugs
- Medical Devices
- Nanotechnology Task Force- Report 2007



OSHA and NIOSH

- NIOSH- Research and Guidance for Workplace Exposures
- Testing of PPE
- Pilot Field Studies for Manufactured Nanomaterials
- REL for Nano Sized TiO₂ Proposed at 200 $\mu\text{g}/\text{m}^3$
- OSHA- Recent Interest in Carbon Nanotube Exposure Issues (Exposure Limits)



Consumer Product Safety Commission

- Limited resources devoted to reviewing products containing nanomaterials
- Recent review of aerosol products- inhalation concern
- Interest in products containing carbon nanotubes



What We Know? What Have We Learned?

- Hazard Data- Focus on the Uniqueness of the Nano Form That May Create a Hazard; Extent of Information is Material Specific
- Exposure Data- Primarily Workplace Exposure and Materials with Inhalation as Primary Route of Exposure
- Risk Management in the Absence of Complete Information- Good Practices



Issues to Address

- Regulatory Uncertainty- National, International, Regional
- Life Cycle Considerations- Environmental Exposure
- Rapid Technological Developments- Material and Product Life Cycles- Differs by Product Use
- Public Reactions and Acceptance to New Technologies
- Technical Data Gaps- Manageable



ACC Nanotechnology Panel: Focus for ACC

- Producers, Users, Researchers of Manufactured Nanomaterials- Founded in 2005
- Representing Wide Range of Company Sizes and Types of Nanomaterials- In Commerce and Research and Development Phases
- Based on the Business of Chemistry and Responsible Care®
- Early, Continuing Supporter of Research and Product Stewardship Programs
- International Focus