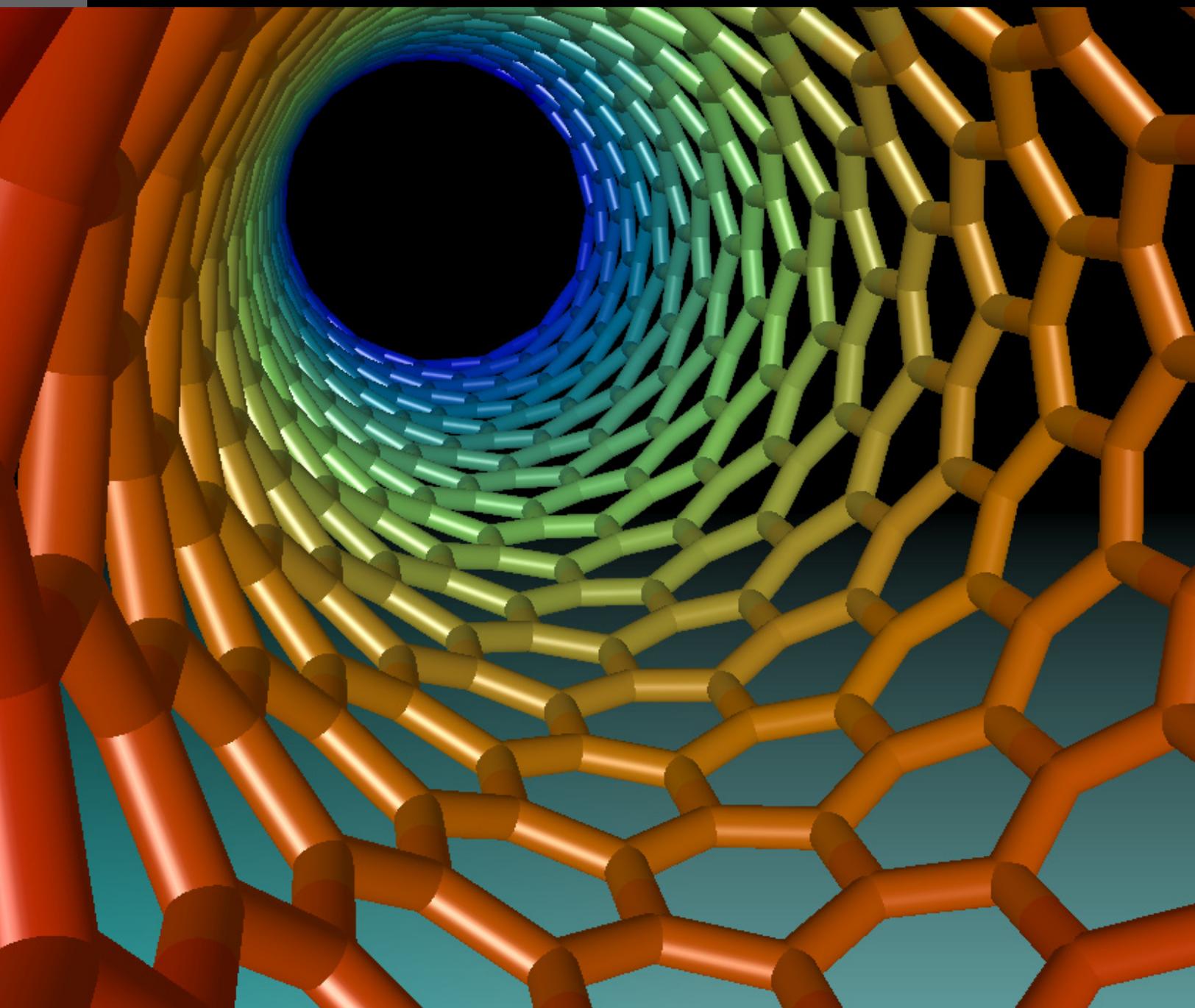


# RESPONDING TO DTSC'S DATA CALL-IN FOR CARBON NANOTUBES

December 3, 2009  
San Francisco, California



# Responding to DTSC's Data Call-In for Carbon Nanotubes

December 3, 2009

Registration		8:00 am
8:00 am (PST)	<b>Continental Breakfast</b> <i>(provided to those attending the session in San Francisco)</i>	
11:00 am (EST)	<b>Lunch</b> <i>(provided to those attending the session in Washington, DC)</i>	
Welcome and Opening Remarks		8:30 am – 9:40 am
Framing the California and National Implications of the DTSC Carbon Nanotube Data Call-In		
8:30 am	<b>Ann Grimaldi – McKenna Long &amp; Aldridge LLP</b>	
8:40 am	<b>Bill Gullede – ACC Nanotechnology Panel</b>	
8:55 am	<b>Tom Jacob – California Nano Regulatory Committee</b>	
9:10 am	<b>Vincent Caprio – NanoBusiness Alliance</b>	
9:25 am	<b>Jeff Wong – California DTSC</b>	
Evaluation of the DTSC Data Call-In Questions		9:40 am – 12:30 pm
9:40 am	<b>Ann Grimaldi – McKenna Long &amp; Aldridge LLP</b> Addressing DTSC questions 1, 5 & 6 (quoted directly from the DTSC letter to manufacturers) <b>Q1.</b> What is the value chain for your company? For example, in what products are your carbon nanotubes used by others? In what products? In what quantities? Who are your major customers? <b>Q5.</b> What methods are you using to protect workers in the research, development, and manufacturing environment? <b>Q6.</b> When released, does your material constitute a hazardous waste under California Health & Safety Code provisions? Are discarded off-spec materials a hazardous waste? Once discarded, are the carbon nanotubes you produce a hazardous waste? What are your waste handling practices for carbon nanotubes?	
10:10 am	<b>Rick Canady – McKenna Long &amp; Aldridge LLP</b> Addressing DTSC questions 2-4 (quoted directly from the DTSC letter to manufacturers) <b>Q2.</b> What sampling, detection, and measurement methods are you using to monitor (detect and measure) the presence of your chemical in the workplace and the environment? Provide a full description of all required sampling, detection, measurement, and verification methodologies. Provide full QA/QC protocol. <b>Q3.</b> What is your knowledge about the current and projected presence of your chemical in the environment that results from manufacturing, distribution, use, and end-of-life disposal? <b>Q4.</b> What is your knowledge about the safety of your chemical in terms of occupational safety, public health, and the environment?	
10:40 am	<b>Michael Boucher – McKenna Long &amp; Aldridge LLP</b> Cross-cutting issues raised by the DTSC questions CBI consideration: <ul style="list-style-type: none"><li>▪ Data sharing - across companies, agencies, governments</li><li>▪ Data submission: How much is enough?</li><li>▪ Can data be viewed as “eyes only” or through “read across” data compilations?</li><li>▪ Submitting information about the value chain (i.e., your customers or suppliers)</li></ul> Relation of DTSC reporting to TSCA and CEPA reporting and regulation Public perception issues of differing opinions of safety and “hazardous waste” and of a lack of monitoring information Influence of responses on next steps for DTSC	
11:10 am	<b>Jeff Wong – California DTSC</b> The DTSC Nanotechnology program: background, purpose, and plan	
11:40 am	<b>Jeff Wong – California DTSC</b> Questions for DTSC from the participants	
12:10 pm	<b>Rick Canady – McKenna Long &amp; Aldridge LLP</b> Closing remarks - what is next?	
Lunch		12:30 pm
<i>(provided to those attending the session in San Francisco)</i>		

## Responding to DTSC's Data Call-In for Carbon Nanotubes –

### One Perspective

Presented by:

**Ann Grimaldi, Esq.**

McKenna Long & Aldridge LLP  
December 3, 2009  
San Francisco, California

## Introduction

- Recent California laws
  - AB 484 (requires disclosure of carcinogens and reproductive toxins in cosmetics)
  - AB 1108 (bans certain phthalates in certain children's products)
  - SB 1713 (would have banned BPA in certain products above 0.1 ppb)
  - Green Chemistry Initiative – AB 1879 and SB 509
  - AB 289 (data call-in law)
- What does all this mean?

## What Do The People Want?

- Information
  - Make informed choices
  - Use leverage to effect market change
  - Use voting power to effect legislative/regulatory change

## What Does Government Want?

- Information
  - Promote a well-informed public
  - Understand appropriate regulatory targets
  - Craft balanced regulatory policy
  - Refine use of limited resources (public using market leverage)

## What Does Industry Want?

- Information
  - Promote a well-informed public
  - Promote a well-informed government
- Push for innovation and competitiveness in the marketplace
- Protect investment-backed interests

## Trends

- Collaborative efforts
- Transparency
- Balance
  
- All driven by information flow

## AB 289

- Requires chemical manufacturers to provide answers to specific questions about chemicals they make or import into California – identify information and information gaps
- Requires the agency first to publicly “express interest” in obtaining information about specified chemicals – an invitation to a dialogue
- Requires the manufacturer to collaborate and cooperate to the extent practicable
- Questions focused on analytical test methods, fate and transport, but covers “other relevant information” related to fate and transport

## AB 289

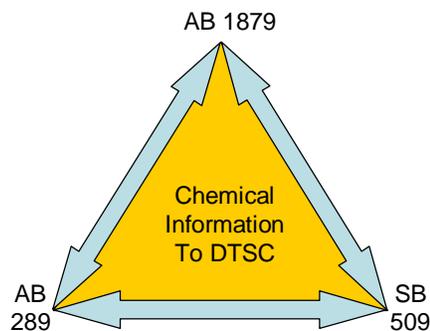
- DTSC issued the first DCI, targeting 26 entities that manufacture CNTs
- Responses due January 2010

## AB 289

- Responses will be posted publicly
  - Fact that submitter has designated information as trade secret will be posted publicly, although trade secret information itself will not (subject to procedures for the protection of trade secrets)

## AB 1879, SB 509 and AB 289

- Responses will be used to implement new Green Chemistry Initiative laws
  - AB 1879 (Safer Alternative Regulation)
  - SB 509 (Toxic Information Clearinghouse)



## Let's Not Kid Ourselves

- AB 289 responses will not exist in a vacuum
- Information will establish foundation for regulatory policy in California, nationally and internationally
  - Supply chain concerns
- Industry will be getting pressure from regulators and the public to be forthcoming

# ACC Nanotechnology Panel

Bill Gulledge



## 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





## ACC Nanotechnology Panel

- Policy Development and Advocacy- National (Congress, EPA, NIOSH, NIEHS, FDA, CPSC), International (OECD/BIAC, SAICM)
- Technical Analysis and Publication- Definition Considerations, Research and Testing Matrices, ANSI/ISO, Material Characterization Base Set
- Product Stewardship- Surveys, NMSP, Information
- Communications- Press Statements, Website, Publications



## ACC and Nanotechnology- Board Position, Adopted 2005

- Support Global Coordination of Regulatory, Research, and Standard-Setting Activities
- Assess Existing Legislative and Regulatory Frameworks For Application to the Characterization and Properties of Nanomaterials
- Apply Product Stewardship Principles of the Global Chemicals Management Policy and Responsible Care® to Nanotechnology Related Activities
- Support the Increased Funding of Methods to Assess Impacts of Nanotechnology on Environment, Health, and Safety and for Research Programs to Apply Those Methods





## 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
- Public Reactions and Acceptance to New Technologies
- Technical Data Gaps





## Nanotechnology Industry Programs

- Codes of Conduct and Corporate Programs
- Principles and Multi-Stakeholder Initiatives
- ED/DuPont Nano Risk Framework
- Product Stewardship Programs
- OECD Nanomaterials Testing



## 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





## Industry Commitment to Nanotechnology

- Research- Toxicology, Measurement Methods, Controls and Worker Protection, Collaborative Research
- Guidance- Material Characterization, Risk Characterization and Management, Nanomaterial Testing Methods, Standards Development



## Industry Participation in Guidance and Standards Development Activities

- Industry Representatives:
  - ISO TC 229 and ANSI TAG
  - OECD WPMN
  - OECD WPN
  - Other Coalitions, Associations, Etc.
- Definitions





## ACC Contact Information

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## Responding to DTSC's Data Call-In for Carbon Nanotubes –

### Value Chain, Worker Protection & Hazardous Waste

Presented by:

**Ann Grimaldi, Esq.**

McKenna Long & Aldridge LLP  
December 3, 2009  
San Francisco, California

## DTSC's CNT DCI Questions

- DTSC asked 6 questions
- Three of them:
  - Value chain
  - Worker protection
  - Hazardous waste
- How might those answers affect the value chain?
  - Supply chain concerns
  - Customers as regulatory targets?
  - Public identification of specific uses
  - Potential for tort liability?
- What information, if any, would it be in the value chain's interests to contribute?

## DTSC Question 1

- What is the value chain for your company? For example, in what products are your carbon nanotubes used by others? In what quantities? Who are your major customers?
  - DTSC wants to understand the business life cycle of CNTs
  - Agency interest in identifying intervention points, e.g., end of life/disposal
  - How should the response and DTSC's interests track an expanding market? Are today's uses informative of uses in 5 years?
  - Identify other potential recipients of a DCI notice -- will responders name names?
  - How will responses affect perceptions of risk (volume of use and type of uses)?

## DTSC Question 5

- What methods are you using to protect workers in the research, development and manufacturing environment?
  - Many unknowns
  - Protections include general and specific, and negatives are hard to prove
    - Are conventional methods sufficient?
    - How do you assure that they are?
  - Implications
    - What conditions, if any, will be imposed on downstream customers? Some of this already happening via TSCA Consent Orders
    - Investment hurdle for "all CNTs and products" and potential for supply chain disruption for those not already managing this issue
    - How much is enough protection?
      - Prevent injuries
      - Avoid liability
      - Avoid bad public perception

## DTSC Question 6

- When released, does your material constitute a hazardous waste under California law? Are discarded off-spec materials a hazardous waste? Once discarded, are the CNTs you produce a hazardous waste? What are your waste handling practices for CNTs?
  - California's hazardous waste scheme is complicated – does not entirely mirror RCRA
  - What kind of data exists to support one conclusion or another?
  - How will responses affect the value chain?
    - Should users be addressing HW issues the same way as manufacturers/suppliers? What is the basis for the answer to this question?
    - Supply chain disruptions

## What To Do?

- Identify interests at each point of the value chain
- What information, if any, would serve those interests?
  - Does that information exist?
  - Would voluntary submission in concert with responders assist in clear messaging about the use of CNTs in products?
    - Identify the message
    - What information exists to support the message
    - How to submit the information
  - Would voluntary **generation** of data serve those interests and support a clear message?
    - How to accomplish? – A challenge
- Ask suppliers what they're doing. Other coordination?
- Be ready to respond to questions from up and down the supply chain

## Let's Not Forget

- Public posting of information
  - Be ready to respond to questions, press releases
- Green Chemistry Initiative – an overarching regulatory scheme with AB 289
  - AB 1879 Safer Alternatives Regulation
    - Identification of chemicals of concern (COCs)
    - Prioritization of COCs
    - Safer alternatives analysis (with life cycle analysis)
    - Regulatory response actions
  - SB 509 Toxics Information Clearinghouse
  - And more to come....

## Let's Not Forget (cont.)

- DTSC needs to demonstrate “success” with this DCI
  - What does that mean?
  - DTSC will submit response to UCLA for a critique
  - What happens if legislators conclude that this process was not successful?

## Responding to DTSC's Data Call-In for Carbon Nanotubes –

### Monitoring, Presence in the Environment, and Safety

Presented by:

**Rick Canady, PhD DABT**

McKenna Long & Aldridge LLP  
December 3, 2009  
San Francisco, California

## DTSC's CNT DCI Questions on Safety

- Three of the DTSC questions (Questions 2-4) get at what we know about safety and how we know it
  - Monitoring methods for CNT in workplace and environment
  - Knowledge of presence in the environment
  - Knowledge of safety
- How might answers affect?
  - Public perception of the effectiveness of risk management
  - Identification of “differential toxicity” across CNTs
  - Identification of regulatory risk management needs
  - Identification of data and methods needs

## DTSC Question 2

*What sampling, detection and measurement methods are you using to monitor (detect and measure) the presence of your chemical in the workplace and the environment? Provide a full description of all required sampling, detection, measurement, and verification methodologies. Provide full QA/QC protocol.*

- How will responses to this question affect perceptions of responsible product stewardship?
- Monitoring methods are specific to risk management needs: what are the goals?
- Proving a negative: how to confirm low release rates relative to possible health/environmental effects?
- Start with an understanding of the physics; Use a suite of tests?
  - Dust monitoring to electron microscopy – but not Raman spectroscopy (yet)

## DTSC Question 3

*What is your knowledge about the current and projected presence of your chemical in the environment that results from manufacturing, distribution, use, and end-of-life disposal?*

- Again – how will these responses affect perceptions of stewardship? This is an overall risk communication message for the entire industry.
- Knowledge is a weight of evidence evaluation
- Evidence about presence in the environment comes from
  - Physics of the material and its uses (what release rates are likely, from where?)
  - Generalizable knowledge from other similar materials
  - Data specific to the material
- Expectation of low release and limited movement but – again – what does it take to confirm a negative?

## DTSC Question 4

*What is your knowledge about the safety of your chemical in terms of occupational safety, public health, and the environment?*

- A call for risk communication text or data?
- Safety has toxicity and exposure components
- Knowledge is a weight of evidence evaluation
- Evidence comes from
  - Knowledge of presence in environment and exposure (see Q2 and Q3)
  - Knowledge of protections in place (see Q5)
  - Data on toxicity - each CNT is a specific material with a specific toxicity profile
  - Generalizable information from the open literature can add to the weight of evidence, but the data combination rules for “meta-analysis” are not clear yet

## Generalizable Information

- CNT dimensions affect macro structure and behavior
  - agglomeration and its persistence in key media
  - biological and environmental fate
  - “dustiness” in terms of free CNTs
- Key factors to *critical toxicity* endpoints
  - aspect ratio, rigidity, defect rate, biological fate, persistence, more?
- Matrix uses keep CNTs in place, limit their release (and their movement if released - Data?)

## Data Set is Growing – How Do We Use it?

- Public data – eg, MWCNT studies
  - A negative chronic cancer study for one type, positive “asbestos like” for another type, positive immune, inhalation toxicity, etc (about a dozen recent studies).
  - OECD testing program, METI testing program, INNO:CNT testing program?
- Private data
  - EPA PMN submissions and consent orders
    - varying numbers of supporting studies in the submissions
    - more than a dozen 90 day inhalation studies in process?
  - R&D data on physical characteristics and toxicity?

## Risk Communication Challenges

- Confirming an expectation of low release
- Conveying meaning of “low” in comparison to “detectable” and “levels that show effects in animals”
- Demonstrating safety of material choices amid public (and regulatory) perceptions that “nano is dangerous” and “carbon nanotubes are asbestos like”
  - *Un-ringing a bell*: How can you say “this particular CNT is not asbestos-like” without saying “asbestos”?

## What To Do?

- Establish a “cross-material” dialogue with regulators on safety: and **show** the dialogue publicly.
  - DTSC is providing a platform and an audience
- Build coherent public awareness of the generalized properties and uses that limit risk.
- Generate data to confirm low releases and environmental presence from the uses.
- Show that safe choices are made in materials, uses, and risk protections.

## Repeat - Let's Not Forget

- Public posting of information – *on safety of products coming into the market now and in critical R&D pipelines*
  - Lack of response to “knowledge of presence and knowledge of safety” is not a good thing...
  - Lack of response ignores data that is responsive, and ignores an opportunity to start a positive dialogue
  - Be ready to respond to questions and press releases
- Inter-relationship of this action with other processes
  - Green Chemistry Initiative – an overarching regulatory scheme with AB 289
  - EPA Section 8e and Section 4 rulemaking **in process**
  - REACH, Canada CEPA DCI, OECD data sets and reporting

## Let's Not Forget (*cont.*)

- DTSC needs to demonstrate “success” with this DCI
  - What does that mean?
  - DTSC will submit response to UCLA for a critique
  - What happens if legislators conclude that this process was not successful?

## Responding to DTSC's Data Call-In for Carbon Nanotubes –

### Other Issues Raised by DTSC's Questions

Presented by:

**Michael Boucher, Esq.**

McKenna Long & Aldridge LLP  
December 3, 2009  
Washington, DC

## Overview

- Other reporting requirements for carbon nanotubes (CNTs)
- Sharing and protecting data
- Conflicting views on safety
- Next steps for DTSC

## Other Reporting Requirements

- USA/Toxic Substances Control Act (TSCA)
  - US EPA's position is that all CNTs are "new chemicals" requiring pre-manufacture notification (PMN) (73 Fed. Reg. 64,946 (Oct. 31, 2008))
  - PMN form contains numerous, detailed questions
  - Studies are optional, unless PMN submitter already has them (or acquires them during PMN review period)
  - But US EPA has imposed TSCA § 5(e) Consent Orders on every notified CNT
  - And Consent Orders require 90-day inhalation study, materials characterization data, worker PPE, limitations on processing, use, and distribution, and recordkeeping, and may prohibit releases to water (prospective)

## Other Reporting Requirements (*cont'd*)

- USA/Toxic Substances Control Act (*cont'd*)
  - R&D substances exempt from PMN requirement
  - But all manufacturers, importers, processors, and distributors must report "substantial risk" information under TSCA § 8(e)
  - Also, EPA will address gaps not filled by NMSP by proposing
    - TSCA § 8(a) information-gathering rule to obtain data on existing uses, production volumes, specific physical properties, chemical and structural characteristics, methods of manufacture and processing, exposure and release information, and available health and safety data on nanoscale materials
    - TSCA § 4 test rule to require testing of several manufactured nanomaterials (CNTs?) for health and environmental effects

## Other Reporting Requirements *(cont'd)*

- USA/Toxic Substances Control Act *(cont'd)*
  - And TSCA § 14 allows US EPA to disclose data from any “health and safety study”
    - “Any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to [TSCA].”

## Other Reporting Requirements *(cont'd)*

- Canada/Canadian Environmental Protection Act 1999 (CEPA)
  - Environment Canada (EC) has said that a DSL-listed substance is “new” and requires new substance notification (NSN), if it has unique structures or molecular arrangements (e.g., fullerenes) (New Substances Program Advisory Note 2007-06)
  - NSNs have quantity thresholds, and data requirements are tiered to import/manufacture quantities
  - R&D substances not exempt from NSN
  - EC may amend NSN Regulations to address nanomaterials
  - And EC may use significant new activity (SNAc) authority to gather information on DSL-listed nanomaterials

## Other Reporting Requirements (*cont'd*)

- **Canada/Canadian Environmental Protection Act 1999 (CEPA) (*cont'd*)**
  - Also, importers, manufacturers, transporters, processors, and distributors of a substance must report “information that reasonably supports the conclusion that the substance is toxic or is capable of becoming toxic” under CEPA § 70
  - And EC will demand information from manufacturers and importers of CNTs under a forthcoming CEPA § 71 notice
  - But CEPA §§ 313-321 allow substantiated confidentiality claims, and disclosure “in public interest” is allowed but only on a case-by-case basis, and with notice to submitter

## Other Reporting Requirements (*cont'd*)

- **EU/REACH Regulation**
  - Nanomaterials are covered by “substance” definition in REACH
  - Manufacturers and importers must submit registration dossiers for substances manufactured or imported at or above one ton/year
  - At or above ten tons/year, registrant also must produce a chemical safety report
  - Where substances on market as bulk substance are produced or imported at nanoscale without modifications, manufacturers and importers will cover nanoscale form in registration for bulk substance

## Other Reporting Requirements *(cont'd)*

- EU/REACH Regulation *(cont'd)*
  - Additional information about nanoscale form would be required where properties or uses differ between nanoscale and bulk forms
  - To address specific properties, hazards, and risks of nanomaterials, additional testing or information may be required
  - To determine specific hazards of nanomaterials, current test guidelines may need to be modified
  - Until specific test guidelines for nanomaterials exist, testing will be carried out under existing guidelines

## Other Reporting Requirements *(cont'd)*

- EU/REACH Regulation *(cont'd)*
  - Substances manufactured or imported under one ton/year are exempt (covers many R&D substances)
  - And PPORD substances get five-year registration exemption upon filing a notification (Art. 9)
  - Also, following registration, registrant must update his registration with any new information (Art. 22(1)(e))
  - Some commercial information is confidential (Arts. 118(2), 119(2)), but European Chemicals Agency (EChA) will publish health and safety data on the Internet (Art. 119(1))

## Other Reporting Requirements (*cont'd*)

- In responding to DTSC, ask whether you have information reportable to EPA, EC, or EChA
  - TSCA § 8(e) and CEPA § 70 cover (commercial) R&D substances and have no *de minimis* quantities
  - CEPA § 70 also covers TSCA “articles”
  - Art. 22(1) of REACH only requires updates to “registrations”
    - If there is no registration, there is no reporting obligation
    - Substances below one ton/year are not registered
    - PPORD substances are exempt for five years upon notice

## Other Reporting Requirements (*cont'd*)

- There will be lots of new information on CNTs, but there also will be data gaps
  - PMNs/Consent Orders exclude R&D substances
  - NSNs have varying quantity thresholds, and NSN data are tiered to import/manufacture quantities
  - REACH registrations have a quantity threshold, and REACH delays registration of PPORD substances
  - TSCA § 8(a) and CEPA § 71 information collections will allow confidentiality claims
  - TSCA § 14 allows disclosure of “health and safety studies,” but CEPA §§ 313-321 requires notice and “public interest” finding
  - Art. 119(1) of REACH will publish health and safety data, but registration deadlines extend out to 2018

## Protecting and Sharing Data

- Data available to DTSC from other reporting requirements will be “public” data
- How does industry provide DTSC responsive data without disclosing trade secrets?
  - Health & Safety Code § 57020 protects “trade secrets”
    - "Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that (1) derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use, and (2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy
    - Can include customer or supplier lists, business plans, spreadsheets, corporate minutes and agendas, and bid specifications

## Protecting and Sharing Data (cont'd)

- How does industry provide DTSC responsive data without disclosing trade secrets? (cont'd)
  - Also, DTSC may accept robust summaries of health and safety studies
  - Actual or virtual “reading room” could
    - Provide read-only access to information without creating “records” subject to public disclosure under “FOIA” laws
    - Facilitate industry’s sharing of data with DTSC and other regulators
    - Be operated for industry by third party under contract with appropriate safeguards to ensure confidentiality
- Should companies share data with one another?

## Conflicting Views on Safety

- What is a “safe” CNT?
- What data support a conclusion that a given CNT is or is not a “hazardous waste?”
- Lack of monitoring and environmental fate data
  - Helps to fuel irrational public hysteria
  - Is there an opportunity for industry to jointly develop data that support the use of CNTs?
    - Pure materials
    - As used in specific products or applications

## Next Steps for DTSC

- DTSC’s main goal is to obtain a baseline of information for itself, other California agencies, and the public
  - For example, Department of Industrial Relations may want to develop new guidelines or regulations to protect workers
- But responses will go into the Online Toxic Information Clearinghouse (SB 509), part of the Green Chemistry Initiative (GCI)
- CNTs could be identified as a “chemical of concern” under the GCI
- And DTSC has authority to regulate chemicals under other state laws

## PRACTICES:

- Environment, Energy & Product Regulation
  - Chemicals, Pesticides and Product Regulation
  - Green Chemistry
  - Nanomaterial Regulation
  - Pesticides
  - Toxic Substances Control Act (TSCA)
- EU Environmental
  - Occupational Safety and Health (OSHA)
- International
  - Canada-U.S. Practice
  - EU Environmental
- Public Policy and Regulatory Affairs
  - Canada-U.S. Practice
  - Cosmetics
  - Drugs
  - Food

## INDUSTRIES:

- Chemicals
- Nanotechnology



## Michael Boucher

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## Experience

Michael Boucher provides regulatory compliance and litigation services to Global 500 companies in the areas of international chemical and consumer product safety and regulation; environmental inspections, enforcement, and self-auditing; hazardous materials and chemicals of concern; worker safety; international environmental issues; environmental advertising, claims, and labeling; pre- and post-acquisition environmental due diligence; federal agency rulemaking and litigation; and task force formation and administration.

Mr. Boucher's environmental counseling and litigation practice focuses on the international regulation and sale of chemical and pesticide products, including agricultural and antimicrobial pesticides; industrial and consumer chemicals; products of "green chemistry," nanotechnology, and biotechnology; precursor and dual-use chemicals; and chemicals and pesticides controlled under international agreements on prior informed consent (PIC), persistent organic pollutants (POPs), and chemical weapons.

Mr. Boucher represents companies in U.S. Environmental Protection Agency (U.S. EPA) inspections and enforcement actions under the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Emergency Planning and Community Right to Know Act (EPCRA) and conducts compliance auditing under U.S. EPA's Audit Policy. He provides counsel on human testing, R&D, endangered species, data protection, and task force issues.

Mr. Boucher also advises consumer product manufacturers and retailers about consumer product safety standards, packaging and labeling requirements, regulation of advertising and claims, consumer warranties, user manuals, substantial product hazard reporting, product take-back and recycling, and voluntary and mandatory product recalls under laws administered by the Consumer Product Safety Commission, the Federal Trade Commission, and the U.S. states.

Mr. Boucher participated in one of only two pesticide review boards ever convened under the Pest Control Products Act (PCPA) in Canada and advises U.S. companies on the assessment of high-priority, potentially toxic substances under Canada's Chemical Management Plan.

## Notable Engagements

- Managing all legal aspects of a 60-facility, multi-media environmental compliance systems audit in the U.S.R.
- Representing several companies in U.S. EPA and U.S. state environmental inspections, enforcement actions, and self-audits.

## + Publications:

- *Pesticide Regulation Handbook*, 4th Edition, McKenna Long & Aldridge LLP, (2007), co-editor and co-author.
- *The TSCA Handbook*, 4th Edition, Government Institutes, (2006), co-author.
- "China's Regulation of Agricultural Biotechnology," *Metropolitan Corporate Counsel*, (December 2006), co-authored with John Connor, Jr. and Jeffrey Li.

## + Seminars And Presentations:

- "Summary of Microbial Commercial Activity Notice Requirements under TSCA," Chemical Notification World Summit 2009, (September 15, 2009), Arlington, Virginia.
- "Chemical Management Update: USA, Canada, and California," Chemical Daily Co., Ltd.: Toward TSCA Amendment, (September 14, 2009), Tokyo, Japan.
- "Chemical Management Models: USA, Canada, and California," REACH, TSCA Reform and the Global Challenges of Chemicals Management, (June 11, 2009), Washington, DC.
- "After the Data Call-Ins: Possible Next Steps in the Regulation of Chemical Nanotechnology," Nanomaterial Data Call-ins and their Regulatory and Enforcement Implications, (April 15, 2009), Washington, DC.
- "General Certifications of Conformity," Southern Aerosol Technical Association Spring 2009 Meeting, (March 26, 2009), Atlanta, Georgia.
- "Regulation of Claims for Antimicrobial Consumer Products," IntertechPira Antimicrobials in Consumer Applications Conference, (November 17, 2008), Tampa, Florida.

## + Professional Activities:

- American Bar Association, Section of Environment, Energy, and Resources

- Leading the legal defense of three widely used silicones undergoing environmental, health, and safety assessment in Canada under Canada's Chemical Management Plan.
- Counseling several companies about requirements for marketing chemical and consumer products in jurisdictions around the world.
- Advising several manufacturers and retailers regarding consumer product labeling, safety, and testing issues, including regulatory compliance issues affecting ongoing product liability litigation.
- Advising two major chemical industry trade associations with respect to industry policy and federal legislation and rulemaking.
- Represented a U.S. company in one of only two pest control product review boards ever convened in Canada.
- Provided pre- and post-acquisition environmental due diligence in half a dozen large mergers and acquisitions in the agricultural and industrial chemical industries.
- Prepared and filed several petitions challenging U.S. EPA rulemakings.

### Representative Matters

- Managing all legal aspects of a 60-facility, multi-media environmental compliance systems audit in the U.S.
- Representing several companies in US EPA and U.S. state environmental inspections, enforcement actions, and self-audits.
- Leading the legal defense of three widely used silicones undergoing environmental, health, and safety assessment in Canada under Canada's Chemical Management Plan.
- Counseling several companies about requirements for marketing chemical and consumer products in jurisdictions around the world.
- Advising several manufacturers and retailers regarding consumer product labeling, safety, and testing issues, including regulatory compliance issues affecting ongoing product liability litigation.
- Advising two major chemical industry trade associations with respect to industry policy and federal legislation and rulemaking.
- Represented a U.S. company in one of only two pest control product review boards ever convened in Canada.
- Provided pre- and post-acquisition environmental due diligence in half a dozen large mergers and acquisitions in the agricultural and industrial chemical industries.
- Prepared and filed several petitions challenging US EPA rulemakings.

### Education

- J.D., Olin Prize in Law and Economics, Georgetown University Law Center, 1993
- A.B., *magna cum laude*, Phi Beta Kappa, Georgetown University, 1987

### Admitted

- District of Columbia
- New York
- U.S. Supreme Court

- American Bar Association, Section of Administrative Law and Regulatory Practice
- District of Columbia Bar
- International Consumer Product Health and Safety Organization

## PRACTICES:

- Environment, Energy & Product Regulation
  - Chemicals, Pesticides and Product Regulation
  - Nanomaterial Regulation
- Government Contracts
  - Life Sciences and Public Health Preparedness
    - Personalized Medicine
  - Pharmaceutical Compliance
- Public Policy and Regulatory Affairs
  - Cosmetics
  - Drugs
  - Food
  - Life Sciences and Public Health Preparedness
  - National Government Affairs
  - State and Local Government Affairs

## INDUSTRIES:

- Chemicals
- Life Sciences and Public Health Preparedness
- Nanotechnology



## Richard A. Canady\*

Senior Advisor - Washington, DC

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## Experience

Richard A. Canady recently joined McKenna Long & Aldridge from the Food and Drug Administration's Office of the Commissioner and serving for FDA in the Office of Science and Technology Policy of the Executive Office of the President. He is widely recognized as one of the leading experts in the development of environmental, health, and safety (EHS) regulatory policy for nanotechnology. He has represented FDA to White House interagency working groups and policy coordination groups on EHS, led FDA policy reviews in the Office of the Commissioner of FDA, led OECD guidance development on testing of nanomaterials, developed and led workshops and served on numerous panels and peer reviews on topics ranging from toxicity assessment to standard reference materials, research needs, and nanomaterial characterization both in U.S. and in EU.

To this specific expertise in nanomaterials, Mr. Canady brings over 20 years experience in policies for use of toxicology and exposure information in regulation of air and water safety, hazardous waste, and chemicals regulations at EPA; occupational safety regulation under OSHA; and food, cosmetic and medical product regulation at FDA. He has broad international risk assessment policy experience over more than a decade of work with UN agencies (WHO, FAO), OECD, and in bilateral discussions between US FDA and relevant regulatory agencies of major U.S. trading partners.

## Education

- Ph.D., Neurophysiology, Physiology, Behavior, Rockefeller University, 1986
- B.S., Psychology, Biology, University of Michigan, 1979
- Professional certification: Diplomat, American Board of Toxicology (DABT)

\* Non-attorney professional

## + Publications:

- *OECD Guidance Manual for Sponsors of OECD Sponsorship Programme for the Testing of Manufactured Nanomaterials*, (2009), task group co-chair and lead author.
- "Seven challenges for nanomedicine," *Nature Nanotechnology*, 3:242-244, (2008), co-authored with Sanhai, Sakamoto, Ferrari.
- FDA Nanotechnology Task Force report, (2007), lead author.
- "Risk Management Methods" section of National Nanotechnology Initiative documents on US Environmental Health and Safety research needs, (2006-2008), interagency task group lead and lead author.

## + Seminars And Presentations:

- Carbon Nanotube discussant, OECD Workshop on Risk Assessment of Manufactured Nanomaterials in a Regulatory Content, (September 16-18, 2009), Washington, DC.
- "nanoEHS Perspectives," panel member, Nanotechnology Health and Safety Forum, (June 2009), Seattle, WA.
- "Science and Regulatory Policy Landscape," lecture and panel member, The Use of Engineered Nanomaterials in Food, Society of Toxicology Roundtable Session, (2009), Baltimore, MD.
- "Introduction to the discussion on the implementation of the existing legislation: Examples from the chemical, medical, and food areas," Chair of session, Second Annual Safety for Success Dialogue, European Commission, (2008), Brussels, Belgium.
- Plenary presentation, Workshop on research on the safety of nanomaterials, European Commission, DG Research, (2008), Brussels, Belgium.
- Introduction, discussion moderator, and summary presentations for FDA-Alliance for NanoHealth Nanotechnology Initiative Scientific Workshop, (2008), Houston, TX.

**+ Professional Activities:**

- Society for Risk Analysis (SRA)
- Society of Toxicology
- American Board of Toxicology

## PRACTICES:

- Environment, Energy & Product Regulation
- California Environmental Law and Policy
- Green Chemistry
- Proposition 65
- Chemicals, Pesticides and Product Regulation
- Green Chemistry
- Nanomaterial Regulation
- Proposition 65
- Toxic Substances Control Act (TSCA)
- Occupational Safety and Health (OSHA)

## INDUSTRIES:

- Chemicals
- Nanotechnology



## Ann G. Grimaldi

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## Experience

Ann G. Grimaldi maintains a diverse practice centered on chemical regulation, with a primary focus on California's Proposition 65 and the federal Toxic Substances Control Act (TSCA). She has substantial experience defending Proposition 65 lawsuits, including through appeal, and has represented a broad range of entities in Proposition 65 litigation and counseling matters, including chemical manufacturers, consumer product manufacturers, distributors and retailers, and defense companies.

Ms. Grimaldi has assisted numerous clients in undertaking environmental TSCA audits, developing TSCA compliance manuals, and self-disclosing potential TSCA violations pursuant to U.S. EPA's audit policy. She also has assisted companies in receiving regulatory approvals under TSCA.

Representing pesticide companies as real parties in interest, Ms. Grimaldi also has defended challenges to the California pesticide regulatory program brought under the California Environmental Quality Act. Ms. Grimaldi is experienced in pesticide data rights issues and is well-versed in the California Public Records Act as it applies to the disclosure of pesticide data, and registrants' rights under that law and others, including the California Uniform Trade Secrets Act.

Ms. Grimaldi is experienced in other areas of environmental law, advising clients on compliance with the federal and California Hazard Communication Standards, the California Appliance Efficiency regulations and California's Electronic Waste Recycling Act. She also counsels clients on the still-evolving California Green Chemistry Initiative. Ms. Grimaldi has prepared formal comments to environmental regulations and has testified at agency hearings.

## Education

- J.D., University of California Hastings College of the Law, *magna cum laude*, 1992
- B.S., University of California, 1985

## Admitted

- California

## + Publications:

- "California Goes Green(er) Through New Chemical Initiative," *Washington Legal Foundation*, (August 14, 2009).
- *The TSCA Handbook*, 4th Edition, Government Institutes, (2006), co-author.

## + Seminars And Presentations:

- "DTSC Data Call-In: Practical Considerations," Nanomaterial Data Call-ins and their Regulatory and Enforcement Implications, (April 15, 2009).