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Governance of Nanotechnology

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Lots Going On

- Many ongoing global initiatives involving diverse governance aspects of nanoscale materials
- Many countries continue to make progress in:
  - Defining nanoscale materials
  - Addressing related definitional challenges
  - Developing suitable governance approaches to manage potential risks
  - Developing good practices
  - Conducting testing/developing alternative test methods

Global Governance Constructs

- Legislative Initiatives
- Regulatory Initiatives
- Voluntary Initiatives
  - Government -- National Institute for Occupational Safety and Health (NIOSH), U.S. Environmental Protection Agency (EPA)
  - Corporate Stewardship Initiatives -- Testing, "best practices," related public-private initiatives
  - Collaborative Initiatives -- Organization for Economic Cooperation and Development (OECD) and NanoRisk Framework, to name a few
- Standard-Setting Initiatives, for Example:
  - ISO -- TC-229
  - ASTM -- E56

Global Consensus on Use of Existing Governance Tools

- Consensus globally that existing laws are sufficiently robust to regulate the safety of nanoscale materials
  - OECD member countries share this view -- *See* 2013 Recommendation approved by OECD Governing Council
  - National Nanotechnology Initiative (NNI) -- Broad, bipartisan support over the last 15 years (EPA, U.S. Food and Drug Administration (FDA), U.S. Occupational Safety and Health Administration (OSHA), other U.S. agencies) -- endorses this view
  - Other thought leaders share this view (American Bar Association (ABA))
  - Not all agree, however (certain non-governmental organizations (NGO), among others)

OECD -- Testing Program of Manufactured Nanomaterials

- OECD announced on June 9, 2015, that its seven-year testing program "showed that the standard test guidelines used for normal chemical substances are in the most part suitable for use on nanomaterials"
- OECD investigated 11 commercially viable nanomaterials over 111 unique endpoints
  - The nanomaterials tested include:
    - Cerium oxide
    - Dendrimers
    - Fullerenes (C60)
    - Gold nanoparticles
    - MWCNTs
    - Nanoclays
    - Silicon dioxide
    - Silver nanoparticles
    - SWCNTs
    - Titanium dioxide (NM100-NM105)
    - Zinc oxide
- OECD coordinated the results from across 11 countries with tests and data generated from dozens of government agencies, universities, research institutions, and businesses

OECD -- Testing Program of Manufactured Nanomaterials (cont'd)

- Over 780 studies on the specific properties of nanomaterials were undertaken to fill in the gaps of understanding nanomaterials
- The testing program provides member countries confidence that use of OECD test guidelines to determine the impact nanomaterials may have on environment/human health is suitable
- OECD intends now to focus on how to adapt better the test guidelines to account for the intrinsic properties of nanomaterials

U.S. Developments -- FIFRA

- In June 2011, EPA issued a proposed policy on nanoscale materials in pesticide products
  - EPA proposed obtaining information concerning nanoscale materials using either Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 6(a)(2), which concerns adverse effects reporting, or a data call-in (DCI) under FIFRA Section 3(c)(2)(B)
  - EPA also proposed to apply an initial presumption that nanoscale ingredients are potentially different from those conventionally sized counterparts, rebutted on a case-by-case basis
  - No new policies issued since

U.S. Developments -- FIFRA (cont'd)

- On December 1, 2011, EPA registered a nanosilver-based antimicrobial pesticide product incorporated into textiles
  - As a condition of registration, EPA is requiring the registrant, HeiQ, to conduct a number of studies within four years
  - On January 26, 2012, the Natural Resources Defense Council (NRDC) filed a lawsuit challenging the conditional registration
  - NRDC urged the court to set aside the authorization until the data EPA has requested are generated, submitted, and reviewed
  - On November 7, 2013, the court granted in part and denied in part the petition for review

U.S. Developments -- FIFRA (cont'd)

- On May 19, 2015, EPA announced a conditional registration for a second nanosilver product, Nanosilva
- On July 27, 2015, two petitions for review were filed in the U.S. Court of Appeals for the Ninth Circuit
- NRDC and the Center for Food Safety and International Center for Technology Assessment filed petitions for review
- The petitioners asked the court to set aside EPA's final order granting the conditional registration
- The court has consolidated the cases

U.S. Developments -- FIFRA (cont'd)

- EPA's March 8, 2016, brief responding to the petitions notes that when the petitioners commented on EPA's proposed decision, they failed to raise most of the arguments brought before the court
- EPA states that it properly found that use of the nanosilver product is in the public interest because it could reduce the environmental silver load and risks associated with silver
- Oral argument will be held November 17, 2016

U.S. Developments -- FIFRA (cont'd)

- On March 19, 2015, EPA responded to the International Center for Technology Assessment's 2008 petition for rulemaking requesting that EPA regulate products containing nanosilver as pesticides and for related other forms of relief
- In general, the response does not alter EPA's legal position with regard to nanosilver and its regulation under FIFRA, or otherwise contribute any new interpretations of existing EPA pesticide registration or enforcement policy

U.S. Developments -- TSCA

- Since 2005, EPA has received more than 170 premanufacture notifications (PMN) for nanoscale chemicals
  - EPA has reviewed primarily carbon nanotubes and nanofibers, as well as fullerenes, quantum dots, silica derivatives, and titania derivatives
- EPA has allowed most of the 170 new nanoscale chemicals to enter into commerce
- Due to uncertainties about nanoscale chemicals, however, EPA has taken a number of actions to control and limit exposures to these chemicals, including:
  - Limiting uses
  - Requiring the use of personal protective equipment, such as impervious gloves and NIOSH-approved respirators
  - Limiting environmental releases
  - Requiring testing to generate health and environmental effects data

U.S. Developments -- Proposed TSCA Section 8(a) Rule

- On April 6, 2015, EPA proposed reporting and recordkeeping requirements for certain chemical substances when they are manufactured or processed at the nanoscale
  - Persons that manufacture or process these substances would be required to report electronically to EPA certain information, including the specific chemical identity, production volume, methods of manufacture and processing, exposure and release information, and existing data concerning environmental and health effects
  - Any persons who intend to manufacture or process chemical substances as discrete nanoscale materials after the effective date of the final rule would be required to notify EPA of the same information at least 135 days before the intended date of commencement of manufacture or processing

U.S. Developments -- Proposed TSCA Section 8(a) Rule (cont'd)

- Comments on the proposed rule were due July 6, 2015
- EPA held a public meeting on June 11, 2015
- It appears EPA intends to obtain information concerning what nanomaterials are on the market before determining new uses that merit a SNUR
- EPA submitted a final rule to the Office of Management and Budget (OMB) for review on October 7, 2016

U.S. Developments -- Office of Water

- On June 27, 2016, EPA announced the availability of its *Preliminary 2016 Effluent Guidelines Program Plan*
- EPA has continued its review of engineered nanomaterials in industrial wastewater, as presented in the *Final 2014 Plan Effluent Guidelines Program Plan*
- EPA intends to provide an update on its review as part of the *2016 Annual Effluent Guidelines Review Report*, or as new information becomes available

U.S. Developments -- FDA

- In 2014, FDA published final guidances on FDA-regulated products, cosmetics, food ingredients, and food contact substances
- In 2015, FDA published final guidance on the use of nanomaterials in food for animals
- Will continue to consider specific characteristics of individual products
- Encourages manufacturers to consult with FDA before taking products to market

U.S. Developments -- RCC

- EPA working with Canada through the Regulatory Cooperation Council (RCC) to improve regulatory alignment in a number of areas, including nanotechnology
  - Will provide more targeted advice on information needs for industrial nanomaterials
  - Information submitted by notifiers will be used in a consistent, efficient, and aligned manner with increased predictability
  - More informed risk assessments and more targeted risk management

Canada -- Mandatory Survey of Certain Nanomaterials

- The July 25, 2015, *Canada Gazette* includes a notice requiring the submission of information with respect to certain nanomaterials in Canadian commerce
- The notice applies to a substance that has a size of between 1 and 100 nm in at least one external dimension, or internal or surface structure; and is included on the list in Schedule 1 of the notice
- The list includes over 200 chemical substances
- The notice applies to any person who, during the 2014 calendar year, manufactured a total quantity greater than 100 kg of a listed substance
- The notice also applies to any person who, during the 2014 calendar year, imported a total quantity greater than 100 kg of a listed substance, at any concentration, whether alone, in a mixture, or in a product
- Responses were due February 23, 2016

Canada -- Bill to Create Framework to Regulate Nanotechnology

- On June 8, 2016, the House of Commons held its first reading of an Act to amend the Canadian Environmental Protection Act, 1999 (CEPA) (nanotechnology) (C-287)
- The bill would add CEPA Part 6.1 primarily to implement procedures for the investigation and assessment of nanomaterials
- The bill would also create a national inventory regarding nanotechnology using information collected under CEPA Sections 46 and 71 and “any other information to which the Ministers have access”
- Member Peter Julian, New Democratic Party of Canada House Leader first introduced a similar bill in 2010

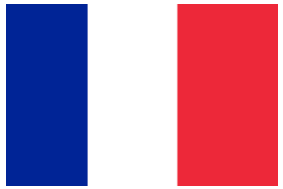
Canada -- Proposed Prioritization Approach

- On July 27, 2016, Canada began a consultation on a proposed prioritization approach for nanoscale forms of substances on the Domestic Substances List (DSL)
- Canada will use the proposed approach to:
  - Establish a list of existing nanomaterials in Canada for prioritization;
  - Identify how the information available will be used to inform prioritization of nanomaterials for risk assessment; and
  - Outline the proposed outcomes of the prioritization process

Canada -- Proposed Prioritization Approach (cont'd)

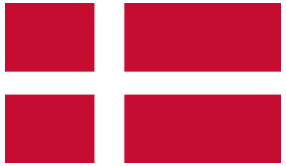
- Based on the results of the 2015 survey, Canada will prepare a final list of confirmed existing nanomaterials in Canada and will use the list for subsequent prioritization
- Canada proposes that, where possible, the substances identified via the survey be "rolled up into" their broader parent nanomaterial groups for the purposes of prioritization
- The results of prioritization will be no further action at this time; nanomaterials prioritized for risk assessment; and nanomaterials that will be set aside for future consideration due to insufficient information
- Comments were due September 25, 2016

International Developments -- Nano Product Inventories



- French Nano Decree No. 2012-232
  - According to a 2014 report, 10,417 declarations were submitted by June 1, 2014, compared to 3,409 declarations submitted as of July 1, 2013
- Belgium Registry

  - Nanomaterial substances had to be registered by January 1, 2016
  - Mixtures containing nanomaterial substances must be registered by January 1, 2017
- Danish Registry



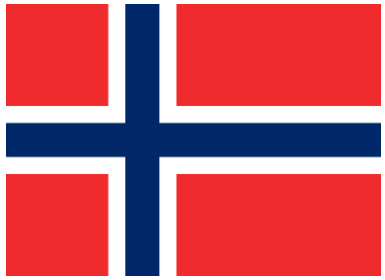
  - First reports, for the period beginning June 20, 2014, and ending June 20, 2015, were due August 30, 2015

International Developments -- Nano Product Inventories (cont'd)

- KEMI is drafting a regulation that would require companies to provide information on nanomaterials in chemical products and articles to the Swedish Products Register by February 28, 2019
- The first reports would concern nanomaterials manufactured or imported in 2018
- Product groups already exempt from reporting requirements -- waste, food and animal feed, pharmaceuticals, cosmetics, and tattoo ink -- would remain so
- KEMI intended to refer the regulation for a consultation period from mid-June to mid-September 2016

International Developments -- Nano Product Inventories (cont'd)

- Norwegian Registry



- Italy/United Kingdom -- Voluntary reporting approach

- Finland -- Different approach, opposes such registries and favors enhanced communication strategies

International Developments -- Nano Product Inventories (cont'd)

- EU Nano Product Registry?
  - Consultation on transparency measure for nanomaterials in the market ended August 5, 2014
  - During the March 2016 meeting of the CARACAL Subgroup on Nanomaterials, European Commission (EC) officials stated that the EC prefers to improve transparency through a public website that would provide existing information on nanomaterials instead of a European Union (EU) register
  - According to EC officials, revising the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Annexes to require manufacturers to provide specific data concerning nanomaterials would be more useful and better to address any risks posed by nanomaterials

International Developments -- REACH Annexes

- Although the EC intended to update the Annexes in 2015, it has not done so
- Updates are expected to focus on:
  - Legally-binding definition of nanomaterials
  - Terminology explaining what is understood by the "form" of a substance, as one substance registration dossier can cover several forms
  - Rules requiring registrants to explain the applicability of the information submitted in the registration to the nanoforms of the registered substance
  - Requirements to characterize nanoforms by submitting information on their names, particle distribution, surface treatment, shape, morphology, surface area, and test conditions

International Developments -- REACH Annexes (cont'd)

- EC reportedly is "working very intensely" on the final impact assessment
- It reportedly is balancing the need for clarity with the costs for companies, especially for small- and medium-sized enterprises (SME)
- The European Chemicals Agency (ECHA) intended to have a draft or final update of all registration guidance on its website, including what is required in the context of nanomaterials, before the effective date of the guidance moratorium, May 31, 2016
- In May and June 2016, ECHA submitted several draft guidance documents concerning nanomaterials to Partner Expert Groups for consultation

International Developments -- REACH Annexes (cont'd)

- At its September 28-29, 2016, meeting, the ECHA Management Board reviewed a draft delegation agreement that ECHA intends to sign with the EC to create an EU-wide observatory on nanomaterials
- The EC foresees the observatory "as a complement" to the amended REACH Annexes that are expected to be adopted "in the near future"
- The observatory is intended to collect and disseminate available information for various audiences on nanomaterials and their safety aspects

Closing Thoughts

- Growing body of scientific data -- tox, nanomaterial-specific data, and test methods
- Slowly gathering ecological effects data
- Some progress on chemical identity and speciation issues
- Extensive array of best practices and helpful “how tos” available to laboratories, small, medium, and large manufacturers, and others to protect workers
- Growing body of law, regulations, and guidance on how to apply existing governance standards and regulations to nanomaterials
- Willingness of regulators to be flexible in addressing new and novel nanomaterials under existing law (particularly non-dispersive uses)

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Thank You

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