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Sustainable Nanotechnology Conference 2015

Regulatory and Policy Initiatives in the US and EU

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The Business Proposition

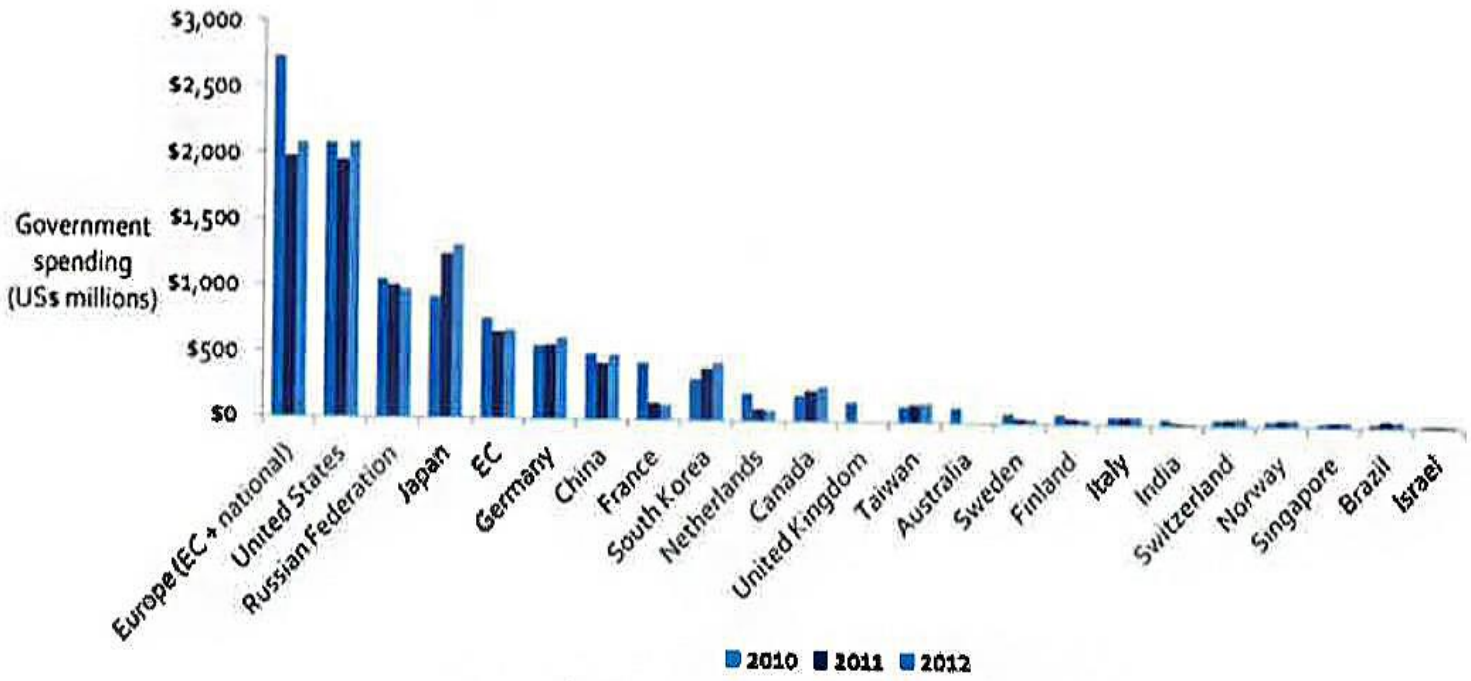
- According to Lux Research*
  - U.S. leads in government nanotechnology funding -- $2.1 billion spent in 2012
  - Europe's collective spending was approximately $2 billion in 2012
  - The National Nanotechnology Initiative (NNI) is 14 years old, and U.S. government has invested a total of $20 billion in nanotechnology
  - While some countries, including the U.S., maintain centralized government programs to coordinate nano activities, most no longer do, thus it is difficult to determine the level of nanotechnology funding by country

* **Nanotechnology Update: Corporations Up Their Spending as Revenue for Nano-enabled Products Increase (2014)**

The Business Proposition (cont'd)

- Nano-enabled product revenue grew from $339 billion in 2010 to $731 billion in 2012, an increase of 116%

Past Leaders Continue to Support Nanotechnology



Business Projections

- Revenues from products that contain some element of nanotechnology are expected to reach $3.2 trillion by 2018
- Materials/manufacturing sectors have achieved the most revenues from nano-enabled products
- Only modest differences among Asia, the Americas, and Europe in revenues generated by nano-enabled products
- Nano-intermediates and nanomaterials also continue to increase the value brought to suppliers

Headlines Regarding Global Environmental, Health, and Safety (EHS) Regulatory Developments

- Much progress made to "institutionalize" regulatory policy domestically and globally, and demands for nano-specific regulation continue
  - Risk assessment methodology
  - Definitional coherence
  - Notification/registration of nanomaterials in industrial chemicals, food materials, cosmetics, pesticide applications
- Governmental responses to such demands vary and are considered either "measured" or "inadequate" depending upon the source
- Non-governmental organizations (NGO) continue to advocate for a "sui-generis, nano-specific regulatory regime" and prefer a strong precautionary approach in U.S., European Union (EU), and elsewhere

Global Consensus on Utility of Existing Governance Tools

- Global government consensus that existing laws and regulatory adjustments are sufficiently robust to regulate the safety of nanoscale materials
  - Organization for Economic Cooperation and Development (OECD) member countries share this view -- *See* 2013 Recommendation approved by OECD Governing Council
  - NNI -- Broad, bipartisan support over the last 14 years (U.S. Environmental Protection Agency (EPA), U.S. Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), other U.S. agencies) endorses this view
  - Other thought leaders share this view -- American Bar Association, American Chemistry Council, Society of Chemical Manufacturers and Affiliates (SOCMA), other industry groups
  - Not all agree, however, including prominent members of the NGO community

Global Consensus on Utility of Existing Governance Tools (cont'd)

- Global regulatory authorities have adopted largely preliminary/incremental measures to address nanomaterial safety (reporting, labeling) within existing regulatory frameworks
- Measures are product-specific (carbon nanotubes (CNT), chemicals, cosmetics) rather than nanomaterials/technology as a class

U.S. Developments -- Toxic Substances Control Act (TSCA)

- Since 2005, EPA has received more than 160 premanufacture notices (PMN) for nanoscale materials
  - EPA has reviewed primarily CNTs and nanofibers, as well as fullerenes, quantum dots, silica derivatives, and titania derivatives
- EPA has allowed most of the 160-plus new nanoscale materials to enter into commerce
- Due to uncertainties about nanomaterials, however, EPA's consent to manufacture has come with requirements
  - Requirements to prevent human and environmental exposure
  - Requirements to develop data
  - 100% of PMNs for nanomaterials require further review, and generally take 6-24 months to review

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

- Type of nano PMNs (assessed as respirable, poorly soluble particulates)
  - Fullerenes: Modified Fullerenes
  - CNTs
  - Quantum dots
  - Nanopolymers
  - Silica derivatives
  - Titanium derivatives

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

- Recent proposed significant new use rules (SNUR), issued in July 2014, require companies to monitor and analyze wastewater discharged to the city sewer
- No surface water releases, except for limited water releases resulting in no more than one ppb wastewater effluent concentration

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

- EPA is developing reporting and recordkeeping requirements under TSCA Section 8(a) that would require persons who manufacture these nanoscale materials notify EPA of certain information, including:
  - Production volume;
  - Methods of manufacture and processing;
  - Exposure and release information; and
  - Available health, toxicity, safety data
- EPA submitted a proposed rule to the Office of Management and Budget (OMB) on October 6, 2014
- Appears EPA intends to obtain information concerning what nanomaterials are on the market before determining new uses that merit a SNUR

U.S. Developments -- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

- On June 17, 2011, EPA issued a proposed policy on nanoscale materials in pesticide products
  - EPA proposed obtaining information concerning nanoscale materials using either 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
    - The presumption could be rebutted on a case-by-case basis

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

- On December 1, 2011, EPA announced a conditional registration for a nanosilver-based antimicrobial pesticide product that will be incorporated into textiles
  - As a condition of registration, EPA is requiring the registrant, HeiQ, to conduct certain 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 had requested were generated, submitted, and reviewed
  - On November 7, 2013, the court granted in part and denied in part the petition for review, widely viewed as a win for the registrant and EPA
  - No final registration has been issued for the second nanosilver registration

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

THE CENTER FOR FOOD SAFETY

- The Center for Food Safety (CFS) filed a law suit on December 16, 2014, against EPA over its failure to regulate novel nanomaterial pesticides
  - CFS filed a legal petition in 2008 requesting that EPA regulate nanosilver products as pesticides
  - EPA opened a public comment period on November 19, 2008, but according to CFS, "nearly six years later the agency has still failed to respond"
  - CFS claims that since 2008, "hundreds of new pesticidal nano-silver products have reached the market without any pesticide oversight from EPA"

U.S. Developments -- Office of Water

- On September 16, 2014, EPA announced its decision to collect information on potential industrial wastewater discharge hazards associated with nanomaterials manufacturing and formulating
- EPA requested comment on data available on the wastewater hazards and discharges associated with the manufacture of nanomaterials and their use in manufacturing or formulating products

U.S. Developments -- FDA

- Recently published final guidances on FDA-regulated products, cosmetics, food ingredients, and food contact substances
- Comment period on draft guidance on food for animals ended September 10, 2014
- Will continue to consider specific characteristics of individual products
- Encourages manufacturers to consult with FDA before taking products to market

Future EPA Directions

- Development of chemical categories for nanomaterials
  - Continued engagement with OECD
  - Continued engagement with Regulatory Cooperation Council (RCC)
- Integration of data into risk assessments and risk management
  - Development of screening test/read-across properties
- Identify criteria of concern/no concern

U.S. Developments -- RCC

- EPA working with Canada through the 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

EU Developments -- Nanomaterials State of Play

EU Nano Regulation

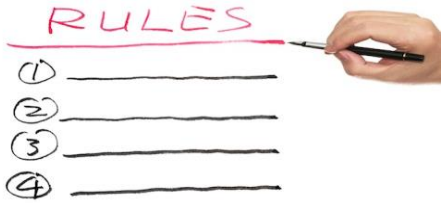
- Nanomaterials are increasingly regulated
  - Regulations are vertical and apply to specific products (as opposed to horizontal)
  - Enhanced regulation under the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) will expand the horizontal reach of regulation, and close monitoring of REACH regulations is essential

EU Developments -- Nanomaterials State of Play (cont'd)

- **EU Cosmetic Regulation** -- The Regulation of Cosmetic Products imposes, as of July 2013, reporting and labeling requirements regarding the presence of nanomaterials in cosmetic products
- **Nanomaterials in Food** -- Draft Legislation Concerning Nano Foods -- On November 24, 2014, European Parliament Committee on Environment, Public Health, and Food Safety considered draft regulations concerning nano foods during which the Committee:
  - Proposed a moratorium on use of nanomaterials in food
  - Proposed that foods requiring risk assessments, including nanomaterials, should not be authorized until approved by the European Food Safety Authority (EFSA)
  - Proposed all nano foods should be subject to post-monitoring
- **Biocides Regulation of Nano** -- Biocidal Products Regulation (BPR) has specific provisions for nanomaterials

EU Developments -- REACH Annexes

- The European Commission (EC) intends to update the annexes in early 2015
- 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

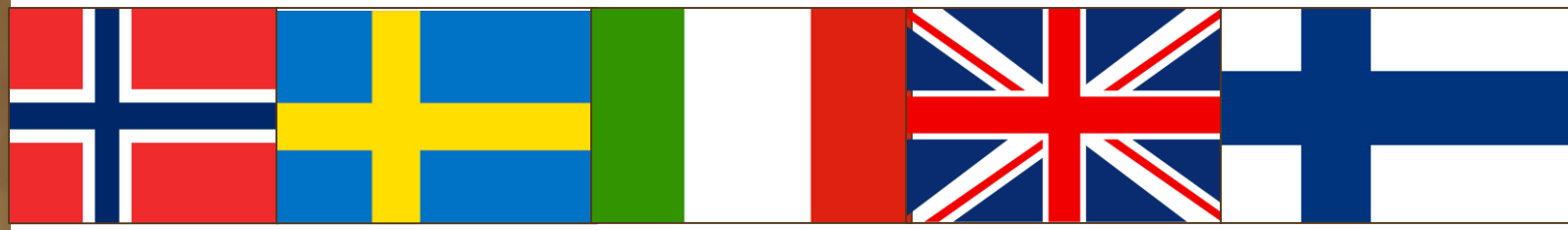


EU Developments -- Nano Product Inventories

- 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
  - Will open January 1, 2016, for nanomaterial substances
  - Will open January 1, 2017, for mixtures containing nanomaterial substances
- Danish Registry
  - First reports, for the period beginning June 20, 2014, and ending June 20, 2015, are due August 30, 2015

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

- Norwegian Registry
- Sweden/Italy/United Kingdom -- Voluntary reporting approach
- Finland -- Different approach, opposes such registries and favors enhanced communication strategies



EU 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 December 2014 meeting of CASG Nano, the EC gave its opinion that an EU nanomaterials registry is not an appropriate way to provide information to consumers
  - According to EC officials, revising the REACH annexes to require manufacturers to provide specific data concerning nanomaterials would be more useful and would better address any risks posed by nanomaterials
  - The EC's official position is expected in mid-2015 after the currently carried out impact assessment has been prepared in final

Concluding Thoughts

- Nano regulatory developments are expanding
- Efforts are ongoing to align U.S. and EU governance approaches to nano regulations
- Both U.S. and EU would benefit from greater clarity on the role of “benefits” and “sustainability attributes” in the risk/benefit analysis of nanomaterials
- The Sustainable Nanotechnology Organization (SNO) can help fill this void

Thank You

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