NANOTECHNOLOGY - THE NEXT ASBESTOS?

Strategies for Surviving in an Emerging Regulatory Environment

April 5, 2007
1:00 PM

Jeff Bromme
Joe Kakesh
Arnold & Porter LLP

PRESENTATION OUTLINE

I. FEDERAL STATUTES REGULATING NANOTECHNOLOGY

A. Introduction

1. Several federal agencies are actively involved in nanotechnology research and development. The National Nanotechnology Initiative (NNI) was set up in 2001 as an interagency research and development program "to coordinate efforts in nanoscale science, engineering, and technology." NNI coordinates the nanotechnology activities of 26 federal agencies.

2. The Administration has proposed a budget of $1.5 billion for NNI for fiscal year 2008. NNI funds a wide range of nanotechnology-related activities, including fundamental research in science and engineering, biomedical research on the health implications of nanotechnology, funding for NNI research centers across the United States, research on the implications of nanotechnology on workplace safety, national defense, and environmental protection, and research on the societal and ethical implications of nanotechnology.

3. In addition to participating in NNI, individual agencies, including EPA, the Consumer Product Safety Commission (CPSC), and the Food and Drug Administration (FDA), have their own internal nanotechnology research initiatives. None have, as of yet, led to any nanotechnology-specific regulations.

4. The federal statutes discussed below could have a significant impact on nanotechnology regulation, but so far there have been few nanotechnology-specific applications of these statutes by federal agencies.

B. TSCA[1]

1. Introduction

   a. The Toxic Substances Control Act (TSCA), administered by EPA, regulates "chemical substances," which are "any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part

[1] This summary was based in large part on "Regulation of Nanoscale Materials under the Toxic Substances Control Act, *available at* http://www.abanet.org/environ/nanotech/pdf/TSCA.pdf, and a 2005 paper by EPA's Office of Prevention, Pesticides and Toxic Substances, "Considerations Relevant to Toxic Substances Control Act (TSCA) Application to Nanoscale Materials".

as a result of a chemical reaction or occurring in nature and any element or uncombined radical." TSCA § 3(2)(A), 15 U.S.C. § 2602(2)(A).

b. TSCA is a "cradle-to-grave" statute that allows EPA to regulate chemicals even before their introduction into commerce and, if necessary, throughout their manufacture, processing, use, and disposal. For example, anytime a new chemical will be manufactured (or imported) in the United States, it is subject to a premanufacture notice (PMN) under TSCA § 5(a)(1). In addition, certain existing chemicals that are used in a new way are subject to significant new use rules (SNUR) under TSCA § 5(a)(2).

c. It is EPA's interpretation that TSCA can regulate nanotechnology. In 2005, EPA proposed a pilot program for voluntary reporting of nanoscale materials that are not otherwise excluded under TSCA.

d. A major policy issue in applying TSCA to nanotechnology, however, is determining whether a particular nanomaterial is a "new" substance subject to PMN under TSCA § (5)(a)(1) and, if it is not "new," whether certain uses of nanomaterials should be considered "new uses" subject to SNURs under TSCA § 5(a)(2).

e. Other TSCA provisions that might be applied to nanotechnology include the health and environmental testing provisions (TSCA § 4), provisions regarding the collection of production, health, and environmental information (TSCA § 8), provisions granting EPA the authority to regulate and prohibit the manufacture, processing, distribution, and use of chemical substances (TSCA §§ 6, 7), and citizen suit provisions (TSCA § 21).

2. <u>Distinguishing New and Existing Nanoscale Chemical Substances under TSCA § 5</u>

a. When is a nanomaterial "new" under TSCA Section 5(a)(1)?

(i) Under TSCA § 8(b)(1) EPA, must "compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States." This list is the "TSCA Inventory".

(ii) Generally, "new" substances, *i.e.*, chemical substances not on the TSCA Inventory, cannot be manufactured without a TSCA § 5(a)(1) PMN.

(iii) Whether a substance is "new" under TSCA will depend on its "particular molecular identity." TSCA § 3(2)(A), 15

U.S.C. § 2602(2)(A). Under traditional TSCA practices, nanoscale versions of existing chemical substances are described identically, and thus, having the same "particular molecular identity," would not be "new" chemical substances.

(iv) As noted above, however, nanomaterials having the same chemical structure as chemicals already listed on the Inventory often have, because of their size, different physical characteristics and risk profiles than their conventional-size chemical cognates. Under EPA's traditional interpretation of "molecular identity," therefore, these nanomaterials would escape TSCA § 5(a)(1)'s requirements.

(v) The notion of a "particular molecular identity" is nowhere defined, but the term "particular molecular identity" may be broad enough to encompass physical and other properties in addition to molecular structure in the determination of whether a chemical substance is new.[2]

b. When do nanomaterials qualify as significant new uses of existing chemical substances subject to significant new use rules (SNUR) under TSCA § 5(a)(2)?

(i) When EPA has defined a particular use of a chemical substance as a significant new use, then any person who intends to manufacture or process the chemical substance for that new use must notify EPA 90 days prior to undertaking the new use.

(ii) How to know when a use is "new"?

(a) EPA has not clearly articulated when a use is "new": "if a substance is being used in a particular manner at the time that a SNUR is proposed, that specific use is not 'new' and cannot be the subject of a SNUR."

(b) According to EPA's definition, the longer the agency waits to issue SNURs for nanomaterials, the more nanomaterials may avoid regulation under TSCA.

[2] *See* Regulation of Nanoscale Materials, at 9.

C. CERCLA/Clean Water Act/Clean Air Act[3]

1. CERCLA

a. Introduction

(i) CERCLA's provisions regarding "hazardous substances" may be broad enough to cover nanomaterials. The difficulty is in determining, as a factual matter, whether the nanomaterials are indeed hazardous.

(ii) CERCLA's retroactive applicability provisions may be an important tool in designating liability and response responsibility if EPA determines in the future that certain nanomaterials may be hazardous to human health or the environment. These provisions also may give nanotechnology producers and manufacturers an extra incentive to ensure that their products are safe.

b. Release reporting of nanomaterials as "hazardous substances"

(i) "Hazardous substances"

(a) CERCLA § 102(a), 42 U.S.C. § 9602(a), gives EPA authority to regulate as "hazardous" substances "which, when released into the environment may present substantial danger to the public health or welfare of the environment."

(b) CERCLA's definition of "hazardous substance," § 101(4), may be broad enough to include nanomaterials because it includes substances deemed hazardous under other statutory regimes (*e.g.*, TSCA, RCRA, CAA, CWA).

(ii) "Reportable quantities" of hazardous substances (CERCLA §§ 102, 103)

[3] These summaries were based in large part on three June 2006 briefing papers by ABA SEER: (1) "CERCLA Nanotechnology Issues," *available at* http://www.abanet.org/environ/nanotech/pdf/CERCLA.pdf; (2) "Nanotechnology Briefing Paper: Clean Water Act," *available at* http://www.abanet.org/environ/nanotech/pdf/CWA.pdf; and (3) "ABA SEER CAA Nanotechnology Briefing Paper," *available at* http://www.abanet.org/environ/nanotech/pdf/CAA.pdf.

(a) CERCLA requires reporting of releases of hazardous substances that exceed "reportable quantity" thresholds.

(b) The assumption behind the reportable quantity threshold has been that greater amounts of materials pose greater risk. Where, as with nanotechnology, the scale of material is so small, current reportable quantity thresholds may be a poor fit.

2. Clean Water Act

a. Introduction

(i) One of the goals of the CWA is "the elimination of the discharge of pollutants into navigable waters."

(ii) The term "pollutant," which includes solid waste, incinerator residue, chemical wastes, and biological materials, would appear to be defined broadly enough under CWA § 102(6) to include nanoparticles. *See* 33 § 1362(6).

(iii) But, EPA would likely need to show that nanoparticles have a potential adverse effect on human health or the environment before the Clean Water Act could apply.

b. Effluent guidelines

One challenge to applying effluent guidelines for point source discharges under CWA § 301, 33 U.S.C. § 1311, is determining the best available control technology (BACT).

c. Permitting

Under the permit provisions of NPDES, CWA § 402, "EPA will be required to assemble a reasonable database covering all known effects of specified nanoparticles in water bodies."[4] Also, "EPA will have to evaluate appropriate discharge control mechanisms to determine if they are technologically viable and economically achievable."[5]

3. Clean Air Act

[4] Nanotechnology Briefing Paper: Clean Water Act, at 5.

[5] *Id.* at 6.

a. The ABA SEER authors argue that "EPA must recognize and adapt to a new form of 'quantification' as number, rather than mass. Currently, all CAA standards are based upon mass limitations. . . . It does not appear as though nanoparticulate can be effectively regulated in terms of mass because each particle potentially subject to regulation has an insubstantial weight not practically quantifiable using ordinary methods."[6]

b. NAAQS: criteria pollutants are regulated in terms of mass per volume of air: "it is unlikely that regulation of engineered nanoparticles based on mass limitations would be sufficient or adequate," and the CAA does not limit regulation only in terms of mass.[7] Number is also a possible means of regulation.

D. FIFRA

1. FIFRA, the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 *et seq.*, regulates pesticide products.

2. In nanoscale form, silver and other materials have antimicrobial and pesticide properties.

3. In November 2006 EPA announced that, under FIFRA, it would begin to regulate nanoscale silver materials if they are used as a pesticide. Nanosilver has been used in products, such as washing machines, as an antimicrobial.

E. Food and Drug Act[8]

1. Introduction and Agency Activity

a. Basic regulatory authority for the Federal Food and Drug, and Cosmetic Act: anything that has an "effect on the human body." This is very broad; nanotechnology that can be shown to have an effect on the human body could possibly be covered under the Act.

---

[6] CAA Nanotechnology Briefing Paper, at 4.

[7] *Id.* at 16.

[8] This summary is based on several PowerPoint presentations by Don Beers at Arnold & Porter LLP and by the FDA itself: (1) "FDA Considerations for Regulation of Nanomaterial Containing Products," *available at* http://www.fda.gov/NANOTECHNOLOGY/NIST_meeting_Houston_01-06.ppt; (2) "FDA Perspective on Nanomaterial-Containing Products, *available at* http://www.fda.gov/NANOTECHNOLOGY/powerpoint_conversions/May05_files/800x600/slide1.html; and (3) Don Beers, "Nanotechnology—What is Happening at FDA of Relevance to the Drug, Device and Biotech Industry?"

b. A material meets the FDA definition of nanotechnology only if it contains all of the following:

(i) Products that are at the atomic or macromolecular levels, and where at least one dimension that affects the functional behavior of the product is in the length scale range of approximately 1-100 nanometers;

(ii) Creating and using structures, devices, systems that have novel properties because of their small size; and

(iii) Ability to control or manipulate at the atomic scale.

c. FDA has approved many products with nanosize particulate materials, and many drugs are expected to go through a nanosize phase during the process of absorption into the body.

d. In May 2006 the International Center for Technology Assessment (ICTA) and others petitioned FDA for various relief related to nanotechnology, including clarification of the agency's stance regarding nanoproducts, amendment to FDA regulations to include nanotechnology terminology and comprehensive nano-product regulations, including non-specific toxicity testing and mandatory nano-product labeling.

e. FDA formed an internal Nanotechnology Task Force in August 2006 to address health and safety concerns possibly raised by nanotechnology.

f. FDA believes that its current preclinical system is adequate to address safety concerns posed by nanotechnology.

g. The Center for Drug Evaluation and Research (CDER) is not anticipating any new preclinical or CMC guidance documents regarding nanomaterials in the near future.

2. <u>Regulatory Overview</u>

a. FDA regulates products on a product-by-product basis

(i) Pre-market approval

(ii) Market clearance

(iii) Post-market review

b. General considerations for FDA regulation of nanotechnology products

(i) Characterization

(a) What are the forms in which particles are presented to host, cells, and organelles?

(b) What are the standard tools used for characterization of nanoparticle properties?

(c) What are validated assays to detect and quantify nanoparticles in drug product and tissues?

(d) How do we determine long and short-term stability of nanomaterials (in various environments)?

(e) What are the critical physical and chemical properties, including residual solvents, process variables, impurities, and excipients?

(f) How do physical characteristics impact product quality and performance?

(g) What are the critical steps in the scale-up and manufacturing process for nanotechnology products?

(h) How are characterization and manufacturing procedures assessed for “personalized therapies”?

(ii) Safety

(a) As particle size gets smaller, there may be size-specific effects on activity.

(b) Route-specific issues

(c) Differences in the ADME profile, for nanoparticles versus larger particles of the same drug?

(iii) Environmental impact

(a) Can nanoparticles be released into the environment following human and animal use?

(b) What methodologies would identify the nature, and quantify the extent of nanoparticle release into the environment?

(c) What might be the environmental impact on other species?

c. Special testing requirements for nanotechnology products?

(i) Currently there are no testing requirements that are specific to nanotechnology products

(ii) If research identifies toxicological risks that are unique to nanomaterials, additional testing requirements may become necessary

(iii) The review process for products containing nanomaterials will be essentially the same as that used for other products that do not contain nanomaterials.

3. Challenges for Nanotechnology Regulation under the Food and Drug Act

a. Safety assessment

(i) Adequacy of current toxicological screens for nanoscale materials

(ii) Potential for novel, unanticipated reactions

(iii) Environmental consequences of medical use

b. Efficacy—No experience with clinical testing

c. Industrialization

(i) Understanding physical and chemical parameters that are crucial to product performance

(ii) Developing test methods and specifications to control product/process

(iii) Scale-up to mass production

(iv) Lack of reference materials, standards, and manufacturing standardization

F. Consumer Product Safety Commission[9]

[9] *See generally* "Nanomaterials Statement," *available at* http://www.cpsc.gov/library/cpscnanostatement.pdf, and "Nanotechnology and the CPSC," by

Footnote continued on next page

1. Introduction

a. Although there are no express provisions under the Consumer Product Safety Act governing nanomaterials, "the potential safety and health risks can be assessed under existing CPSC statutes," including the Consumer Product Safety Act (CPSA), and the Federal Hazardous Substances Act (FHSA).

b. 2007 is only the second year in which CPSC budgeted for nanotechnology. CPSC stated that "[i]n 2007, staff will review scientific and economic information to investigate the use of nanotechnology in consumer products and its potential health implications. The staff will also collaborate with other Federal agencies to determine appropriate methodologies for analyzing nanomaterials. A draft status report with recommendations for future activities will be prepared."[10]

2. Consumer Product Safety Act

a. Under the CPSA, CPSC staff determine whether a defective product containing nanomaterials "creates a substantial risk of injury to the public."

b. Producers of nanomaterials have the same obligations under the CPSA as other producers to report to the CPSC if products containing nanomaterials "contain a defect would could create a substantial product hazard or create an unreasonable risk of serious injury or death."

c. CPSC is currently unable to make any general statements about potential consumer exposures or health effects that may result from exposure to nanomaterials during consumer use and disposal.

d. The difficulty with nanotechnology is assessing whether there are different health risks posed by the small size of nanomaterials used in consumer products. A CPSC staff member stated that "[i]dentifying any potential health hazards from a specific product will require characterization of the materials to which a consumer is exposed during product use, including assessment of the size distribution of the materials released. Once the exposure has been characterized, toxicological data that is appropriate for the particle

---

Footnote continued from previous page
Jeff Bromme, 33 Product Safety & Liability Reporter 269 (March 14, 2005), *available at* http://www.arnoldporter.com/docs/resources/Article-Nanotechnology_and_the_CPSC(2005).pdf.

[10] http://www.cpsc.gov/CPSCPUB/PUBS/REPORTS/2007OperatingPlan.pdf.

sizes represented in the exposure assessment will be used in any assessment of health risks."

3. Federal Hazardous Substances Act

a. The FHSA regulates "hazardous substances," defined under a two-part test: (1) The substance must be toxic, corrosive, an irritant, a strong sensitizer, flammable or combustible, or generate pressure through decomposition, heat, or other means; and (2) the substance "may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." 15 U.S.C. § 1261(f)(1)(A).

b. If substance is characterized as a "hazardous substance" under FHSA, it must carry labeling with words like "WARNING" or "CAUTION," along with an affirmative statement of the principal hazard or hazards." 15 U.S.C. § 1261(p).

c. Failure to carry the proper labeling may result in civil and criminal penalties, as may continuing to market banned hazardous substances (*i.e.*, hazardous substances for which no labeling is sufficient to protect the public health). Under the FHSA, CPSC may also recall or seize mislabeled or banned products deemed "hazardous substances."

d. As with other statutes, there remains a factual question of whether nanomaterials meet the FHSA's definition of a "hazardous substance."

G. NIOSH/OSHA[11]

1. Introduction

a. NIOSH was created pursuant to the Occupational Safety and Health Act, and it is "the federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness."

b. The general duty provisions of the Occupational Safety and Health Act, 29 U.S.C. § 654, may be sufficiently broad to encompass

[11] *See generally* "Progress Toward Safety Nanotechnology in the Workplace," *available at* http://www.cdc.gov/niosh/docs/2007-123/pdfs/2007-123.pdf, and "Strategic Plan for NIOSH Nanotechnology Research," *available at* http://www.cdc.gov/niosh/topics/nanotech/pdfs/NIOSH_Nanotech_Strategic_Plan.pdf.

workplace regulation of nanotechnology:

(a) Each employer—

(1) shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees;

(2) shall comply with occupational safety and health standards promulgated under this chapter.

(b) Each employee shall comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to this chapter which are applicable to his own actions and conduct.

2. Update from NIOSH's "Progress Toward Safe Nanotechnology in the Workplace"

a. NIOSH established the Nanotechnology Research Center (NTRC) in 2004 to develop guidance to address the occupational safety and health of workers exposed to nanomaterials. In February 2007 NIOSH then published "Progress Toward Safe Technology in the Workplace," which details NTRC work since its founding.

b. Four goals for NIOSH Nanotechnology research

(i) Understand and prevent work-related injuries and illnesses potentially caused by nanoparticles and nanomaterials

(ii) Conduct research to prevent work-related injuries and illnesses by applying nanotechnology products

(iii) Promote health workplaces through interventions, recommendations, and capacity building

(iv) Enhance global workplace safety through national and international collaborations on nanotechnology

c. NIOSH understands its role in the occupational safety and health of nanotechnology workers in the following way:

"A complete process for managing occupational safety and health implications during the development of new technologies and materials consists of a set of progressive elements: identifying

> and characterizing the hazard, assessing the extent of exposure, characterizing the risk, and developing control and management procedures. As exposure assessment data become available, a determination can be made whether or not an occupational risk exists, and if so, the risk can be assessed and characterized. . . . The problem is that it is difficult to proceed in a classic step by step fashion from hazard identification to risk management because each day, more workers may be exposed to nanomaterials as nanotechnology permeates industrial and commercial sectors. Thus the challenge is to conduct research to address the gaps in knowledge while at the same time drawing on all available information to provide interim guidance."[12]

d. NIOSH has concluded that there are no current occupational risks posed by nanotechnology:

> "It appears that nanomaterials that are presently manufactured have no major physical features that would make them behave differently from fine and ultrafine particles in terms of the ability to control them in the workplace. However, the limits of this assumption need continued evaluation."[13]

e. NIOSH is conducting research in ten "critical topical areas":

(i) Toxicity and internal dose

(ii) Risk assessment

(iii) Epidemiology and surveillance

(a) Determining the relative importance of particular size as a cause of the observed health effect.

(b) Determining whether nanoparticles move throughout the body and potentially affect organ systems other than the one through which they entered the body.

---

[12] NIOSH, Progress Toward Safe Nanotechnology, at 3-4.

[13] *Id.* at 4.

(iv) Engineering controls and personal protective equipment

(a) "A lack of exposure standards for nanomaterials currently exists. Therefore, to evaluate the need and effectiveness of engineering controls an alternative rationale is required."[14]

(b) "Minimizing occupational exposure to the lowest possible level is the most prudent approach for controlling materials of unknown toxicity, such as nanomaterials. Typically, these approaches include substituting a less toxic material if possible, enclosing the hazardous process, removing workers from the exposure by automating the process, isolating workers from the hazard, and/or utilizing local exhaust ventilation where nanomaterials are handled. Improved control approaches will become more evident as the risks of exposure to nanomaterials are better understood."[15]

(c) "When engineering controls are not feasible in reducing exposure to nanoparticles, personal protective equipment such as respirators, protective clothing, and gloves should be considered. . . . A concern has been raised that nanoparticles could pass through the protective barrier of PPE at a higher rate than larger particles due to their smaller size and unique properties. Therefore, NTRC is conducting research to address this concern."[16]

(v) Measurement methods

(a) Evaluate methods to measure dust concentrations to determine if the same methods can be used to measure nanomaterials

(b) Develop and test methods to evaluate their accuracy of measuring airborne nanomaterials in the workplace

---

[14] *Id.* at 28.

[15] *Id.*

[16] *Id.*

(vi) Exposure assessment

"Several exposure assessment methods are being used to characterize exposures including methods that will identify the size, shape, structure, and chemistry of airborne nanomaterials."[17]

(vii) Fire and explosion safety

(viii) Recommendations and guidance

Approaches to Safe Nanotechnology: "draws from the ongoing NTRC assessment of the potential health risks from exposure to nanomaterials and the best practices for minimizing worker exposure."

(ix) Communication and education

NIOSH nanotechnology topic page, http://www.cdc.gov/niosh/topics/nanotech

(x) Applications

3. Other NIOSH work related to nanotechnology

a. Published preliminary guidelines for the safe workplace handling of nanotechnology, "Approaches to Safe Nanotechnology."[18]

b. Joined with EPA to stimulate extramural research

c. Partnered with UK for international symposium on nanotech.

d. Begin developing documentation that will recommend effective, practical ways to control occupational exposures to nanomaterials pending research for more definitive data.

II. INTERNATIONAL REGULATION OF NANOTECHNOLOGY

A. Introduction

1. There are currently no international agreements specifically regulating nanotechnology. There are many calls for the harmonization of characterization, measurement, and risk assessment methods for

[17] *Id.* at 40.

[18] *Available at* http://www.cdc.gov/niosh/topics/nanotech/safenano/.

nanotechnologies, however. The United Nations Environment Program (UNEP) and Organization for Economic Cooperation and Development (OECD) work in this area is discussed, as is the possible application of WTO provisions to nanotechnology.

2. Several countries have started their own nanotechnology research and development programs. Without international cooperation, inconsistent regulatory regimes could develop between countries.

3. Although there are no comprehensive "hard" international regulatory regimes, there are numerous efforts at the national, regional, and international levels to develop new "soft" law and risk governance mechanisms for nanotechnology, including guidelines, best practices, voluntary reporting schemes, and risk governance frameworks.

B. <u>UN protocols</u>

1. In its GEO year book for 2007, UNEP identified nanotechnology as an important environmental issue needing further consideration.[19]

2. UNEP identified several policy considerations for nanotechnology, including:

   a. Standardized nomenclature and test protocols to ensure maximum comparability of test results and to facilitate generalization of findings

   b. Foster cooperation between public and private sectors, between developed and developing countries, and among developing countries

   c. Sensitize national regulatory and environmental agencies to the potential opportunities and risks of nanotechnology

   d. Support and research of nanotechnology applications that contribute to sustainable development

   e. Evaluate the potential environmental and human health impacts of engineered nanomaterials, giving priority to those that are already being mass-produced and potentially released into the environment.

[19] *See* Emerging Challenges: Nanotechnology and the Environment, *available at* http://www.unep.org/geo/yearbook/yb2007/PDF/7_Emerging_Challenges72dpi.pdf.

f. Identify, evaluate, and share private sector risk management methods and best practices for nanoscale materials (including worker safety and material handling procedures)

g. Mobilize the existing knowledge of and lessons learned from chemical policies related to environmental and health issues, to help address nanotechnology challenges

h. Educate the public about the benefits and risks of nanotechnology.

i. Encourage cooperation between governments and intergovernmental organizations to address and share information on the impact of nanotechnologies on the environment and human health.

3. In conclusion, UNEP stated that "it is not clear whether current regulatory frameworks are adequate to deal with the special characteristics of nanotechnology. To date, no government has developed a regulatory framework specific to nanotechnology."

C. World Trade Organization: Applicability of Sanitary and Phytosanitary Measures to Nanotechnologies?

1. Article 20 of WTO "allows governments to act on trade in order to protect human, animal, or plant life or health, provided they do not discriminate or use this as disguised protectionism."

2. As a result of Article 20, WTO passed the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), which applies to all "sanitary and phytosanitary measures which may, directly or indirectly, affect international trade." SPS Agreement Article 1.1.

3. The SPS defines "sanitary or phytosanitary measures" as "any measure applied to protect animal or plant life or health from," among other things, "risks arising from additives, contaminants, toxins, or disease-causing organisms."

4. The SPS called on nations to "base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist."

5. Because of the lack of international standards regarding nanotechnology, countries have little guidance on whether their own regulations conform to those standards.

6. No SPS disputes related to nanotechnology have been brought before the WTO. Given the broad scope of the SPS, however, it is conceivable that such disputes could be governed by the SPS.[20]

D. Organization for Economic Cooperation and Development (OECD)[21]

1. The OECD is the current global "center of gravity" for international law, policy, and regulatory developments related to nanotechnology.

2. In October 2006 OECD had its first Meeting of the Working Party on Manufactured Materials (WPMM), which deals primarily with the environmental, health, and safety (EHS) issues of nanotechnology. The second meeting is scheduled for April 2007. No concrete regulations have as of yet been recommended.

3. The WPMM program is divided into three work areas:

   a. Work Area 1: Identification, Characterization, Terminology, and Standards

      (i) Provide the basis for establishing criteria for the identification of nanomaterials;

      (ii) Develop a general working definition of nanomaterials within the context of human health and environmental safety for use by the WPMM; and

      (iii) Harmonize standard reference materials and working definitions of manufactured nanomaterials among member countries.

   b. Work Area 2: Testing Methods and Risk Assessment

      (i) Harmonize methods for human health and environmental testing of manufactured nanomaterials;

      (ii) Identify priorities for reviewing, developing or modifying test guidelines for the assessment of nanomaterials; and

      (iii) Develop agree risks assessment approaches.

---

[20] *See* James D. Thayer, *The SPS Agreement: Can It Regulate Trade in Nanotechnology*, 2005 Duke L. & Tech. Rev. 15 (2005).

[21] *See generally* OECD's website on Safety of Manufactured Nanomaterials, *at* http://www.oecd.org/topic/0,2686,en_2649_37015404_1_1_1_1_37465,00.html.

c. Work Area 3: Information sharing, cooperation and dissemination

(i) Facilitate harmonization of regulatory practices in the chemicals regulatory area; and

(ii) Initiatives to cooperate and share information on risk assessment and exposure measurements, voluntary schemes programs, and research strategies on manufactured nanomaterials.

d. OECD also has created a Working Party on Nanotechnology, which deals with other nanotechnology-related issues besides EHS, including innovation and basic research. This Working Party is emerging as a global hub for nanotechnology policy among the 30 OECD member countries and key emerging economies.

E. <u>European Union</u>

1. The European Union (EU) maintains a website dedicated to nanotechnology-related issues.[22]

2. The EU Commission released "Nanosciences and Nanotechnologies: An Action Plan for Europe 2005-2009."[23] With regard to public health, safety, environmental and consumer protection within the EU, the Commission resolved to:

a. Identify and address safety concerns by requesting the Scientific Committee on Emerging and Newly Identified Health Risks to provide an opinion on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious nanotechnology products;

b. Promote safe and cost-effective measures to minimize exposure to manufactured nano-scale entities;

c. Develop with member states, international organizations, and others terminology, guidelines, models, and standards for risk assessment throughout the entire lifecycle of nanotechnology products; and

d. Examine and propose EU regulations in light of (i) toxicity thresholds, (ii) measurement and emission thresholds, (iii) labeling

[22] *See* http://cordis.europa.eu/nanotechnology/.

[23] *Available at* http://ec.europa.eu/research/industrial_technologies/pdf/nano_action_plan_en.pdf, in 2005.

requirements, (iv) risk assessment and exposure thresholds, and (v) production import thresholds, below which a substance may be exempted from regulation.

3. With regard to international cooperation, the Commission resolved to (1) intensify dialogue with other countries with the goal of adopting a code of good conduct for the responsible development and use of nanotechnology, and (2) address nomenclature, metrology, and common approaches to risk assessment.

4. The European Parliament approved of the action plan on September 28, 2006.[24]

5. In its October report to the OECD[25], the European Commission detailed some of its recent research and regulatory work regarding nanotechnology:

   a. Performing a regulatory inventory covering EU regulatory frameworks applicable to nanomaterials to examine and propose, where appropriate, adaptations of EU regulations in relevant sectors.

   b. With regard to the chemicals regulatory area, the EU decided, in ways that track similar decisions EPA could make under TSCA, that:

      (i) The decisive criterion of whether a nanomaterial is a new or existing substance is the same as for all other substances;

      (ii) Nanomaterials with specific properties may require a different classification and labeling compared to bulk material; and

      (iii) Further review of the applicability of current testing methods and risk assessment methods should be carried out.

[24] *See* http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P6-TA-2006-0392+0+DOC+PDF+V0//EN.

[25] *available at* http://www.oecd.org/dataoecd/38/20/37774205.pdf.