# APPENDIX 1: RELEVANT FEDERAL AUTHORITIES

The provisions found in the following appendix are a sampling of the federal statutory authorities that may be used to regulate nanotechnology and do not constitute an exhaustive list. There are many regulations promulgated pursuant to these statutes that may be applicable to nanotechnology, including some regulations mentioned specifically in section II above, but that are not included here.

## CLEAN AIR ACT

### CAA § 109; 42 U.S.C. § 7409: Primary and Secondary National Ambient Air Quality Standards (NAAQS)

The Administrator is to promulgate primary NAAQS necessary to protect the "public health" allowing for an adequate margin of safety. The Administrator is also to promulgate secondary NAAQS to protect the "public welfare." "Public welfare" is defined to include "effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate." 42 U.S. C. § 7602(h), CAA § 302(h).

CAA regulations established NAAQS for fine particulates of less than 2.5 micrometers. These standards are applied through state implementation plans.

### CAA § 112; 42 U.S.C. § 7409: Emission Standards for Hazardous Air Pollutants (HAPs)

The CAA lists 189 HAPS and directs EPA to review the list and add pollutants "which present, or may present, through inhalation or other routes of exposure, a threat of adverse human health effects . . . or adverse environmental effects whether through ambient concentrations, bioaccumulation, deposition, or otherwise." EPA is required to promulgate emissions standards for categories and subcategories of major and area sources of HAPs.

## CLEAN WATER ACT

### FWPCA § 301(a); 33 U.S.C. § 1311(a): Pollutant Discharges

Except as permitted by the CWA, the "discharge of any pollutant" is unlawful.

**FWPCA § 301(b)(1)(A) & b(2); 33 U.S.C. § 1311(b)(1)(A) & (b)(2): Effluent Limitations**

Effluent limitations for point sources (other than publicly owned treatment works) shall require the application of "best practicable control technology." If any source discharges into a publicly owned treatment work (POTW), the source must satisfy applicable pretreatment requirements and requirements concerning toxic pollutants. Point source toxic and nonconventional pollutants must comply with effluent limitations requiring "best available technology economically achievable."

**FWPCA § 301(f); 33 U.S.C. § 1311(f): Specific Pollutant Discharges**

It is unlawful to discharge into navigable waters "any radiological, chemical, or biological warfare agent, any high-level radioactive waste, or any medical waste."

**FWPCA § 402(a)(1); 33 U.S.C. § 1342(a)(1): NPDES Permits**

The Administrator is authorized to issue permits for the discharge of any pollutant or combination of pollutants on the condition that the discharge will meet the applicable requirements and standards of the Act.

**FWPCA § 306(b)(1)(B); 33 U.S.C. § 1316(b)(1)(B): New Source Performance Standards**

The Administrator is to propose and publish regulations establishing federal standards of performance for new sources.

**FWPCA § 307(a); 33 U.S.C. § 1317(a): Toxic and Pretreatment Effluent Standards**

The Administrator is to identify toxic pollutants for which the application of best available technology is required. The Administrator may establish effluent standards with additional requirements on discharges of a toxic pollutant. The Administrator is also to promulgate pretreatment standards for the introduction of pollutants into POTWs for "those pollutants which are determined not to be susceptible to treatment by such treatment works or which would interfere with the operation of such treatment works."

**FWPCA § 504(a); 33 U.S.C. § 1365(a): Emergency Powers**

Upon receipt of evidence that "a pollution source or combination of sources is presenting an imminent and substantial endangerment to the health of persons or to the welfare of persons where such endangerment is to the livelihood of such person" the Administrator may sue for immediate restraint of anyone causing or contributing to the pollution, or take any other necessary action.

## COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION AND LIABILITY ACT ("SUPERFUND")

### CERCLA § 103; 42 U.S.C. § 9603: Notification Requirements

Persons who handle, store or dispose of hazardous substances are subject to notification requirements concerning released substances.

### CERCLA § 104(a); 42 U.S.C. § 9604(a): Removal and Remediation Authority

When a hazardous substance or pollutant that may present an "imminent and substantial danger to the public health or welfare" is released or about to be released, the President my remove such substance, provide for long-term remedial action, or take any other action necessary to protect the public health or welfare or the environment.

### CERCLA § 107(a), (o); 42 U.S.C. § 9607(a), (o): Liability; De Micromis Exemption

Owners and operators of facilities at which hazardous substances are located, persons who arrange for the disposal of hazardous substances, and persons who accept hazardous substances for transport to disposal and treatment facilities are liable for response costs incurred by the government consistent with the national contingency plan, natural resource damages and the costs of certain health assessments or health effects studies. If the potentially liable party can demonstrate that only a *de micromis* amount of hazardous substance was involved (as defined by regulation), the party may be exempt from liability. The exemption does not apply if it is determined that the materials containing hazardous substances contributed significantly to the cost of the response action or natural resource restoration.

## NATIONAL ENVIRONMENTAL POLICY ACT

### NEPA § 102(2)(C); 42 U.S.C. § 4332(2)(C): Environmental Impact Statements

Federal agencies are required to prepare a detailed statement on the environmental impacts of "major Federal actions significantly affecting the quality of the human environment."

### NEPA § 102(1); 42 U.S.C. § 4332(1): Laws Interpreted and Administered in Accordance with the National Environmental Policy

Congress mandated that, "to the fullest extent possible," "the policies, regulations, and public laws of the United States shall be interpreted in accordance with the policies" found in section 101. In section 101, Congress declared that the national environmental policy is "to create and maintain conditions under which man and nature can exist in productive harmony, and fulfill the social, economic, and other requirements of present and future generations of Americans." To carry out this policy, it is the responsibility of the Federal Government "to use all practicable means...to improve and coordinate Federal plans, functions, programs, and resources to the end that the Nation may:" (1) protect the interests of future generations; (2) assure the "safe, healthful, productive, and esthetically and culturally pleasing surroundings;" (3) attain the beneficial use of the environment; (4) preserve the national heritage and maintain "an environment which supports diversity and variety of individual choice;" (5) achieve widespread prosperity; and (6) "enhance the quality of renewable resources" and recycle depletable resources.

**NEPA § 102(2)(E); 42 U.S.C. § 4332(2)(E): Appropriate Alternatives**

In addition to the requirement to conduct an environmental impact assessment, all agencies of the Federal Government shall "study, develop, and describe appropriate alternatives" to any action in which there are "unresolved conflicts concerning alternative uses of available resources."

## RESOURCE CONSERVATION AND RECOVERY ACT

**RCRA § 3001(a); 42 U.S.C. § 6921(a): Hazardous Waste Regulation**

EPA is to determine which hazardous wastes should be subject to Subtitle C by identifying "the characteristics of hazardous waste" and by listing specific substances as hazardous wastes.

**RCRA § 3002(a); 42 U.S.C. § 6922(a): Standards for Generators of Hazardous Waste**

EPA is to promulgate standards applicable to generators of hazardous waste as necessary "to protect human health and the environment." These standards are to include requirements for recordkeeping practices, labeling practices, appropriate containers, and tracking of hazardous waste.

**RCRA § 3003(a); 42 U.S.C. § 6923(a): Standards for Transporters of Hazardous Waste**

EPA is to promulgate standards applicable to transporters of hazardous waste as necessary "to protect human health and the environment." These standards are to

include requirements for recordkeeping practices, labeling, compliance with the manifest system and delivering waste to permit-holding treatment, storage, and disposal (TSD) facilities designated on the manifest form.

**RCRA § 3004(a), (o); 42 U.S.C. § 6924(a), (o): Standards for Owners and Operators of Hazardous Waste Treatment, Storage and Disposal Facilities**

EPA is to promulgate standards applicable to owners and operators of facilities for the treatment, storage, or disposal of regulated hazardous waste that are necessary "to protect human health and the environment." Standards for TSD facility owners and operators must include requirements for recordkeeping; manifesting; operating methods, techniques, and practices; facility location, design, and construction; contingency plans to minimize unanticipated facility damage; maintenance, personnel training, and financial responsibility; and permit compliance. EPA is to promulgate regulations for the monitoring and control of air emissions at hazardous waste TSD facilities as necessary "to protect human health and the environment."

**RCRA § 3005(a); 42 U.S.C. § 6925(a): Permit Requirements for TSD facilities**

EPA is to promulgate regulations requiring owners and operators of existing and planned TSD facilities to obtain permits and prohibiting unpermitted treatment, storage, or disposal of characteristic and listed hazardous waste.

## TOXIC SUBSTANCES CONTROL ACT

**TSCA § 3(7); 15 U.S.C. § 2602(7): Definition of "Manufacture"**

The term "manufacture" includes the import of chemical substances.

**TSCA § 3(9); 15 U.S.C. § 2602(9): Definition of "New Chemical Substance"**

"The term 'new chemical substance' means any chemical substance which is not included in the chemical substance list compiled and published under Section 2607(b) of this title."

**TSCA § 4(a); 15 U.S.C. § 2603(a): Testing of Chemicals**

If the Administrator finds that: (1) "the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or any combination of such activities, may present an unreasonable risk of injury to health or the environment;" (2) "there are insufficient data;" and (3) testing "is necessary to develop such data," then the Administrator by rule can require further testing.

**TSCA § 5(a)(1); 15 U.S.C. § 2604(a)(1): 90-day Notice Requirement**

Before manufacturing a new chemical substance or an existing chemical substance for a "significant new use," the manufacturer must submit a notice to the Administrator 90 days prior to manufacture.

**TSCA § 5(a)(2); 15 U.S.C. § 2604(a)(2): Determination of Significant New Use**

In determining whether a use of a chemical substance is a significant new use that requires notification, the Administrator will consider relevant factors, including: "(A) the projected volume of manufacturing and processing of a chemical substance, (B) the extent to which a use changes the type or form of exposure of human being or the environment to a chemical substance, (C) the extent to which a use increases the magnitude and duration of exposure of human being or the environment to a chemical substance, and (D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance."

**TSCA § 5(e); 15 U.S.C. § 2604(e): Restrictions on Manufacture or Use**

If the information in the premanufacture notice received is insufficient to permit "a reasoned evaluation of the health and environmental effects of a chemical substance," the Administrator may issue a proposed order to restrict manufacture or use pending development of further information.

**TSCA §5(f); 15 U.S.C. § 2604(f): Unreasonable Risks**

Prior to the expiration of the notification period, if the Administrator finds that there is a "reasonable basis to conclude" that the chemical substance poses "an unreasonable risk of injury to health or environment," he or she can limit the amount of the substance that can be manufactured or "issue a proposed order to prohibit [its] manufacture."

**TSCA § 5(h); 15 U.S.C. § 2604(h): Exemptions**

A manufacturer is exempt from the testing requirements of this section if the chemical substance is to be manufactured "only in small quantities (as defined by the Administrator by rule)" for "scientific experimentation" or "chemical research." The Administrator may also, "upon application and by rule," exempt any manufacturer from the requirements of this section if he determines that the chemical substance "will not present an unreasonable risk of injury to health or environment."

**TSCA § 6(a); 15 U.S.C. § 2605(a): Existing Chemicals**

If the Administrator finds that there is a "reasonable basis to conclude" that the chemical substance will "present an unreasonable risk of injury to health or the environment," he or she can, by rule, "using the least burdensome requirements," prohibit the manufacture of the substance, limit the amount produced or distributed, require that the substance be marked with warnings or instructions, require that the manufacturer keeps records, or regulate the use of such substance.

**TSCA § 8(a); 15 U.S.C. § 2607(a): Reporting and Record Keeping**

The Administrator has the authority to require each person who manufactures chemical substances to maintain records and submit reports to the Administrator.

**TSCA § 8(c); 15 U.S.C. § 2607(c): Record of Significant Adverse Reaction to Health or Environment**

"Any person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture" and those records must be kept for a prescribed period of time.

**TSCA § 8(d); 15 U.S.C. § 2607(d): Submission of Health and Safety Studies**

Manufacturers of chemical substances must submit to the Administrator copies of health and safety studies conducted by or for the manufacturer or "reasonably ascertainable by him."

**TSCA § 8(e); 15 U.S.C. § 2607(e): Substantial Risk of Injury to Health or Environment**

If the manufacturer "obtains information" that the chemical substance he manufactures presents a "substantial risk of injury to health or the environment," he must "immediately inform" the Administrator of such information.

**TSCA § 12; 15 U.S.C. § 2611: Export of Chemical Substances**

The requirements of this statute do not apply to chemical substances intended for export unless the Administrator finds that the substance presents "an unreasonable risk of injury to health within the United States or to the environment of the United States." However, the exporter must submit a notice to the Administrator if he intends to export a chemical substance that would have been subject to the

statute's requirements so that the Administrator can make available to the government of the importing country any data on that substance.

**TSCA § 18; 15 U.S.C. § 2617: Federal Preemption of State Law under TSCA**

State regulation of the testing of chemical substances and mixtures is generally preempted by federal law. State regulations governing premanufacture notice and regulation of hazardous chemicals are also generally preempted unless such regulation is "identical' to the federal regulation, is adopted pursuant to the Clean Air Act or other federal law, or "prohibits the use of such substance or mixture in such State or political subdivision (other than its use in the manufacture or processing of other substances or mixtures)."

**TSCA § 9; 15 U.S.C. Section § 2608: Preemption of EPA Regulation**

Regulation of hazardous chemical substances and imminent hazards by EPA pursuant to TSCA may be preempted by action of another agency under other federal law. In order for such preemption to occur, the Administrator of EPA must first submit a report to the other federal agency describing the risk and requesting determination of whether the risk may be prevented by action under the other federal law. If the agency receiving the report determines that the activities do not present the risk described in the report or initiates action to protect against such risk, then action by the Administrator to regulate hazardous chemical substances or imminent hazards under TSCA sections 6 & 7 is preempted.