Executive Office of the President
Council on Environmental Quality

Executive Office of the President
Office of Science and Technology Policy

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MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

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SUBJECT: Principles for Nanotechnology Environmental, Health, and Safety Oversight

Nanotechnology is built on recent scientific advances that allow us to see, measure, and control matter at the scale of atoms and molecules. Such capabilities are enabling development of a variety of new products and processes with novel and potentially transformational characteristics. Advances in nanotechnology already are leading to applications in fields ranging from energy and environment to electronics and medicine. Realizing the benefits of nanotechnology will require not only research and development, but also appropriate oversight.

The Office of Science and Technology Policy (OSTP) and the Council on Environmental Quality (CEQ) led a multi-agency consensus-based process to develop a set of principles, shown below, to guide the development and implementation of policies for nanotechnology environmental, health and safety oversight at the agency level. This document is intended to summarize generally applicable principles relevant to such oversight for nanotechnology by the Federal government.

Federal agencies that have regulatory responsibilities, such as the U.S. Environmental Protection Agency, the U.S. Food and Drug Administration, the Occupational Safety and Health Administration, and the National Institute for Occupational Safety and Health, must implement sound policies to protect public health and the environment. In addition, agencies that perform nanotechnology research and development or that use nanotechnology in accomplishing their mission must provide appropriate oversight. These Federal agencies should follow the following principles as they develop policies for environmental, health, and safety oversight related to nanotechnology.

Principles for Nanotechnology Environmental, Health, and Safety Oversight

Purpose: Federal oversight approaches should be cognizant of the potential benefits of nanotechnology, including health, economic and environmental benefits, while recognizing uncertainties surrounding the evolving science and technology. The purpose of considering environmental, health and safety oversight approaches in the context of nanotechnology is to protect human health and the environment.

Current Understanding: The Federal government's current understanding is that existing statutory authorities are adequate to address oversight of nanotechnology and its applications. As with any developing area, as new information becomes available the Federal government will adapt or develop additional oversight approaches, as necessary, to address the area of nanotechnology.

Information Development: Adequate information should be developed with respect to the effects of nanomaterials on human health and the environment. To the extent practicable and respecting confidential information (e.g. Confidential Business Information (CBI)), this information should be developed in an open and transparent manner by stakeholders, including the Federal government and developers of nanomaterials.

Risk Assessment and Risk Management: The Federal government should use standard oversight approaches to assess risks and benefits, and manage risks, considering safety, health and environmental impacts, and exposure mitigation. As experience is gained, these approaches can be refined. The Federal government should strive to reach an appropriate level of consistency in risk assessment and management approaches across the government.

International: Recognizing the global efforts to develop nanotechnology, the Federal government should proactively promote international cooperation. The Federal government should encourage coordinated and collaborative health and environmental research and test data development across the international community. The Federal government should also promote access to information across the international community. These efforts will allow the Federal government to contribute to, and take advantage of, risk assessment and risk management approaches, as appropriate, across the international community.

Regulatory Path Forward: In light of the "Purpose" of oversight as described above, the Federal government should consider the following, to the extent permitted by law and where applicable, in establishing environmental, health, and safety regulations for nanotechnology:

- Regulation should focus where need exists and where scientific information supports action (e.g. targeted to specific groups and classes of materials instead of a "one-size-fits-all" approach);
- Decisions should be based on the best reasonably obtainable scientific, technical, economic, and other information;
- Where possible, regulatory approaches should enable rather than hinder innovation;

- Regulatory approaches should be performance based to the extent feasible and provide predictability and flexibility in the face of evolving science and technology;
- Benefits of regulation should justify their costs;
- Regulations should be developed in an open and transparent manner; and
- Regulations and guidance should consider established requirements and guidance such as the following:
    - Executive Order 12866 – Regulatory Planning and Review. Federal Register Vol. 58, No. 190, Monday, October 4, 1993, 51735-51744, available at http://www.whitehouse.gov/omb/inforeg/eo12866.pdf;
    - Information Quality Act (Sec. 515 of the Treasury and General Government Appropriations Act for FY 2001, Pub. L. No. 106-554); Information Quality Guidelines: OMB (2002) Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (2002), 67 Fed. Reg. 8452 (Feb. 22, 2002) [hereinafter Information Quality Guidelines], available at http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf;
    - National Technology Transfer and Advancement Act of 1995. Public Law 104-113, available at http://standards.gov/standards_gov/nttaa.cfm;
    - Office of Management and Budget (OMB) Circular A-119, Transmittal Memorandum, Federal Participation in the Development and Use of Voluntary Standards (02/10/1998), available at http://www.whitehouse.gov/omb/circulars/a119/a119.html;
    - OMB Final Information Quality Bulletin for Peer Review (December 16, 2004, available at http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf;
    - OMB Bulletin No. 07-02 (M-07-07), Issuance of OMB's "Final Bulletin for Agency Good Guidance Practices" (January 18, 2007), available at http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf; and
    - OMB/OSTP Memorandum: M-07-24, Updated Principles for Risk Analysis (September 19, 2007), available at http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf