



Executive Office of the President
Office of Management and Budget



Executive Office of the President
United States Trade Representative

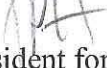



Executive Office of the President
Office of Science and Technology Policy

JUN 9 2011

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM:

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SUBJECT:

Policy Principles for the U.S. Decision-Making Concerning Regulation
and Oversight of Applications of Nanotechnology and Nanomaterials

“Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science.”

President Obama, Executive Order 13563, January 18, 2011.

The ability to image, measure, model, and manipulate matter on the nanoscale is leading to new technologies and promising new materials and applications across many fields – including medicine, information technology, aerospace, energy, and transportation – that will affect virtually every sector of our economy and our daily lives. Examples of potential nanotechnology applications include smart anti-cancer therapeutics, solar cells as cheap as paint, and the next revolution in computing. Companies are already offering nanotechnology-enabled products with breakthrough capabilities in areas such as disease detection, lighter and stronger materials, and next-generation batteries.

Advances in nanotechnology can drive economic growth, create quality jobs, and address a broad range of national challenges. Realizing these possibilities requires continued research, accelerated innovation, and flexible, adaptive, science-based approaches to regulation that protect public health, safety, and the environment while promoting economic growth, innovation, competitiveness, exports, and job creation.

The National Nanotechnology Initiative (NNI), one of the Obama Administration's top science and technology priorities, has invested almost \$14 billion in research and development since its inception in FY 2001. A key goal of the NNI is the responsible development of nanotechnology, which requires maximizing the benefits of nanotechnology while understanding and managing the relevant risks. As the President's Council of Advisors on Science and Technology noted, "In the absence of sound science on the safe use of nanomaterials and of technologies and products containing them, the chance of unintentionally harming people and the environment increases. At the same time, uncertainty and speculation about potential risks threaten to undermine consumer and business confidence." Accordingly, the Federal Government has significantly increased funding on the environmental, health and safety dimensions of nanotechnology, from \$37.7 million in FY 2006 to \$123.5 million in FY 2012.

The National Economic Council (NEC), the Office of Management and Budget (OMB), the Office of Science and Technology Policy (OSTP), and the Office of the U.S. Trade Representative (USTR) led a multi-agency consensus-based process to develop a set of principles to guide development and implementation of policies for the oversight of nanotechnology applications and nanomaterials. This document is intended to summarize generally applicable principles relevant to promoting a balanced, science-based approach to regulating nanomaterials and other applications of nanotechnology in a manner that protects human health, safety, and the environment without prejudging new technologies or creating unnecessary barriers to trade or hampering innovation. These principles build on the foundation provided by current regulatory statutes and do not supersede existing legal authorities or hinder Federal agencies from enforcing or applying their existing statutory and regulatory authority as mandated by law. Federal agencies that have regulatory responsibilities, such as the U.S. Environmental Protection Agency, the U.S. Food and Drug Administration, and the Occupational Safety and Health Administration, must continue to implement sound policies to protect public health, safety, and the environment.

The Federal Government is responsible for protecting human health and the environment and takes regulatory and oversight actions to ensure the safe production, processing, use, and disposal of many kinds of products – including foods and consumer products, chemicals used in the workplace, medical products, and pesticides. This framework for oversight and regulation of nanomaterials and applications of nanotechnology builds on existing laws and individual authorities, such as the risk-based approaches currently in use by some Federal agencies to meet this overarching responsibility. A fundamental element of these risk-based approaches is to examine those characteristics and properties of a material that are relevant to considerations about human and environmental safety—such as exposure, biodistribution (including absorption, distribution, metabolism, and excretion), persistence, bioaccumulation, toxicity, and pharmacokinetics—and therefore present issues of potential regulatory relevance. Such risk-based approaches reflect awareness that regulation should be grounded in the best available science and able to evolve as scientific insights mature and the body of evidence grows and evolves. Consistent with current law, regulatory agencies should take a science-based approach to risk management.

Descriptors for Regulatory Purposes

Nanotechnology has been described by the NNI as "the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications."¹ Size is by far the driving characteristic in all of the definitions developed for nanotechnology and nanomaterials to date. Materials in the nanoscale may have properties that are different from those of the

¹ National Nanotechnology Initiative Website, <http://www.nano.gov/html/facts/whatIsNano.html>.

conventionally-scaled material. The appearance of unique properties can also occur, however, even where the material or end product itself is not within the nanoscale range. Most definitions of nanomaterials contain a size-specific range (e.g., within the nanoscale range, which is commonly referred to as approximately 1-100 nm) along at least one dimension, but some definitions apply the size range to two or more dimensions--using either external or internal structures as units to be measured. Some definitions also include criteria related to physical or chemical characteristics (e.g. size distribution, shape, charge, or the ratio of surface area to volume) or to the display of unique or novel properties or "nanoscale phenomena."

The NNI description provides a valuable reference point. For oversight and regulation, however, the critical issue is whether and how such new or altered properties and phenomena emerging at the nanoscale create or alter the risks and benefits of a specific application. A focus on novel properties and phenomena observed in nanomaterials may ultimately be more useful than a categorical definition based on size alone. Properties and phenomena emerging at the nanoscale enable applications that may alter the safety, effectiveness, performance, or quality of products—giving rise to both risks and benefits. These properties and phenomena may be due to altered physical, chemical, or biological properties, or other distinct characteristics of materials in the nanoscale. These changes may positively or negatively affect not only the safety, effectiveness, performance, or quality of the products, but also their impact on public health and the environment.

For purposes of simplicity and comprehension, the remainder of this document will refer to materials or products or other applications that involve the use of nanotechnology simply as "nanomaterials". In this document, the term will also be used when referring broadly to regulatory oversight that is exercised over the life cycle of the material, the product that may contain it, or products produced using the material.

Framework for the Review and Oversight of Nanomaterials

As noted above, existing regulatory statutes provide a firm foundation for the regulation and oversight of nanomaterials; in particular these statutes address a range of potential applications for the technology. Under the relevant statutes, Federal agencies have the authority to evaluate safety, effectiveness, public health, and environmental impact of these applications. In exercising their authority, agencies seek to use the best available scientific and technical information to take into account the unique properties and behaviors associated with nanomaterials.

For purposes of regulation and oversight, Federal agencies focus on whether the properties or phenomena observed in nanomaterials (and/or their applications) present issues related to risk, safety, benefits, or other regulatory criteria. Federal agencies should avoid making scientifically unfounded generalizations that categorically judge all applications of nanotechnology as intrinsically benign or harmful. In this regard, identification of specific risks in the context in which they arise—based on scientific evidence to support that judgment—will help to ensure that perceptions of specific nanomaterials are based on scientific evidence rather than unsupported generalizations.

Building consumer trust and confidence in a sound regulatory regime is integral to fostering innovation and promoting the responsible development of nanotechnology applications. Federal agencies will strive to provide their stakeholders with clear information that delineates the specific risks identified and the context in which they arise. It is important that Federal agencies manage expectations realistically--neither overselling nor underselling the potential benefits or risks.

This framework is expected to evolve in response to the experiences of the Federal agencies and other stakeholders. As noted above, future scientific and other developments will almost certainly lead to refinements in agencies' approaches. Indeed, as experience with other technological innovations has shown, scientific progress and greater awareness of the effects of emerging technologies have enabled regulatory approaches to be modified to reflect a more complete understanding of the potential risks and benefits involved. A similar evolution is anticipated in the regulation and oversight of nanomaterials. Over time, modifications may need to be made through administrative or legislative actions.

In addressing issues raised by nanomaterials, agencies will adhere to the Principles for Regulation and Oversight of Emerging Technologies. Specifically, to the extent permitted by law, Federal agencies will:

- To ensure scientific integrity, base their decisions on the best available scientific evidence, separating purely scientific judgments from judgments of policy to the extent feasible;
- Seek and develop adequate information with respect to the potential effects of nanomaterials on human health and the environment and take into account new knowledge when it becomes available;
- To the extent feasible and subject to valid constraints (involving, for example, national security and confidential business information), develop relevant information in an open and transparent manner, with ample opportunities for stakeholder involvement and public participation;
- Actively communicate information to the public regarding the potential benefits and risks associated with specific uses of nanomaterials;
- Base their decisions on an awareness of the potential benefits and the potential costs of such regulation and oversight, including recognition of the role of limited information and risk in decision making;
- To the extent practicable, provide sufficient flexibility in their oversight and regulation to accommodate new evidence and learning on nanomaterials;
- Consistent with current statutes and regulations, strive to reach an appropriate level of consistency in risk assessment and risk management across the Federal Government, using standard oversight approaches to assess risks and benefits and manage risks, considering safety, health and environmental impacts, and exposure mitigation;
- Mandate risk management actions appropriate to, and commensurate with, the degree of risk identified in an assessment.
- Seek to coordinate with one another, with state authorities, and with stakeholders to address the breadth of issues, including health and safety, economic, environmental, and ethical issues (where applicable) associated with nanomaterials; and
- Encourage coordinated and collaborative research across the international community and clearly communicate the regulatory approaches and understanding of the United States to other nations.

Because nanotechnology is a rapidly emerging field of research and development, protection of public health and the environment makes it essential that regulatory agencies gather information on an ongoing basis about developments in both basic science and applications. Agencies may use the authority provided by their existing statutes to gather information. In all domains, compliance with law is of course required. If statutory frameworks limit mandatory reporting or other information gathering systems to those circumstances where a risk or harm has already been identified, and there is an insufficient basis to establish such risk of harm, agencies should explore other legally available means to obtain the information necessary to assess risk and possible harms. In pursuing these strategies, agencies should be

careful to avoid actions that could improperly characterize nanomaterials as inherently hazardous or benign.

To further understanding, enhance risk management, improve risk and hazard communication, and promote coordination, simplification, and harmonization in regulatory actions, a working group established by OSTP, OMB, and USTR will coordinate an approach and choice of terminology relevant to the regulation and oversight of nanomaterials. This working group will further develop this framework, acting consistently with current law and applying the framework to new circumstances and the wide variety of nanomaterials. Moreover, the interagency working group will enable the relevant regulatory agencies to remain involved in and influence ongoing research into nanotechnology, identifying possible areas of uncertainty and concerns of regulatory significance. Wherever possible, agency input into research direction should be used as a critical part of relevant information gathering.

In sum, agencies will continue their science-based approaches subject to the particular rules governing each area of regulatory oversight and their existing statutory authorities. Federal agencies that have regulatory responsibilities must continue to implement sound policies to protect public health, safety, and the environment. Technical assessments underlying regulatory and other risk management responses will be evidence-based and application-specific as appropriate under the applicable regulatory programs, taking into account the effects of nanomaterials in the particular biological and mechanical context of each application and their intended use.

Nanomaterials should not be deemed or identified as intrinsically benign or harmful in the absence of supporting scientific evidence, and regulatory action should be based on such scientific evidence. Where there is evidence of either safety or likely harm, the corresponding regulatory actions are usually clear. For some statutes, the mere existence of a hazard, regardless of the probability of it causing harm, may trigger some form of regulatory action. In general, however, and to the extent consistent with law, regulation should be based on risk, not merely hazard, and in all cases the identification of hazard, risk or harm must be evidence-based. In applying these principles, regulators should use flexible, adaptive, and evidence-based approaches that avoid, wherever possible, hindering innovation and trade while fulfilling the Federal Government's responsibility to protect public health and the environment.