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Principles For Regulating Nanotech

Law360, New York (June 15, 2011) -- On June 9, 2011, the Office of Science and Technology Policy (OSTP) announced that the White House Emerging Technologies Interagency Policy Coordination Committee (ETIPC) has developed a set of principles specific to the regulation and oversight of applications of nanotechnology. The principles are intended to guide the development and implementation of policies, as described in the title "U.S. decision-making concerning regulation and oversight of nanotechnology and nanomaterials" that occur at the agency level.

According to OSTP, the principles reinforce the overarching principles for the regulation and oversight of emerging technologies released on March 11, 2011. The principles also reflect recommendations from a report on nanotechnology prepared by the President's Council of Advisors on Science and Technology and, importantly, reflect the results of a multi-agency, consensus-based process lead by the National Economic Council (NEC), the Office of Management and Budget (OMB), OSTP and the Office of the U.S. Trade Representative (USTR).

OSTP states that the goals of all of these documents "are to achieve consistent approaches across different emerging technologies and to ensure the protection of public health and the environment while avoiding unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers." The principles concerning regulation and oversight of applications of nanotechnology and nanomaterials are available online.

According to the ETIPC, the principles are intended to guide development and implementation of policies for the oversight of nanotechnology applications and nanomaterials. The document summarizes 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, creating unnecessary barriers to trade or hampering innovation.

The principles, according to the ETIPC, build on the "firm 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. ETIPC notes that 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."

ETIPC states that, for oversight and regulation, the critical issue in describing nanomaterials "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." According to ETIPC, 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, and these properties and phenomena may be due to altered physical, chemical or biological properties, or other distinct characteristics of materials in the nanoscale. "For purposes of simplicity and comprehension," the principles refer to materials or products or other applications that involve the use of nanotechnology "simply as 'nanomaterials.'"

ETIPC cautions federal agencies from making "scientifically unfounded generalizations that categorically judge all applications of nanotechnology as intrinsically benign or harmful." ETIPC states that 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. According to ETIPC, it is important that federal agencies manage expectations realistically — "neither overselling nor underselling the potential benefits or risks."

Future scientific and other developments "will almost certainly lead to refinements in agencies' approaches," and experience has already shown that "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." ETIPC anticipates a similar evolution in the regulation and oversight of nanomaterials, and that "[o]ver time, modifications may need to be made through administrative or legislative actions."

In addressing issues raised by nanomaterials, ETIPC states that agencies will adhere to its "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 U.S. to other nations.

ETIPC states that "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." ETIPC recommends agencies use the authority provided by their existing statutes to gather information. If statutory frameworks limit mandatory reporting or other information gathering systems to those circumstances where a risk or harm has already been identified, however, 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."

For some statutes, ETIPC notes, 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, ETIPC states that "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."

Observations

The document provides a careful and balanced discussion of policy principles for regulatory oversight of nanotechnology and nanomaterials. It strongly encourages the use of science- and evidence-based regulatory approaches that, to the extent consistent with law, should be based on "risk, not merely hazard" and "avoid, wherever possible, hindering innovation and trade while fulfilling the federal government's responsibility to protect public health and the environment."

Perhaps it is to be expected that a process led by the NEC, OMB, USTR and OSTP would articulate policy principles that instruct regulatory agencies to "use flexible, adaptive and evidence-based approaches that avoid, wherever possible, hindering innovation and trade." It is nonetheless remarkable that the principles represent a consensus-based process that undoubtedly included the regulatory agencies noted, including EPA, OSHA and FDA.

However, the principles could cause policy approaches to shift in unpredictable ways, particularly with regard to the principles' encouragement of a "focus on novel properties and phenomena" and for agencies to "explore other legally available means to obtain the information necessary to assess risk and possible harm." It is notable that the principles for regulatory oversight focus both on the applications of the technology (nanotechnology) as well as the products of that technology (nanomaterials). In this regard, while oversight of nanomaterials has been underway for years, it is less clear what the policy intends by its encouragement of a regulatory focus on the applications of the technology.

On a more political level, this document, with the earlier "principles" document, seems to have two primary goals. First, to address the concerns and issues identified by the wide range of interested parties that have sought to have the Obama administration declare how it plans to approach generally nanoscale materials/nanotechnology issues arising from both the private sector and NGO advocacy communities. Second, the document captures, or successfully avoids, some of the issues vetted decades ago in the biotechnology debate. The government issued principles in the 1986 Coordinated Framework for Regulation of Biotechnology.

At the same time, reflecting the democrats' desire to be more sensitive to environmentalist concerns, today's policy pronouncement explicitly puts a marker down on the ideas that there may be a need for new laws and regulations to control new or novel risks presented by nanotechnology. In contrast, the biotechnology policy essentially stated that no new laws were, or would be, needed. And of course, all this is to be done with the overarching directives of using a transparent process that utilizes the most modern and accurate science, within a global construct that is sensitive to the need for both international coordination and state authorities input. No small feat.

The more nuanced discussion and articulation of how the government agencies should both encourage and control nanomaterials reflects some of the ways we have learned to understand better how emerging technologies might be both nurtured and controlled. The policy also reflects some of the more fully developed policy rhetoric focused on addressing public sensitivities about emerging technologies and any risks — real, imagined, potential or theoretical — in the modern political context.

On the whole, the principles represent an important development regarding the future oversight of nanomaterials over the duration of the Obama administration. As such, and in combination with the president's January 2011 executive order, the principles may provide additional but measured constraints on the actions taken by regulatory agencies.

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