Regulation of Nanotechnology in the Environment

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ABSTRACT

In this paper we examine the current state and likely future path of nanotechnology regulation by the U.S. Environmental Protection Agency ("EPA" or "the Agency"). We also explore several voluntary initiatives to address the environmental impacts of nanotechnology which have arisen in parallel with the development of a national regulatory program.

Keywords: environment, regulation, EPA, TSCA, stewardship

1 INTRODUCTION

EPA's mandate is to preserve the nation's natural resources and environment and to protect human health outside the workplace. For this reason, EPA is particularly interested in nanotechnology. On the one hand, innovations made possible by advances in nanotechnology may provide important tools for preventing and remediating environmental contamination. On the other hand, many experts are concerned about the potential adverse effects that might arise from widespread distribution of nanoscale materials and products. These types of concerns fall squarely within EPA's purview.

2 BACKGROUND

Since 2001, EPA has played a leading role in various nanotechnology initiatives. Together with twenty-two other government agencies, EPA is an active participant in the National Nanotechnology Initiative ("NNI"), a federal research and development program established to coordinate federal government efforts in nanoscale science. EPA has also vigorously funded research into the potential environmental benefits that may be achieved through the use of nanotechnology. [1]

However, while the potential environmental benefits of nanotechnology are significant, EPA has also expressed concern over the possible adverse impacts that widespread dissemination of nanoscale materials might have on health and the environment. These concerns reflect the inherent difficulties scientists face in predicting how nanoscale materials will behave in the environment and interact with biological systems, because of their small size and unique properties. [1]

3. CURRENT STATE OF REGULATION BY EPA

EPA's efforts at regulating nanotechnology are still in their early stages. Indeed, much of the effort so far has focused on assessing the legal infrastructure and the scientific knowledge base needed to effectively regulate nanotechnology.

In 2004, EPA convened a cross-Agency Nanotechnology Workgroup to develop a white paper on the environmental implications of nanotechnology and the means by which EPA can regulate it. A final version of the white paper was published in February 2007. [1] Ultimately, though, the white paper may have raised more questions than it answered: it focused extensively on the need for additional research into environmental applications and possible health and environmental impacts. Key recommendations included:

- Additional research on detection, fate and lifecycle of nanoscale materials in the environment; human and ecological exposure pathways; chemical identification and characterization; health and environmental effects; and remediation applications;
- Conducting case studies and hosting interdisciplinary workshops to determine an appropriate risk assessment paradigm; and
- Establishing a cross-EPA nanotechnology workgroup to foster information-sharing between the agency's different offices; and expanding training for EPA scientists and managers dealing with nanotechnology. [1]

These recommendations underscore the information gap facing EPA as the Agency considers how to approach the regulation of nanoscale materials in the environment.

Although EPA is grappling with the question of precisely *how* to regulate nanotechnology, at least a preliminary consensus appears to have developed that existing environmental statutes provide EPA and other agencies with sufficient *authority* to regulate nanotechnology in a manner that protects human health and the environment. For example, in recent public meetings, the Agency indicated that it believes the current statutory system to be a sufficient starting point for regulation of nanotechnology. [2] EPA expressed the same view in its white paper. Thus, although the Agency has not ruled out the potential need to modify existing laws or regulations in order to adequately regulate nanotechnology, it does not seem inclined to ask Congress to drastically overhaul the existing statutory tools available to the Agency.

3.1 Regulation Under Existing Laws

Over the past several months, EPA has made attempts to clarify how the Agency will adapt the existing statutes and regulations to regulate nanotechnology.

For example, in July 2007, EPA released a guidance document for comment entitled "TSCA Inventory Status of Nanoscale Substances – General Approach" (the "General Approach" document). [3] In this guidance document, EPA clarified that the Agency does not intend to use particle size to distinguish "new" substances from "existing" substances for the purposes of the Toxic Substances Control Act ("TSCA"). This is significant because "new" chemical substances are arguably subjected to greater scrutiny than "existing" substances under TSCA.

Similarly, EPA seems ready to apply its existing regulations to nanotechnology products under other statutory regimes, on a case-by-case basis. For example, in September 2007, EPA announced that it would regulate a washing machine that generates anti-bacterial silver ions as a pesticide under the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA"). [4] This ruling was significant because initial reports indicated that the washing machine generated nanoparticles of silver – which would have provided EPA with its first known opportunity to regulate a nanotechnology product under FIFRA. However, after gathering data on the product, EPA concluded that the washing machine operated by generating silver ions and did not, in fact, employ nanotechnology. [5]

EPA has also taken steps to regulate nanoscale products under the Clean Air Act. For example, EPA is reviewing an application to register a new diesel fuel additive comprised of nano-sized particles of cerium oxide, which is already approved for use in the United Kingdom as a diesel fuel catalyst and is purported to reduce fuel consumption by 5-10%. [1] EPA will decide under the Clean Air Act whether to approve this additive for use in the U.S.

3.2 Satisfying EPA's Data Needs

One of the resounding themes of the white paper is that EPA believes it needs more data about nanoscale materials in order fill a sizeable information gap. The Agency is pursuing a multi-pronged approach to satisfy these research needs. In addition to EPA laboratories conducting their own research, as of 2007 the Agency has also funded more than $17 million in Science to Achieve Results (STAR) grants to research environmental fate and monitoring and detection of nanomaterials. [6] Additionally, as discussed in more detail later, EPA has launched a voluntary stewardship program that is also intended to generate data to help fill EPA's information needs.

4 WHAT LIES AHEAD

By proceeding from the assumption that existing laws are adequate and current regulatory programs can be modified to adequately regulate this new technology, EPA would be adopting essentially the same stance towards the regulation of nanotechnology that the Agency took with respect to biotechnology in the 1980's.

If the Agency's experience with regulating biotechnology is indicative, then EPA will likely experience "growing pains" in confronting the unique regulatory challenges that nanoscale materials present. For example, in the case of biotechnology, EPA found it necessary to issue new regulations for genetically modified microbes and plants (40 CFR Parts 725 and Part 174). FDA published policy statements, industry guidance, and a proposed rule to address foods derived from new plant varieties [7], and USDA

embarked on an overhaul of its regulations to better address the introduction of genetically engineered crops into agriculture. [8] Similar revisions to the existing regulatory framework may also be needed as EPA begins to more actively regulate nanotechnology products.

A full discussion of possible regulatory developments under *all* of the environmental statutes administered by EPA is beyond the scope of this paper. Instead, we focus on one statute with especially broad reach: the Toxic Substances Control Act.

4.1 Toxic Substances Control Act

Whereas most other environmental statutes regulate "pollution" in one form or another (e.g., air emissions, wastes, etc.), TSCA provides EPA with broad authority to regulate chemicals ***before*** they are allowed to be manufactured or imported into the United States, as well as after their introduction into commerce. Key to the TSCA regulatory program is the "Chemical Substances Inventory," which is a list maintained by EPA that identifies all chemical substances which are known to be manufactured or imported into the United States. For TSCA purposes, a "new" chemical substance is one that is not listed on the Inventory. Section 5 of TSCA provides EPA with broad authority to regulate both "new" chemical substances and "significant new uses" of "existing" chemical substances.

With respect to TSCA regulation of nanoscale materials, an especially controversial question has been whether nanoscale versions of conventional-sized materials that are *already listed* on the TSCA Inventory should nevertheless be regulated as "new" chemical substances under section because of their unique properties.

Under TSCA section 5(a)(1), a company may not manufacture or import a "new" chemical substance without first submitted to EPA a pre-manufacture notification ("PMN") at least 90 days prior to initiating manufacture or import. The PMN must provide certain information pertaining to the chemical identity and the health and environmental effects of the chemical substance. Based on its PMN review, EPA may permit the substance to be placed on the Inventory -- allowing it to be manufactured, processed, distributed, or imported without restriction -- or the Agency may invoke section 5(e) to impose restrictions on manufacture and use, to require the submission of more data on the substance, or to ban the chemical outright.

In contrast, the process for regulating "existing" chemicals under TSCA is more cumbersome. Specifically, Section 5(a)(2) of TSCA provides EPA with authority to regulate "significant new uses" of an *existing* chemical substance, through the promulgation of a "significant new use rule" ("SNUR"). Through the SNUR process EPA can impose restrictions on manufacture and use of a substance for any use that is deemed to be a significant new use – similar to the restrictions that can be imposed on "new" substances under section 5(e). However, in order to designate the use of a substance as being a "significant new use" EPA must engage in a rulemaking process that includes public notice and an opportunity to comment, in order to promulgate a SNUR --a more time consuming and more burdensome process for EPA, than regulating a "new" substance under section 5(e).

As indicated previously, EPA recently issued a draft guidance document in which the Agency suggested that nanoscale substances will ***not*** be subject to regulation as "new" chemical substances if they do not differ in molecular identity from chemicals already in the TSCA inventory. In addition, the Agency has indicated that it does ***not*** intend to modify the PMN process to require manufacturers of "new" substances to indicate whether those substances will be manufactured as nanoscale materials. Instead, rather than regulating nanoscale materials as "new" substances, EPA seems more focused, for now, on encouraging companies to generate data on nanoscale materials.

5. NON-REGULATORY INITIATIVES

Anticipating that comprehensive EPA regulation of nanoscale materials will not happen in the near future, both EPA and private-sector stakeholders have designed voluntary risk management and data development programs for producers of nanoscale materials. Two programs are most prominent: in June 2007, DuPont and Environmental Defense released their joint

"Nano Risk Framework;" and in January 2008, EPA launched a voluntary "Nanoscale Materials Stewardship Program." We briefly outline the main features of these two programs, below.

5. 1 DuPont - Environmental Defense Nano Risk Framework

The stated goal of the DuPont-Environmental Defense Nano Risk Framework is to "promote responsible development, facilitate public acceptance, and support the safe development of a practical model for reasonable government policy on nanotechnology safety". [9] It is intended to be used by industry stakeholders to establish a ***process*** for systematically identifying, managing, and reducing potential environmental, health, and safety risks of engineered nanomaterials across all stages of a product's 'lifecycle'. The Framework also suggests a series of tests that participants conduct to develop base sets of safety information.

5.2 EPA Nanoscale Materials Stewardship Program

In January 2008, EPA launched its voluntary "Nanoscale Materials Stewardship Program" or "NMSP." The NMSP has two parts – a "basic" program and an "in depth" program. Participants in the "basic" program are asked to voluntarily report ***available*** information on the nanoscale materials they manufacture, import, process or use; they are not asked to develop any ***new*** data. Participants in the "in depth" program agree to voluntarily develop data – either individually or as part of data development consortia.

At the end of the day, if EPA concludes that these voluntary efforts are not providing the Agency with the information it needs in order to assess the health and environmental impacts of nanoscale materials, EPA can ***require*** companies that manufacture, import or process nanoscale materials to generate the desired data, by issuing a "test rule" that requires such testing under Section 4(e) of TSCA.

6 CONCLUSION

As the foregoing demonstrates, EPA is still contemplating how nanotechnology should be regulated. Based on recent developments and past precedent we should expect EPA to make use of existing statutory authorities; however, we can also anticipate that as our understanding of the unique characteristics and special risks posed by nanotechnology grows, revisions to the existing regulatory framework will be needed to ensure that nanoscale materials are adequately regulated.

REFERENCES

[1] U.S. EPA, Nanotechnology White Paper (February 2007)

[2] Federal Register Notices and Supporting Materials for both meetings are available at: http://www.regulations.gov/fdmspublic/component/main

[3] U.S. EPA, TSCA Inventory Status of Nanoscale Substances – General Approach (July 12, 2007), available at: http://www.epa.gov/oppt/nano/nmspfr.htm

[4] 7 U.S.C. §§ 136 *et seq.*

[5] See http://www.epa.gov/oppad001/ion_gen_equip.htm; http://yosemite.epa.gov/opa/admpress.nsf/0/690EA71A584AC6448525735D0058F99D

[6] Full list of grant solicitations and research projects available at: http://es.epa.gov/ncer/rfa/2007/2007_star_nanotech.html and: http://es.epa.gov/ncer/rfa/2007/2007_gro_nano.html

[7] *See* http://vm.cfsan.fda.gov/~lrd/biotechm.html (provides index of FDA policy statements and guidance documents on biotechnology).

[8] *See* http://vm.cfsan.fda.gov/~lrd/biotechm.html (provides index of FDA policy statements and guidance documents on biotechnology)

[9] The Nano Risk Framework is available at http://nanoriskframework.com/page.cfm?tagID=1095