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PREFACE

Environmental Law Confronts the New Industrial Revolution

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Futurist writers Robert OlsOn and David Rejeski describe the convergence of developments in biotechnology, nanotechnology, and information systems as building blocks of a new industrial revolution full of promise for economic, environmental, and social progress. They observe correctly that "the environmental movement as we know it arose in the early 1970s and has spent much of the last thirty years dealing with the damages of a century old revolution in industrial production."[1] Our U.S. environmental laws were designed to mitigate pollution from that first industrial revolution and the

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1. ENVIRONMENTALISM AND THE TECHNOLOGIES OF TOMORROW: SHAPING THE NEXT INDUSTRIAL REVOLUTION 1-2 (Robert OlsOn & David Rejeski ed., 2003).

past century's methods of manufacturing, energy generation, municipal sanitation, transportation, and agriculture. In that context, federal and state laws have achieved considerable success, though the work of protecting the environment from old-time abuses is not finished. The question for environmental law and lawyers today is whether our existing laws and, indeed, our ways of thinking about environmental risks and remedies are able to address the challenges of major new and transformative technologies. Can we escape a new cycle of control and cleanup of environmental damage, including adverse health consequences? Can public and private sector initiatives succeed in identifying and preventing harm earlier in the development of new technologies and materials? This issue of the Pace Environmental Law Review presents a set of articles to shed new light on those questions in the case of the products of nanotechnology. For comparison, the issue also includes an article on the regulation of genetically modified organisms in agriculture in the United States and Brazil, an early effort to govern the risks of a major new technology.

The National Nanotechnology Initiative launched by the U.S. government in 2001 defines nanotechnology as "the control and restructuring of matter at the nanoscale, in the range of approximately 1-100 nanometers, in order to create materials, devices, and systems with fundamentally new properties and functions due to their small structure. . . . A nanometer is one billionth of a meter."[2] The small size and large surface area of nanoparticles create "novel electrical, catalytic, magnetic, mechanical, thermal, or imaging features that are highly desirable for applications in commercial, medical, military, and environmental sectors."[3] Today, some of the better known applications are the use of carbon nanomaterials in sporting

2. PRESIDENT'S COUNCIL OF ADVISORS ON SCI. & TECH., EXEC. OFFICE OF THE PRESIDENT, REPORT TO THE PRESIDENT AND CONGRESS ON THE FOURTH ASSESSMENT OF THE NATIONAL NANOTECHNOLOGY INITIATIVE 1 (2012), *available at* http://nano.gov/sites/default/files/pub_resource/pcast_2012_nanotechnology_final.pdf.

3. OFFICE OF THE SCI. ADVISOR, U.S. EPA, EPA 100/B-07/001, NANOTECHNOLOGY WHITE PAPER 10 (2007), *available at* http://www.epa.gov/osainter/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf.

goods and metallic nanomaterials in sunscreens and fabrics.[4] The main health and environmental concerns stem from the fact that small particles can be inhaled or ingested and because of their size and other properties, will penetrate living cells; they have been shown to cause lung damage in mice, injury to fish, and DNA damage.[5]

Taryn L. Rucinski's article is a comprehensive guide to the wealth of published references on nanomaterials and their implications. She points out that numerous analysts have examined U.S. environmental laws to see whether their provisions encompass nanomaterials in products or processes involving exposures to people and the environment. Most agree that the terms of our air, water, waste, and chemicals regulation regimes do encompass nanoscale substances.[6] However, there are unique practical difficulties in making existing pollution control statutes work to manage nanomaterial risks. These include defining what nanomaterials are, setting protective standards, and measuring whether standards are met.

David A. Dana explores the complexity of defining nanomaterials, a task that has bedeviled many technical standard setting organizations as well as numerous regulatory bodies considering options for oversight. He reviews alternative approaches and suggests ways to define the subject in a manner that excludes materials less likely to merit regulatory attention and removes them from more extensive oversight.[7] Beyond developing a working definition, there are larger obstacles to using our existing pollution control laws at both the beginning and the end of the regulatory process.

First, environmental laws generally call for a threshold finding of a significant risk of harm to health or the environment to support controls; the specific wording of various statutory tests

4. *Id.* at 11.

5. JOHN F. SARGENT, JR., CONG. RESEARCH SERV., RL 34511, NANOTECHNOLOGY: A POLICY PRIMER 9 (2009), *available at* http://www.fas.org/sgp/crs/misc/RL34511.pdf.

6. Taryn L. Rucinski, *Searching for the Nano-needle in a Green Haystack: Researching the Environmental, Health, and Safety Ramifications of Nanotechnology*, 30 PACE ENVTL. L. REV. 397 (2013).

7. David A. Dana, *The Case for an Information-Forcing Regulatory Definition of "Nanomaterials,"* 30 PACE ENVTL. L. REV. 441 (2013).

may vary, but a minimum level of scientific data and analysis is required to support regulatory action. Most would concur in the observation in the article by Louis Theodore and Leo H. Stander that there is not enough published scientific work on health and environmental effects to perform conventional risk assessments.[8] And at the end of the regulatory process, action generally requires methods of detecting and measuring pollutants or contaminants in materials, emissions, effluents, or soil. The lack of standard and cost-effective test methods for nanomaterials makes the monitoring and enforcement procedures common to most environmental regulatory regimes impossible.[9]

These limitations on the use of conventional pollution control tools suggest that oversight of any nanomaterial risks needs to take place when nanomaterial products and processes are developed and before they are in wide use in products or processes affecting the environment. In the United States, the responsibility for preventing adverse health or environmental effects from nanomaterials falls to agencies such as the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) with authority to regulate the products in which the materials are used or, in the case of EPA, new and existing chemicals regulated under the Toxic Substances Control Act (TSCA).[10]

EPA has been slow to use TSCA's authority to address nanomaterials. As Nadia Kaddour explains in her article, EPA does not regard nanomaterials as "new chemicals" requiring notification because their molecular structure is the same as existing chemicals. However, the agency has issued Significant New Use Rules which can impose notification and management requirements on materials such as carbon nanotubes where EPA has imposed conditions on new chemical notifications containing

8. Louis Theodore & Leo H. Stander, *Regulatory Concerns and Health/Hazard Risks Associated with Nanotechnology*, 30 PACE ENVTL. L. REV. 469 (2013).

9. Development of test methods, especially in environmental media, is a priority for nanotechnology research programs. OFFICE OF THE SCI. ADVISOR, *supra* note 3, at Appendix C.

10. 15 U.S.C §§ 2601-2692 (1976).

such nanomaterials.[11] Stronger oversight of nanomaterials requires government agencies to obtain basic information from producers on the quantities, uses, and any health or safety data they have on the nanomaterials produced. There is ample authority under TSCA for EPA to issue Significant New Use Rules for broader categories of nanomaterials or establish a general reporting rule for particular classes of uses.[12] Information reporting rules are not simple to develop, and compliance is burdensome, to be sure. But a reporting requirement is far less burdensome than controls on the manufacture or use of products and should not demand the same level of evidence of risk to health or the environment to support a rule. However, EPA's proposal in 2010 to set an information reporting rule under its TSCA authorities has not been acted on by the Office of Information and Regulatory Affairs (OIRA) in the Executive Office of the President.[13] No public explanation of the proposal or its apparent demise has been offered by either agency.

Two jurisdictions have acted to establish reporting requirements for use of nanomaterials. The first was the ordinance adopted by the City of Berkeley, California and analyzed in the article by Drew Lerer.[14] The other is the first national rule requiring reporting for nanomaterials set by France and described in detail in the Kaddour article.[15] Initial reports under the French law are due May 1, 2013. Given the likely protection of much of this information as trade secrets or confidential business information, it is unclear whether interested persons other than regulatory agency personnel will have broad access to the data. Still, the information will enable governmental officials to understand better the potential for

11. Nadia Kaddour, *No Laws in Nanoland: How to Reverse the Trend? The French Example*, 30 PACE ENVTL. L. REV. 486 (2013).

12. LYNN BERGESON & TRACY HESTER, NANOTECHNOLOGY DESKBOOK 26-27 (2008).

13. *See* OFFICE OF INFO. & REGULATORY AFFAIRS, www.reginfo.gov/public/jsp/EO/eodashboard.jsp (last visited Mar. 17, 2013).

14. Drew Lerer, *Big Things In Small Packages: Evaluating the City of Berkeley's Nanotechnology Ordinance as a Model of Target Transparency*, 30 PACE ENVTL. L. REV. 523 (2013).

15. Kaddour, *supra* note 11.

exposure to specific materials in the event further research reveals significant risks to health or the environment.

There are lessons to be learned from the U.S. record in governance of the use of genetically modified organisms (GMOs) to make crops more pest and herbicide resistant, described in Heather Leibowitz's article on the U.S. and Brazilian experience. In both countries, GMO seeds are increasingly used in soybean and corn crops; and there is concern that regulatory requirements have not effectively prevented cross-contamination of untreated crops, among other possible adverse impacts.[16] Given the scale and economic power of this segment of agribusiness, it will be a struggle to tighten the controls needed to prevent ecological harm. Today, pressure for improving the separation of GMO and untreated crops may come less from national government action than from increasing public advocacy for labeling of food products containing GMOs under state law or from voluntary action by food retailers to label or limit offering of GMO modified products, most recently by Whole Foods Market, Inc.[17]

Information reporting would be an important first step to provide government with early warning of exposures of concern to nanomaterials and to secure public confidence in the safety of products containing them. Experience under the two new reporting laws will help to demonstrate whether such laws can provide these public benefits without unduly burdening the development and commercialization of new technologies that promise to provide significant health, environment, and economic value. The articles in this issue advance an important policy debate on how environmental law can provide new forms of governance of the technologies of today's industrial revolution.

16. Heather Leibowitz, *Harmony with Nature and Genetically Modified Seeds: A Contradictory Concept in the United States and Brazil?*, 30 PACE ENVTL. L. REV. 558 (2013).

17. Stephanie Strom, *Major Grocer to Label Foods with Gene-Modified Content*, N.Y. TIMES, Mar. 9, 2013 at A1; *see also* Stephanie Strom, *Major Grocer to Label Foods with Gene-Modified Content*, N.Y. TIMES, Mar. 9, 2013, *available at* www.nytimes.com/2013/03/09/business/grocery-chain-to-require-labels-for-genetically-modified-food.html/?ref=wholefoodmarketinc&_r=0.