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ARTICLE

NO LAWS IN NANOLAND: HOW TO REVERSE THE TREND? THE FRENCH EXAMPLE*

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Nanotechnology is on its way to becoming the Industrial Revolution of the 21st Century. Research and Development departments of multinational companies, university scientists, and governments are working hard to discover and implement the numerous applications that this technology promises to offer. According to a January 2012 report from the National Academy of Sciences, the nanotechnology sector generated approximately \$225 billion dollars in product sales in 2009.¹ Nanotechnology is currently used in a wide variety of applications such as, but not limited to, environmental protection, consumer products, electronics, and medical devices; according to Lux Research, nanotechnology is expected to generate \$2.5 trillion dollars in

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1. THE NAT'L ACAD. OF SCIS., A RESEARCH STRATEGY FOR ENVIRONMENTAL, HEALTH, AND SAFETY ASPECTS OF ENGINEERED NANOMATERIALS 3 (THE NAT'L ACADS. PRESS 2012), *available at* http://www.nap.edu/catalog.php?record_id=13347.

2015 (Lux Research lowered its previous projections for revenues resulting from nanotechnology by 21% due to the recession). In December 2010, National Science Foundation Senior Nanotechnology Adviser Mihail Roco indicated that “[c]urrent trends suggest that the number of nanotechnology workers and products worldwide will double every three years, reaching a \$3 trillion market with six million jobs by 2020.”² Among the numerous examples of the benefits of nanotechnology cited on the website of the National Nanotechnology Initiative³ are the use of nanotechnology in the early diagnosis of atherosclerosis, the use of gold nanoparticles to detect early-stage Alzheimer’s disease, and the potential use of nanoparticles in the emergency treatment of brain injury by quickly restoring blood flow to the brain and thereby reducing the damage to it.⁴ With regard to the environmental benefits of nanotechnology, the EPA website cites the use of carbon nanotubes in an epoxy to manufacture windmill blades that are longer, stronger, and lighter-weight than other blades in order to increase the amount of electricity that windmills can generate, and the use of nanomaterials to provide clean water from polluted water sources or to detect and clean up environmental contaminants.⁵

Employment creation, innovation, medical advances, and environmental protection are some of the claimed benefits of nanotechnology. However, have the risks and impacts on public health and the environment been assessed prior to introducing into the market products derived from nanotechnology? The answer: not really. Numerous products containing engineered nanomaterials are manufactured and commercialized without first assessing their potential impacts on the environment and

2. MIHAIL C. ROCO ET AL., NANOTECHNOLOGY RESEARCH DIRECTIONS FOR SOCIETAL NEEDS IN 2020, RETROSPECTIVE & OUTLOOK SUMMARY 6 (2010), available at <http://www.wtec.org/nano2/docs/Nano2-Brochure-Final-04-14-11.pdf>.

3. The National Nanotechnology Initiative is a U.S. government initiative launched in 2001 to coordinate nanotechnology research and development across the federal government.

4. *Benefits and Applications*, NANO.GOV, <http://www.nano.gov/you/nanotech-nology-benefits> (last visited Feb. 11, 2013).

5. *Environmental Assessment: Nanomaterials*, EPA, <http://cfpub.epa.gov/ncea/CFM/nceaQFind.cfm?keyword=Nanomaterials> (last visited Feb. 11, 2013).

public health. It seems that “learning lessons from the past” is not an art yet mastered by governments and industries. Asbestos is a typical example of a once considered fantastic chemical substance, which later on was identified as a serious health hazard. Asbestos is now listed as a hazardous air pollutant under section 112(b) of the Clean Air Act.⁶

Nanotechnology is a perfect example to show how difficult it is to balance the necessary industrial, technological, and scientific development of our society with the protection of the public health and the environment. It is even more complex in the case of nanotechnology because of the numerous applications expected from this technology in the fields of medicine and environmental protection. This paper will first present an introduction to nanotechnology and its potential environmental, health, and safety (EHS) issues. It will then briefly review the current United States’ situation with regard to nanotechnology regulation before examining the new French regulation on engineered nanomaterial substances, which is a good first step toward a nano-specific legal framework.

I. INTRODUCTION TO NANOTECHNOLOGY AND ITS POTENTIAL RISKS

A. What is Nanotechnology?

The nanoworld is the world of the invisible since nothing in nanosize can be seen with the naked eye. So one wonders how it is possible to monitor and regulate the invisible. Nanotechnology has its own vocabulary, which seems to take inspiration from science fiction, e.g. fullerenes, quantum dots, dendrimers, buckyballs.

a. Definition and Classification of Nanomaterials

There are various definitions of nanotechnology. One of them is from the National Nanotechnology Initiative (NNI). NNI defines nanotechnology as “the understanding and control of matter at dimensions between approximately 1 and 100

6. Clean Air Act, 42 U.S.C. § 7412 (2012).

nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering, and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale.”⁷

A nanometer (nm) is one billionth of a meter.⁸ To better visualize how minuscule a nanometer is, keep in mind that a head of a pin is one millimeter or about one million nanometers across; “[a] sheet of paper is about 100,000 nanometers thick,” and a nanometer is about one hundred thousand times smaller than the diameter of a human hair.⁹

In its 2007 Nanotechnology White Paper, EPA classified the most current nanomaterials into the following four types: carbon-based materials, metal-based, dendrimers (nanosized polymers built from branched units), and composites—a combination of nanoparticles or of nanoparticles and larger bulk-type materials.¹⁰

The development of nanotechnology is evolving toward more and more complexity, from passive and active nano-structures to nanosystems and molecular nanosystems.¹¹

b. What Makes Nanotechnology so Special?

The minuscule size of nanomaterials and particles makes them have different or enhanced properties compared with those of the corresponding bulk materials.¹² Nobel Prize physicist Richard Feynman stated in *The Feynman Lectures on Physics* that “things on a small scale behave *nothing like* things on a large scale. That is what makes physics difficult—and very interesting.

7. SUBCOMM. ON NANOSCALE SCI., ENG’G & TECH., NAT’L SCI. & TECH. COUNCIL, RESEARCH AND DEVELOPMENT LEADING TO A REVOLUTION IN TECHNOLOGY AND INDUSTRY, SUPPLEMENT TO THE PRESIDENT’S FY 2011 BUDGET 3 (2010), *available at* http://www.nano.gov/sites/default/files/pub_resource/nni_2011_budget_supplement.pdf.

8. *Id.*

9. *Id.*

10. OFFICE OF THE SCI. ADVISOR, U.S. EPA, 100/B-07/001, NANOTECHNOLOGY WHITE PAPER 7-10 (2007), *available at* <http://www.epa.gov/osa/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf>.

11. *Id.* at 29.

12. *See, e.g., id.* at 78 (it is believed that toxic properties differ between the nanoparticles and the corresponding bulk material).

It is hard because the way things behave on a small scale is so ‘unnatural’; we have no direct experience with it.”¹³ This was part of his introduction to the theory of quantum mechanics, which is particularly important in nanotechnology.¹⁴

The larger surface area of nanomaterials explains their unusual and extraordinary properties; smaller particles have a higher surface area due to the higher number of atoms in the surface of the particle, and they also have a higher reactivity.¹⁵ Additionally, the quantum effects at the nano-level can significantly change the optical, magnetic, or electrical properties of a material.¹⁶ For the purpose of this paper, simply remember that a material at the nano-scale exhibits fantastic properties, which can be used in many fields such as, but not limited to, electronics, energy, computers, and medicine.

c. Examples of Nanomaterial Applications

a) Electronics: components and structural features of integrated circuits.

b) Energy/fuels/environment: liquid fuels and plastics, catalytic converters to remove pollutants from automobile exhaust.

c) Medicine: nanoparticulate formulations of drugs used in the treatment of cancer and infectious disease.

d) Material: use of carbon nanotubes to manufacture lighter and more conductive wires.

e) Consumer products: according to the consumer products inventory provided by The Project on Emerging Nanotechnologies, there are currently 1,317 nanotechnology based consumer products, produced by 587 companies, and

13. RICHARD FEYNMAN ET AL., *THE FEYNMAN LECTURES ON PHYSICS* 2-6 (The New Millennium ed., 1963).

14. In his Lectures, Richard Feynman defined quantum mechanics as the description of the behavior of matter and light in all its details, and in particular on an atomic scale. *Id.* at 37-1.

15. *Defining Nanomaterials*, NANOWERK, http://www.nanowerk.com/nanotechnology/introduction/introduction_to_nanotechnology_3.php (last visited Feb. 16, 2013).

16. *Id.*

located in thirty countries.¹⁷ Listed below are some of the consumer products available in the United States:

Wilson nCode and [K]Factor tennis racquets, Behr PREMIUM PLUS Exterior Paint, Black & Decker DeWalt Cordless Power-tool Set, Apple iPod Nano, Serge Lutens Blusher, Banana Boat Kids Tear Free SPF 30, Burt's Bees Chemical-Free Sunscreen SPF 15, Chantecaille Nano Gold Energizing Cream, Lexon Nano-Silver Sock, LG Antibacterial Mobile Phone, Callaway Golf Mens Nano Tech Woven Shirt, Dockers Go Khakis pants, Brooks Brothers Stain Resistant Tie, and RBC Life Sciences, Inc. Nanoceuticals Slim Shake Chocolate.¹⁸ It is estimated that “[n]ew nanotechnology consumer products emerge at a rate of three to four per week.”¹⁹

B. The Potential Risks of Nanotechnology

The March 2010 Report to the President and Congress on the Third Assessment of the National Nanotechnology Initiative, prepared by the Executive Office of the President, President's Council of Advisors on Science and Technology (PCAST),²⁰ stated that “[r]esearch to date suggests that some products of nanotechnology have the potential to present new or unusual risks to human health and the environment.”²¹ The conclusion of the 2012 Fourth Assessment of the National Nanotechnology

17. *Consumer Products*, THE PROJECT ON EMERGING NANOTECHNOLOGIES, <http://www.nanotechproject.org/inventories/consumer/> (last visited Feb. 16, 2013). This inventory is not exhaustive.

18. *Id.*

19. NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, DEP'T OF HEALTH & HUMAN SERV., PUBL'N NO. 2009-125, APPROACHES TO SAFE NANOTECHNOLOGY: MANAGING THE HEALTH AND SAFETY CONCERNS ASSOCIATED WITH ENGINEERED NANOMATERIALS iii (2009), available at <http://www.cdc.gov/niosh/docs/2009-125/pdfs/2009-125.pdf>.

20. The President's Council of Advisors on Science and Technology (PCAST) is an advisory group of the nation's leading scientists and engineers appointed by the President to augment the science and technology advice available to him from inside the White House and from cabinet departments and other federal agencies.

21. PRESIDENT'S COUNCIL OF ADVISORS ON SCI. & TECH., REPORT TO THE PRESIDENT AND CONGRESS ON THE THIRD ASSESSMENT OF THE NATIONAL NANOTECHNOLOGY INITIATIVE 38 (2010), available at <http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-nano-report.pdf>.

Initiative, published in April 2012, continues to underline concerns over the health and safety risks of nanomaterials.²²

The following is a non-exhaustive list of recent findings in connection with the environmental and health implications of intentionally produced nanomaterials. It is to be noted that despite the increased availability of products containing nanomaterials, no adverse effects have been officially reported in either the workplace, the environment, or among consumers. However, the studies listed below suggest that there might be a risk in the long run.

a. Impacts of Nanomaterials on the Environment

Releases to the environment can occur during the production process of nanomaterials, discharges from wastewater treatment plants, clean-up activities, or from the disposal of consumer products and other products containing nanomaterials.²³ The following are recent studies on the impacts of nanomaterials on the environment:

- In a study on the impact of uncoated fullerenes on largemouth bass, researchers noticed that the water of the tank that had been dosed with fullerenes was visibly clearer than the water in the control tank.²⁴ The conclusion was that uncoated fullerenes might act as a bactericide and kill beneficial bacteria normally found in aquatic environments.²⁵
- Initial results showed that silver nanoparticles have antimicrobial properties causing toxicity to *Escherichia*

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

23. *Engineered Nanomaterials in the Environment*, EPA, <http://www.epa.gov/athens/research/nano.html> (last updated Jan. 10, 2013).

24. Eva Oberdörster, *Manufactured Nanomaterials (Fullerenes, C60) Induce Oxidative Stress in the Brain of Juvenile Largemouth Bass*, 112 ENVTL. HEALTH PERSP. 1058, 1059 (2004).

25. *Id.*

coli.²⁶ Silver nanoparticles were able to enter mammalian cells and cause DNA damage and ultimately cell death.²⁷

- Nanoparticles leach from commercial products into sewage but can be removed during wastewater treatment.²⁸ Thus, nanosilver in socks could enter the environment through a number of different vectors.²⁹ It is likely that other nanoparticles behave in similar ways as nanosilver, where the nanoparticles can pass from commercial products into sewage and enter the environment.³⁰
- In January 2012, a study published by scientists from the Bren School of Environmental Science & Management, University of California, Santa Barbara, showed “that relatively low levels of ultraviolet light, consistent with those found in nature, can induce toxicity of [titanium dioxide] nanoparticles to marine phytoplankton.”³¹ The study concludes that marine ecosystems will have a decreased resiliency in waters contaminated by titanium dioxide.³²

b. Impacts of Nanomaterials on Public Health

As more and more products containing nanomaterials are manufactured and commercialized, an increasing number of scientific studies have been conducted in connection with the impact of nanomaterials on public health.

- A team of scientists affiliated with the National Institute for Occupational Safety and Health (NIOSH) investigated the pulmonary toxicity of multi-walled carbon

26. M. Ahamed et al., *DNA Damage Response to Different Surface Chemistry of Silver Nanoparticles in Mammalian Cells*, 233 TOXICOLOGY & APPLIED PHARMACOLOGY 404 (2008).

27. *Id.*

28. T. Benn & P. Westerhoff, *Nanoparticle Silver Released into Water from Commercially Available Sock Fabrics*, 42 ENVTL. SCI. & TECH. 4133 (2008).

29. *Id.*

30. *Id.*

31. Robert J. Miller et al., *TiO₂ Nanoparticles Are Phototoxic to Marine Phytoplankton*, BREN SCHOOL OF ENVTL. SCI. & MGMT. (2010).

32. *Id.*

nanotubes.³³ The reported data indicate that multi-walled carbon nanotubes exposure rapidly produces significant adverse health outcomes in the lungs (doses used estimated human occupational exposures).³⁴

- A study conducted by a team of scientists from UCLA's Jonsson Comprehensive Cancer Centre was the first to show that titanium dioxide nanoparticles (a commonly used nanomaterial, particularly in cosmetics) caused systemic genetic damage in mice.³⁵ The titanium dioxide nanoparticles induced single- and double-strand DNA breaks and also caused chromosomal damage, as well as inflammation—all of which increase the risk for cancer.³⁶ The study underlines that once in the system, the titanium dioxide nanoparticles accumulate in different organs because the body has no way to eliminate them.³⁷ And because the nanoparticles are so small, they can go everywhere in the body—even through cells—and may interfere with sub-cellular mechanisms.³⁸ These results raise strong concerns with regard to the safety of consumer products containing titanium dioxide.³⁹
- NIOSH research has shown that some nanoparticles, including certain types of carbon nanotubes and metal oxides, can be toxic to the hearts and lungs of mice and

33. The National Institute for Occupational Safety and Health (NIOSH) is the federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness. Vincent Castranova et al., *Persistent Pulmonary Fibrosis, Migration to the Pleura, and Other Preliminary New Findings after Subchronic Exposure to Multi-Walled Carbon Nanotubes*, NIOSH SCIENCE BLOG (Mar. 19, 2009, 10:24 AM), <http://blogs.cdc.gov/niosh-science-blog/2009/03/nano-2/>.

34. D.W. Porter et al., *Mouse pulmonary dose- and time course-responses induced by exposure to multi-walled carbon nanotubes*, 269 TOXICOLOGY 136 (2010).

35. Bénédicte Trouiller et al., *Titanium Dioxide Nanoparticles Induce DNA Damage and Genetic Instability In vivo in Mice*, 69 CANCER RES. 8784 (2009).

36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.*

rats in laboratory experiments.⁴⁰ NIOSH recommends that specific precautions should be taken to protect workers who might be exposed to any level of nanoparticles or nanoparticle-containing materials.⁴¹

- In the 2009 September issue of the *European Respiratory Journal*, Y. Song, X. Li, and X. Du of the Chaoyang Hospital of the Capital University of Medical Sciences in Beijing, China, published a study on what some said is the first medical case of exposure of workers to nanomaterials.⁴² Seven young women workers were diagnosed with serious heart and lung disease after working at a print plant exposed to a chemical “paste” mixture containing undefined “nanoparticles” of approximately thirty nanometers in diameter.⁴³ Two workers died.⁴⁴ Because of the lack of exposure data, the study cannot scientifically answer whether their exposure to nanoparticles caused or contributed to their disease. However, the workers’ clinical symptoms were consistent with the outcomes of animal studies in which nanoparticles have been intentionally introduced into the lungs.⁴⁵ The evidence demonstrated that nanoparticles ended up in the workers’ lungs.⁴⁶ Issues relating to the workplace safety (absence of ventilation) and the use of other chemicals in the “paste” mixture may also explain these workers’ illnesses.⁴⁷
- In a final report regarding the state of science on nanosilver published in August 2010 by EPA, it was cited that silver has been shown to be toxic to humans or animal cells when in nanoparticle form, with reported observations of a

40. John Howard et al., *Occupational Disease & Nanoparticles*, NIOSH SCIENCE BLOG (Aug. 15, 2010, 4:15 PM), http://www.cdc.gov/niosh/blog/nsb/082409_nano.html.

41. *Id.*

42. Y. Song et al., *Exposure to Nanoparticles Is Related to Pleural Effusion, Pulmonary Fibrosis and Granuloma*, 43 *EUR. RESPIRATORY J.* 559 (2009).

43. *Id.*

44. *Id.*

45. *Id.*

46. *Id.*

47. *Id.*

cytotoxic response nearly identical to that for chrysotile asbestos.⁴⁸

Numerous publications, including governmental reports, have emphasized an increased concern that exposure to engineered nanomaterials may cause adverse effects on the environment and public health. So what could be done to start developing a nano-specific regulation?

II. HOW TO DEVELOP NANOTECHNOLOGY REGULATION? FILLING THE KNOWLEDGE GAP AS A FIRST STEP: THE FRENCH EXAMPLE.

Nanotechnology has been the subject of many reports, publications, blogs, and research from a diversity of sources. One common trait that emerges from all these sources is the knowledge gap: the lack of sufficient information particularly on the environmental, health, and safety risks of nanotechnology (e.g. insufficiency of toxicity, exposure, and potential releases studies).

Due to this knowledge gap, a nanotechnology regulation can only be achieved progressively. This paper will first briefly assess what is the current nanotechnology regulatory framework in the United States, and thereafter it will examine the new French regulation on nanotechnology which became effective as of January 1, 2013 and addresses one of the main obstacles to nano-specific regulation: the knowledge gap.

A. United States' Current Regulatory Framework on Nanotechnology

a. At the Federal Level

At the federal level, there are currently no nano-specific regulatory instruments. The only federal legislation relating to nanotechnology is the 21st Century Nanotechnology Research and Development Act (Public Law 108-153) which was adopted in

48. EPA, OFFICE OF RESEARCH & DEV., EPA/600/R-10/084, STATE OF THE SCIENCE LITERATURE REVIEW: EVERYTHING NANOSILVER AND MORE 100 (2010).

2003.⁴⁹ The 21st Century Nanotechnology Research and Development Act focuses essentially on research and development activities (including investments) and the implementation of strategies and goals of a national nanotechnology program, providing also for education and training.⁵⁰ In the list of priorities of the national nanotechnology program, the ethical, legal, and environmental considerations during the development of nanotechnology is one of the last subjects to be mentioned.⁵¹

Senate Bill, S. 1662, entitled “Nanotechnology Regulatory Science Act of 2011,” was introduced on October 6, 2011 by Senator Mark L. Pryor.⁵² One of its purposes is to amend the Federal Food Drug and Cosmetic Act in order to establish within the Food and Drug Administration a program for the scientific investigation of nanomaterials included, or intended for inclusion, in products regulated under the Federal Food Drug and Cosmetic Act (food, drugs, cosmetics) so that the potential toxicology, effects, and interactions on biological systems of nanomaterials can be addressed.⁵³ Even though this Bill emphasizes the need for additional data and information with regard to nanomaterials, it does not impose any obligation on manufacturers, distributors, or importers to disclose the presence of nanomaterials in their products to federal agencies.

EPA is the federal agency which has so far proved to be the most active on the regulatory front. Currently, two environmental federal statutes are being used to regulate or attempt to regulate nanomaterials: the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).⁵⁴ TSCA seems to be the “natural”

49. The 21st Century Nanotechnology Research and Development Act of 2003, 15 U.S.C. ch. 101 (2012).

50. *Id.*

51. *Id.*

52. Nanotechnology Regulatory Science Act of 2011, S. 1662, 112th Cong. (2011), available at <http://www.gpo.gov/fdsys/pkg/BILLS-112s1662is/pdf/BILLS-112s1662is.pdf>.

53. *Id.*

54. See Toxic Substance Control Act, 15 U.S.C. §§ 2601–2695d (2012); Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136y (2012).

statutory instrument to regulate nanomaterials as it regulates chemical substances and mixtures that pose unreasonable risks, including requiring pre-manufacture notification to EPA for new chemicals or significant new uses of existing chemicals.⁵⁵ Since the nano form of chemical substances listed on the TSCA Inventory are considered existing chemical substances (as opposed to new chemical substances), they are not subject to the 90-day pre-manufacture notice applicable to new chemical substances under TSCA. However, under § 5(a)(2) of TSCA, EPA has the authority to require notification of significant new uses of existing chemical substances such as certain nanomaterials.⁵⁶ Using this authority, EPA issued two final significant new use rules in connection with carbon nanotubes: the first one in September 2010, which became effective on October 18, 2010,⁵⁷ and a second in May 2011,⁵⁸ which became effective on June 6, 2011. The rules mention that these actions are necessary because carbon nanotubes may be hazardous to human health and the environment.

On December 28, 2011, pursuant to the authority granted under § 5(a)(2) of TSCA, EPA proposed significant new use rules for seventeen chemical substances which were the subject of pre-manufacture notices.⁵⁹ The rule is not yet final. Among the chemicals subject to the proposed rule are certain fullerenes, as well as certain single and multi-walled carbon nanotubes.⁶⁰

Another environmental statute used in connection with the attempt to regulate nanosubstances is FIFRA: § 6(a)(2) (submission of additional information) and § 3(c)(2)(B) (data call-in notices). FIFRA applies only to pesticides and has therefore a limited scope in terms of products coverage. The Office of Pollution Prevention and Toxics of EPA has indicated that with regard to FIFRA, no change is required to subject nanosubstances

55. 15 U.S.C. § 2605 (2012).

56. 15 U.S.C. § 2604(a)(2) (2012).

57. *See* Significant New Uses of Chemical Substances Rule, 40 C.F.R. §§ 721.10155, 721.10156 (2012).

58. *See id.* § 721.10183.

59. *See* Significant New Use Rules on Certain Chemical Substances, Fed. Reg. 76,249 (proposed Dec. 28, 2011) (to be codified at 40 C.F.R. pt. 721), available at <http://www.gpo.gov/fdsys/pkg/FR-2011-12-28/pdf/2011-33261.pdf>.

60. *Id.*

to it, and § 6(a)(2) and § 3(c)(2)(B) are both already used to regulate nanosubstances.⁶¹ Whether or not industries comply with these provisions is difficult to tell, but the Office of Pollution Prevention and Toxics indicated that they were currently not getting any information on nanosubstances under § 6(a)(2).⁶² Another provision that could subject nanosubstances to FIFRA regulation is § 3(g), which requires that the registrations of pesticides be periodically reviewed.⁶³ Pursuant to § 3(g) and the Procedural Regulations Review, EPA published a notice of registration review of several pesticides in July 2012, and in particular established the Nanosilver Registration Review case.⁶⁴ The Office of Pollution Prevention and Toxics explained that they have information indicating that at the time of registration of several silver-based pesticide products currently on the market, registrants did not disclose to EPA the presence or characteristics of nanosilver contained in these pesticide products.⁶⁵ Among the products under registration review are two pesticide products recently registered as conditional registrations.⁶⁶ In the Nanosilver Registration Review document, EPA acknowledges the fact that it did not anticipate nanosilver to be acutely toxic; however, they had no data relating to long-term exposure effects, and the one study on nanosilver inhalation toxicity revealed toxic effects in the liver and lungs.⁶⁷ EPA considers these to be

61. Telephone Interview with Jed Costanza, Env'tl. Eng'r, Office of Pesticide Programs, EPA (Sept. 18, 2012).

62. *Id.*

63. See *Registration Review Final Rule*, EPA, http://www.epa.gov/oppsrrd1/registration_review/rule-making.htm (last visited Feb. 17, 2013).

64. See *Registration Review; Pesticide Dockets Opened for Review and Comment and Other Actions*, 77 Fed. Reg. 40048-01 (July 6, 2012).

65. CHEM. SAFETY & POLLUTION PREVENTION, U.S. EPA, EPA-HQ-OPP-2011-0370, NANOSILVER SUMMARY DOCUMENT REGISTRATION REVIEW: INITIAL DOCKET 5 (2012).

66. On December 1, 2011, EPA registered two nanosilver containing products: HeiQ AGS-20 (EPA Registration Number 85249-1) and HeiQ AGS-20 U (EPA Registration Number 85249-2). As part of the conditional registrations, HeiQ is required through the terms of its conditional registrations to provide additional data.

67. EPA, REGISTRATION REVIEW DOCUMENT: HUMAN HEALTH DATA SUMMARY FOR NANOSILVER 4 (2012).

adverse effects.⁶⁸ The Office of Pollution Prevention and Toxics indicated that one of the issues regarding nanosubstances is not that industries do not want to disclose information on the nanosubstances that they are using in their pesticide products, but rather they do not want to assume the high costs of testing.⁶⁹

In addition to the rules, proposed rules, and review processes presented above, several federal agencies have developed guidelines and recommendations relating to nanotechnology. For instance, NIOSH published a report in 2009 entitled “Approaches to Safe Nanotechnology, Managing the Health and Safety Concerns Associated with Engineered Nanomaterials,” in which NIOSH presents an overview of what is known about the risks of engineered nanomaterials and the measures that can be implemented to limit exposure to these risks.⁷⁰ The report states that “[n]anomaterials have the greatest potential to enter the body through the respiratory system if they are airborne and in the form of respirable-sized particles (nanoparticles). They may also come into contact with the skin or be ingested.”⁷¹ Other guidelines were published in May 2012 by NIOSH, entitled “General Safe Practices for Working with Engineered Nanomaterials in Research Laboratories,” which are considered by NIOSH as “the best information currently available on engineering controls and safe work practices to be followed when working with engineered nanomaterials in research laboratories.”⁷² The report emphasizes minimizing risks exposure and requires safety processes during the entire life cycle of nanomaterials.⁷³

68. See Memorandum from the U.S. EPA on Nanosilver: Summary of Human Health Data for Registration Review (June 22, 2012).

69. Telephone Interview with Jed Costanza, *supra* note 61.

70. See DEP’T OF HEALTH & HUMAN SERVS., NIOSH, PUB. NO. 2009–125, APPROACHES TO SAFE NANOTECHNOLOGY, MANAGING THE HEALTH AND SAFETY CONCERNS ASSOCIATED WITH ENGINEERED NANOMATERIALS v (2009), *available at* <http://www.cdc.gov/niosh/docs/2009-125/pdfs/2009-125.pdf>.

71. *Id.*

72. DEP’T. OF HEALTH & HUMAN SERVS., NIOSH, PUB. NO. 2012–147, GENERAL SAFE PRACTICES FOR WORKING WITH ENGINEERED NANOMATERIALS IN RESEARCH LABORATORIES vii (2012), *available at* <http://www.cdc.gov/niosh/docs/2012-147/pdfs/2012-147.pdf>.

73. *Id.*

In April 2012, the Food and Drug Administration joined the group of “guidelines issuers” by publishing two draft documents: a “Guidance for Industry Safety of Nanomaterials in Cosmetic Products” and a “Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives.”⁷⁴

None of these guidance materials are legally enforceable, and with current environmental statutes not always adapted to nanomaterials, their regulations and EHS risk management are currently inexistent under federal law. A comprehensive regulation applicable to all nanomaterials is required to address EHS risk management, and the first step will consist of filling the knowledge gap.

The April 2012 “Report to the President and Congress on the Fourth Assessment of the National Nanotechnology Initiative”⁷⁵ (the “2012 Report to the President and Congress”) was prepared by PCAST pursuant to the 21st Century Nanotechnology Research and Development Act and Executive Order 13349. While acknowledging the fact that the United States has a leadership position with regard to nanotechnology research and development, as well as capital venture investments, the report shows concern that no efficient strategy is yet in place regarding the management of EHS risks from nanomaterials and that in particular agencies do not have the information resulting from the EHS research and development work to implement such strategy.⁷⁶ Despite admitting the existence of a knowledge gap

74. Guidance for Industry Safety of Nanomaterials in Cosmetic Products, 77 Fed. Reg. 24722 (Apr. 25, 2011), *available at* <http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ucm300886.htm>; Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives, 77 Fed. Reg. 2477 (Apr. 25, 2011).

75. PRESIDENT’S COUNCIL OF ADVISORS ON SCI. & TECH., EXEC. OFFICE OF THE PRESIDENT, REPORT TO THE PRESIDENT & CONGRESS ON THE FOURTH ASSESSMENT OF THE NATIONAL NANOTECHNOLOGY INITIATIVE (2012), *available at* http://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST_2012_Nanotechnology_FINAL.pdf.

76. *Id.*

on EHS risks of nanomaterials, PCAST only suggests that federal agencies shall “engage with companies in a non-regulatory capacity to increase their awareness of and ability to use the latest knowledge and guidance being generated on this topic.”⁷⁷ The Report supports a non-regulatory action from federal agencies to fill the knowledge gap; however, the EPA Nanoscale Materials Stewardship Program launched in 2008 shows that this is not the road to take.⁷⁸ Under its Nanoscale Materials Stewardship Program, EPA asked participants to the Program to submit existing information on the nanoscale materials they manufacture, import, process, or use (Basic Program), and to engage in a test program (In-Depth Program) to assist EPA to obtain useful information on the potential risks of these substances.⁷⁹ In the Nanoscale Materials Stewardship Program Interim Report of 2009 prepared by the Office of Pollution Prevention and Toxics,⁸⁰ EPA noted that although the program provided useful information regarding certain nanomaterials in commerce, the responses were incomplete or inexistent on crucial data such as toxicity or fate studies, exposure, or hazard-related data.⁸¹ Furthermore, it appears from the results of the program that “nearly two-thirds of the chemical substances from which commercially available nanoscale materials are based were not reported under the Basic Program.”⁸² The report concludes that it is uncertain whether the participants reported all of the nanoscale materials that they produce, process, use, or import, or information on their manufacturing processes or uses.⁸³ EPA reaches the conclusion on the future of voluntary action by the industry that “the low rate of engagement in the In-Depth Program suggests that most companies are not inclined to voluntarily test their nanoscale materials.”⁸⁴ The cost of testing

77. *Id.* at 31.

78. *Id.*; OFFICE OF POLLUTION PREVENTION & TOXICS, U.S. EPA, NANOSCALE MATERIALS STEWARDSHIP PROGRAM: INTERIM REPORT (2009), available at <http://epa.gov/oppt/nano/nmsp-interim-report-final.pdf>.

79. See OFFICE OF POLLUTION PREVENTION & TOXICS, *supra* note 78.

80. *Id.*

81. *Id.* at 9.

82. *Id.* at 27.

83. *Id.*

84. *Id.*

is probably one of the reasons for the lack of success of the In-Depth Program.

A Final Report was scheduled to be published in 2010, but the Office of Pollution Prevention and Toxics indicated that the interim report would be the only report to be published on the Nanoscale Materials Stewardship Program implemented by EPA.⁸⁵

The 2012 Report to the President and Congress refers to the results of an interesting survey about nanotechnology employers published in the *Journal of Nanoparticle Research* in January 2012.⁸⁶ The survey, conducted in fourteen countries between 2009 and 2010, targeted engineered nanomaterials private companies from Asia, Europe, North America (59% of the companies were headquartered in North America, with 58% of the total sample in the United States), and Australia.⁸⁷ The survey focused on the positions of engineered nanomaterials industries across the globe regarding nanomaterial EHS risks and regulations.⁸⁸ Despite admitting “uncertainty and moderate-high perceived risk” with regard to nanomaterial potential risks, the industry indicated that they would prefer self-regulation over governmental regulations.⁸⁹ Workers were also considered to be primarily responsible with regard to occupational safety.⁹⁰ However, the survey revealed that almost half of the industry representatives (48%) identified lack of guidance or regulation as

85. Telephone Interview with Jed Costanza, *supra* note 61.

86. PRESIDENT’S COUNCIL OF ADVISORS ON SCI. & TECH., *supra* note 75, at 33 (citing C. D. Engeman et al., *Governance Implications of Nanomaterials Companies’ Inconsistent Risk Perceptions and Safety Practices*, 14 J. NANOPARTICLE RES. 749 (2012)). This research work was supported by Coop. Agreement DBI-0830117 from the U.S. National Science Foundation (NSF) and the EPA to the University of California Center for Environmental Implications of Nanotechnology, and by Coop. Agreements SES 0531184 and SES 093809 from the NSF to the Center for Nanotechnology in Society at the University of California, Santa Barbara.

87. C. D. Engeman et al., *Governance Implications of Nanomaterials Companies’ Inconsistent Risk Perceptions and Safety Practices*, 14 J. NANOPARTICLE RES. 749 (2012).

88. *Id.*

89. *Id.*

90. *Id.*

an impediment to implementing nano-specific practices.⁹¹ Thirty-nine percent of participants disagreed or strongly disagreed that voluntary reporting approaches for risk management were effective.⁹² It appears from the responses to the survey that the industry may take actions with regard to potential risks of nanomaterials as long as the cost is not too prohibitive.⁹³ The survey also shows that the industry does not implement—at least in a consistent manner—the guidelines (recommendations) issued by governmental agencies, and that a significant number of businesses considers “the lack of regulation as a problem and does not trust others in industry to act responsibly.”⁹⁴

This very interesting international survey leads one to conclude that guidelines and voluntary reporting are insufficient to provide a proper response to engineered nanomaterials risk management in order to protect the workplace and the environment. It is to be noted that the survey focused on prevention of nanomaterial EHS risks in the workplace and did not address protection of the environment and public health in connection with consumer products currently on the market.

b. At the State and Local Levels

At the state level, California has been the front runner in attempting to gather information on certain nanomaterials pursuant to the authority granted under the California Health and Safety Code (e.g. carbon nanotubes, nano silver, nano titanium dioxide).⁹⁵ In 2009, as part of the process of evaluating how to obtain the proper information on a volunteer collaborative basis, California Department of Toxic Substances Control visited ten California manufacturing companies producing nanomaterials and nanometal oxides.⁹⁶ The results of these

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

95. *California Health and Safety Code*, CAL. LAW, http://www.leginfo.ca.gov/html/hsc_table_of_contents.html (last visited Mar. 12, 2013).

96. DEP'T OF TOXIC SUBSTANCES CONTROL, OFFICE OF CHIEF SCIENTIST, NANOMATERIALS COMPANY VISITS REPORT 3 (2009), *available at* <http://www.dtsc>.

visits show diversity in nanomaterials companies (big and small companies, producers of raw materials, intermediate, or finished products) and the concerns of small companies relating to testing requirements due to the high costs of testing.⁹⁷ The report concluded that companies should provide a material safety data sheet on nanomaterials and label their products as containing nanomaterials.⁹⁸

The only legislation in the United States specifically related to nanomaterials (as opposed to specific nano-substances such as carbon nanotubes, or specific products such as pesticides) is an ordinance passed by the City of Berkeley, California, in December 2006.⁹⁹ It is to be noted that in April 2006, the City of Berkeley adopted a precautionary principle that probably helped support the adoption of the ordinance on nanotechnology.¹⁰⁰ The ordinance currently has a limited application.¹⁰¹

Following what was exposed so far, one can draw the following conclusions:

- Nanotechnology is a technology with a great potential and is evolving rapidly.
- Most stakeholders agree that there is a lack of information on nanomaterials, in particular nanotechnology's potential risks on the environment and public health.¹⁰²
- There is no specific legislation on nanotechnology in the United States with the exception of the 21st Century Nanotechnology Research and Development Act (Public Law 108-153), which focuses on research and development.

ca.gov/TechnologyDevelopment/Nanotechnology/upload/Nanomaterial-Company-Visit-Report.pdf.

97. *Id.* at 12.

98. *Id.* at 27.

99. BERKELEY, CAL., MUNICIPAL CODE § 15.12.040 (2013).

100. ORDINANCE AMENDING BERKELEY MUNICIPAL CODE (BMC) SECTION 15.12.040 TO ADD SUBSECTION I AND AMENDING BMC SECTION 15.12.050 TO ADD SUBSECTION C.7, REGARDING MANUFACTURED NANOPARTICLE HEALTH AND SAFETY DISCLOSURE, *available at* <http://www.calcupa.net/civica/filebank/blobdload.asp?BlobID=2305>.

101. BERKELEY, CAL., MUNICIPAL CODE § 15.12.040 (2013).

102. Interview with Patricia Blanc, French Ministry of the Env't, DGPR (Aug. 31, 2012).

- Voluntary programs relating to nanotechnology did not result in the collection of needed information on nanomaterials, particularly toxicity and exposure data.
- Contrary to what one may think, industries in the United States may welcome a regulation on nanotechnology that will provide them with a framework of action to ensure that potential risks to the environment and public health risks resulting from nanotechnology are addressed and that safeguards are in place to protect their intellectual property rights. However, testing cost is an issue.
- Existing statutes are limited in their scope of action.

Consequently, the logical course of action will be to put in place a mandatory collection of information for nanomaterials, protective of trade secrets. The newly enacted French regulation could be a starting point.

B. The French Regulation on Nanoparticle Substances

This paper will briefly present the process that led to the adoption of the nanotechnology regulation, and thereafter review the regulation itself.

a. How it Started

An important element, which characterizes France's legal system in the context of risks management, is the introduction in 2004 of the precautionary principle in its Constitution. The 2004 "Charte de l'Environnement" (Environmental Charter) amended the French 1958 Constitution to include new fundamental environmental rights such as the precautionary principle, which is ranked at the same level as the 1789 Human Rights Declaration.¹⁰³ Article 5 of the Environmental Charter of 2004 provides that despite uncertainty in the current scientific knowledge, in the event the environment could be damaged in a serious and irreversible manner, the authorities, applying the precautionary principle and within the scope of their authority, should implement procedures to evaluate the risks and adopt

103. 1958 CONST. CHARTER FOR THE ENVIRONMENT (Fr. 2004).

temporary and proportionate measures to prevent the damage.¹⁰⁴ Therefore, scientific uncertainty and the probable existence of serious irreversible risks are the two conditions required to invoke the precautionary principle.¹⁰⁵

Based on these premises, a consultation with all stakeholders (the government, local authorities, trade unions, businesses, and voluntary sectors) started in 2007 in order to find answers to France's new environmental challenges, in particular climate change and the emergence of new technologies; this process resulted in a major reform of the French environmental policy and legal system.¹⁰⁶ The entire consultation and legislative process was called the "Grenelle de l'Environnement."

The purpose of the "Grenelle de l'Environnement" was to define a plan of action to address environmental issues, such as—but not limited to—climate change and the emergence of new technologies. The name "Grenelle" came from the 1968 meetings among all stakeholders to resolve the May 1968 crisis that resulted in weeks of social riots.¹⁰⁷ The 1968 meetings took place in Paris, 127 rue de Grenelle, the headquarters of the French Ministry of Labor.¹⁰⁸

The "Grenelle de l'Environnement" is composed of five main pieces of legislation (not including the Finance Laws which also contain provisions in favor of the environment), among which are the Grenelle 1 Law—a framework law—and the Grenelle 2 Law, which implements the provisions of the Grenelle 1 Law.¹⁰⁹ Provisions on nanotechnology are found in the Grenelle 2 Law.

As indicated by the Nanotechnology Department of the French Ministry of the Environment, the "Grenelle de l'Environnement" movement was generally well received by businesses: there were no immediate signs of the coming

104. *Id.* art. 5.

105. *Id.*

106. Interview with Patricia Blanc, *supra* note 102.

107. KLAUS BOSSELMANN ET AL., IUCN, GOVERNANCE FOR SUSTAINABILITY: ISSUES, CHALLENGES, SUCCESSES 63 (2008), *available at* www.iucn.org/dbtwwpd/edocs/eplp-070.pdf.

108. *Id.*

109. *Grenelle Process*, LE GRENELLE ENVIRONNEMENT, <http://translate.google.com/translate?hl=en&sl=fr&tl=en&u=http%3A%2F%2Fwww.legrenelle-environnement.fr%2F> (last visited Feb. 25, 2013),

recession in 2007, there was a general consensus on the urgency of certain environmental issues (climate change for instance), and on the government side consultations were made and decisions were taken at the highest political level (there was also a consensus among all political parties).¹¹⁰ Another important point is that the European Union was closely watching what was happening in France and gave its approval to the French legislation on nanotechnology.¹¹¹ The recently enacted French legislation on nanotechnology essentially imposes a reporting obligation of all nanomaterials used.¹¹² It is the first step of a regulatory process on nanosubstances. There is a demand among citizens, but also other stakeholders, to know more about the nanosubstances that are used, in which kind of products, and in which business activities.¹¹³ Products labeling will come next at the European level, and a further step will consist of developing the tools to evaluate and manage the risks.¹¹⁴ One of the main issues is the necessity to increase the budget in order to evaluate the risks resulting from nanomaterials.¹¹⁵ The French Chemical Industries Trade Association, which was contacted, explained the reasons why the industry accepted the regulation on nanotechnology: several European Union initiatives, such as the fact that nanomaterials will be more and more integrated into the REACH program, the 2008 EU Regulation on the classification, labeling, and packaging of chemical substances, and the current work on labeling cosmetic products.¹¹⁶ The industry emphasizes that it will not agree on anything unsupported by the European Union.¹¹⁷ A second reason was the obvious need to answer many stakeholders' requests for additional information on nanoscale substances, which would develop more confidence toward this new technology.¹¹⁸

110. Interview with Patricia Blanc, *supra* note 102.

111. *Id.*

112. *Id.*

113. *Id.*

114. *Id.*

115. *Id.*

116. Telephone Interview with M. Philippe Prudhon, Dir., Technical Affairs of the Chem. Indus. Trade Ass'n (Sept. 20, 2012).

117. *Id.*

118. *Id.*

Without sufficient and adequate information, it will not be possible to assess and manage the risks of nanomaterials. The French regulation, which is described below, is an attempt to fill the existing knowledge gap on nanomaterials.

b. The French Regulation on Nanoparticle Substances

The French “Nanomaterial” regulation has three levels: a law (Article 185 of the Grenelle 2 Law dated July 12, 2010),¹¹⁹ and two decrees (Decree No. 2012-232 of February 17, 2012¹²⁰ and Decree No. 2012-233 of February 17, 2012).¹²¹ This paper will focus on Decree No. 2012-232 relating to the Annual Declaration of Nanoparticle Substances adopted pursuant to Article 185 of the Grenelle 2 Law, and a Ministerial Order dated August 6, 2012 relating to the Content and Requirements of the Annual Declaration of Nanoparticle Substances, adopted pursuant to Articles R523-12 and R523-13 of the Environmental Code (the “Ministerial Order”).¹²²

Article 185 of the Grenelle 2 Law, dated July 12, 2010, (the “Law”), added a new chapter to the French Environmental Code entitled “Prevention of Public Health and Environmental Risks Resulting from Exposure to Nanoparticle Substances”, codified as Article L523-1 through Article L523-5 of the French Environmental Code, pursuant to which anyone who manufactures, imports, or distributes a nanoparticle substance “as is” or incorporated in a mixture in an unbound state—or a

119. Loi 2010-788 du 12 juillet 2010 [Law 2010-788 of July 12, 2010], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] No. 0160 [OFFICIAL GAZETTE OF FRANCE], July 13, 2010, p. 12905.

120. Décret 2012-232 du 17 février 2012 [Decree 2012-232 of Feb. 17, 2012], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] No. 0043 [OFFICIAL GAZETTE OF FRANCE], Feb. 19, 2012, p. 2863.

121. Décret 2012-233 du 17 février 2012 [Decree 2012-233 of Feb. 17, 2012], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] No. 0043 [OFFICIAL GAZETTE OF FRANCE], Feb. 19, 2012, p. 2865. This Decree designates the agencies and institutions eligible to receive information relating to the dangers and exposure of nanoparticles substances.

122. Ministerial Order of August 6, 2012, JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] No. 0185 [OFFICIAL GAZETTE OF FRANCE], Aug. 10, 2012, p. 2863.

material intended to release this substance in normal or reasonably anticipated conditions of use—must file an annual declaration with the Ministry of the Environment.¹²³ The purpose of this disclosure obligation is to trace these nanosubstances in order to have a better understanding of their uses, their channels of distribution, the market, and the volume of trade, to be able to collect data on toxicology and ecotoxicology, and to inform the public. The Law is not immediately enforceable and requires the adoption of regulations in order to implement its provisions. On February 17, 2012, Decree No. 2012-232 (Decree) relating to the annual declaration of nanoparticle substances was promulgated to implement the above-mentioned Law.¹²⁴ The Decree recites the provisions of the Law and introduces definitions and more detailed information regarding the implementation of the Law.¹²⁵ This part of the paper will focus on the Decree and the Ministerial Order. The new regulation became effective as of January 1, 2013 and applies to the entire French territory with the exception of New Caledonia, French Polynesia, Wallis and Futuna, and the French South Pole and Antarctic Territories.¹²⁶

1. The Definition of Nanoparticle Substances

The Decree adds a new chapter to the regulation portion of the French Environmental Code entitled “Prevention of Public Health and Environmental Risks Resulting from Exposure to Nanoparticle Substances”; the Decree is codified as Article R523-12 through Article R523-21 of the French Environmental Code.¹²⁷

The definition of a nanoparticle substance in the Decree follows the European Commission Recommendation on the definition of nanomaterial (the European Commission uses the

123. Loi 2010-788 du 12 juillet 2010 [Law 2010-788 of July 12, 2010], *JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE* [J.O.] No. 0160 [OFFICIAL GAZETTE OF FRANCE], July 13, 2010, p. 12905.

124. Décret 2012-232 du 17 février 2012 [Decree 2012-232 of Feb. 17, 2012], *JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE* [J.O.] No. 0043 [OFFICIAL GAZETTE OF FRANCE], Feb. 19, 2012, p. 2863.

125. *Id.*

126. *Id.*

127. *Id.*

term “nanomaterial” rather than “nanoparticle substance”) dated October 18, 2011, with a small exception.¹²⁸ According to Article R523-12 of the Decree, a nanoparticle substance means a substance—as defined in Article 3 of Regulation CE No. 1907/2006—intentionally manufactured at the nanoscale that contains particles in an unbound state, as an aggregate, or as an agglomerate, and where, for a minimal proportion of the particles in the number size distribution (the Ministerial Order specifies that this minimal proportion is 50% of the particles in the number size distribution), one or more external dimensions is in the size range between 1 nm and 100 nm.¹²⁹ The Decree adds (and the European Commission Recommendation provides the exact same details) that in specific cases and where warranted by concerns for the environment, health, safety, or competitiveness, the number size distribution threshold may be replaced by a lower threshold (the European Commission Recommendation is a little bit more specific as it specifies that the lower threshold will be between 1% and 50%).¹³⁰

The Decree provides that by derogation from the above, fullerenes, graphene flakes, and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanoparticle substances.¹³¹ The same derogation is included in the European Commission Recommendation.¹³²

While the Decree refers to a nanoparticle substance as a substance *intentionally* manufactured, the European Commission defines nanomaterial as *a natural, incidental, or manufactured material containing particles*.¹³³ In other words, the French

128. Commission Recommendation of 18 October 2011 on the Definition of Nanomaterial, 2011 O.J. (L 275) 38, 40.

129. *Id.*

130. *Id.*

131. Ministerial Order of August 6, 2012, JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] No. 0185 [OFFICIAL GAZETTE OF FRANCE], Aug. 10, 2012, p. 2863.

132. Commission Recommendation of 18 October 2011 on the Definition of Nanomaterial, 2011 O.J. (L275) 38, 40.

133. Décret 2012-232 du 17 février 2012 [Decree 2012-232 of Feb. 17, 2012], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] No. 0043 [OFFICIAL GAZETTE OF FRANCE], Feb. 19, 2012, p. 2863; Commission Recommendation of 18 October 2011 on the Definition of Nanomaterial, 2011 O.J. (L 275) 38, 40.

definition does not include the “natural or incidental” element. This was a request made by the industries to only target the nanoparticle substances “intentionally” manufactured (also called “engineered” nanomaterials).¹³⁴ It would have been too burdensome if nanoparticle substances which are incidental to processes involving, for instance, combustion, welding, or diesel engines, were also subject to regulation.

The Decree provides other important definitions in its Article R523-12 and most of them are borrowed from Article 3 of the European Parliament and Council Regulation No. 1907/2006 of December 18, 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).¹³⁵

2. Who is Subject to the New French Regulation?

There are four categories of actors concerned with the Decree and the Ministerial Order: the manufacturer, the importer, the distributor, and at a different level, the professional user.¹³⁶

The Decree provides that each manufacturer, importer, or distributor of a nanoparticle substance shall file a declaration as long as it manufactures, imports, or distributes at least 100 grams per year of this substance in the French territory.¹³⁷ The Law and the Decree targeted both the manufacturing and the research and development industries; however, the research and development industry only requires a very small quantity of nanoparticle substances as opposed to the manufacturing industry. This is the reason why the initial version of the Decree mentioned a quantity of ten grams (the traditional quantity used in research and development activities). However, under the

134. Telephone Interview with M. Philippe Prudhon, *supra* note 116.

135. Eur. Parl. & Council Regulation 1907/2006, 2006 O.J. (L 396) 1 Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

136. Décret 2012-232 du 17 février 2012 [Decree 2012-232 of Feb. 17, 2012], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] No. 0043 [OFFICIAL GAZETTE OF FRANCE], Feb. 19, 2012, p. 2863.

137. *Id.*

pressure of the research and development industry, the amount was changed to 100 grams which remains an extremely small amount for the manufacturing industries.

The manufacturer is defined as any person manufacturing, in the course of its business activities in the French territory, for its own use or for sale, with or without compensation, a nanoparticle substance “as is,” or incorporated in a mixture in an unbound state, or a material intended to release this substance in normal or reasonably anticipated conditions of use.¹³⁸ The importer is defined as any person who introduces, in the course of its business activities in the French territory, a nanoparticle substance “as is,” or incorporated in a mixture in an unbound state, or a material intended to release this substance in normal or reasonably anticipated conditions of use, from another member state of the European Union or from any other third party country.¹³⁹ Two other important actors defined under the Decree are the distributor and the professional user. The distributor is defined as any person established in the French territory, including a retailer, who is engaged in storage or sale activities for professional users, with or without compensation, of a nanoparticle substance “as is,” or incorporated in a mixture in an unbound state, or a material intended to release this substance in normal or reasonably anticipated conditions of use.¹⁴⁰ The professional user is defined as any person established in the French territory, who is neither the manufacturer nor the importer, who uses a nanoparticle substance “as is,” or incorporated in a mixture in an unbound state, or a material intended to release this substance in normal or reasonably anticipated conditions of use in the course of its business activities.¹⁴¹

As mentioned above, the obligation to submit an annual declaration of nanoparticle substances used apply to the manufacturer, the importer, and the distributor as long as they manufacture, import, or distribute in the French territory at least 100 grams of a nanoparticle substance per year. Furthermore, it

138. *Id.*

139. *Id.*

140. *Id.*

141. *Id.*

is irrelevant whether or not the contemplated transaction is with or without consideration. Also, only transactions to professional users will require filing a declaration as opposed to transactions to final consumers. For instance, an importer imports in France socks manufactured in the United States which contain nanosilver, a nanosubstance which has been shown to be released in the environment in normal or reasonably anticipated conditions of use. The importer, and we will see the details further below in this paper, must file a declaration if the amount of nanosubstances imported in France exceeds 100 grams per year. Let us assume that the importer sells the nanosilver socks to a French distributor, who in turn sells them to department stores. The French distributor must also file a declaration, but the department stores do not have to file an annual declaration as they do not sell to professional users.

The business activities contemplated under the Decree must be based in France, and a manufacturer of nanoparticle substances is subject to the annual reporting obligation even though the production is made for its own use.

3. The Content of the Declaration

The Law provides the obligation to report the quantities and the uses of the nanoparticle substances produced, distributed, or imported in France.¹⁴² It is in the Ministerial Order that detailed information on the content of the declaration is found.¹⁴³ An “Annexe” or Exhibit lists the information to be reported, which is divided in five categories:

- Information on the identity of the declarant (information relating to the business entity and any of its establishments which is subject to the reporting obligation; capacity e.g. manufacturer, importer, distributor; business activity; whether it is a foreign entity

142. Loi 2010-788 du 12 juillet 2010 [Law 2010-788 of July 12, 2010], *JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE* [J.O.] No. 0160 [OFFICIAL GAZETTE OF FRANCE], July 13, 2010, p. 12905.

143. Ministerial Order of August 6, 2012, *JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE* [J.O.] No. 0185 [OFFICIAL GAZETTE OF FRANCE], Aug. 10, 2012, p. 2863.

and capacity as authorized representative; and for research and development industries it should be indicated whether or not the substance will be placed on the market).¹⁴⁴

- Identity of the nanoparticle substance.¹⁴⁵ Two types of information are to be provided: (i) the mandatory information and (ii) the information to be reported but only if it is available. The mandatory information that should be reported consists of all the nanoparticle substance's chemical information (e.g. name, formula, CAS number, particles size, the number size distribution, aggregation and agglomeration data, qualitative description of the particle form, its coating if applicable, and whether the substance is "as is" or incorporated in a mixture in an unbound state, or if there is a material intended to release the nanoparticle substance in normal or reasonably anticipated conditions of use.¹⁴⁶ Any mixture should specify if it is in a solid, liquid, gaseous, or powder form). The information to be reported only if it is available is as follows: REACH registration number if applicable; information on the presence of impurities, data on crystalline state of the substance, and on specific surface and charge.¹⁴⁷
- Quantity produced, distributed, or imported during the reported year (expressed in kilograms).¹⁴⁸
- Description of all uses planned for the nanoparticle substances including commercial name of the mixture or material placed on the market.¹⁴⁹ As an option, it is also possible to report the properties claimed.
- Identity of the professional users to whom the declarant transferred the nanoparticle substance.¹⁵⁰

144. *Id.*

145. *Id.*

146. *Id.*

147. *Id.*

148. *Id.*

149. *Id.*

150. *Id.*

4. How Will it Work?

Each year, prior to May 1, the manufacturer, importer, or distributor shall file with the Ministry of the Environment a declaration on nanoparticle substances activity for the preceding year.¹⁵¹ As seen above, this annual declaration will contain information on the identity, quantities, and uses of these substances, as well as the identity of professional users to whom they were transferred with or without consideration. Under the provisions of the Ministerial Order, every time a declaration is filed, it will be assigned a number which will be communicated to the declarant.¹⁵² Furthermore, anytime a nanoparticle substance as defined above or a material intended to release this substance in normal or reasonably anticipated conditions of use is sold, with or without consideration, to a professional user or a distributor, both should receive the declaration number assigned to the declarant (for instance a manufacturer).¹⁵³ When the declarant is a distributor, instead of providing the required detailed information on the identity of the nanoparticle substances, it can simply provide the assigned declaration number communicated to it.¹⁵⁴ For the importer, upon its request, the required detailed information on the identity of the nano-substances can be reported either by (i) the European entity who sold to the importer a nanoparticle substance as defined above or a material intended to release this substance in normal or reasonably anticipated conditions of use, or by its authorized European representative, or (ii) for legal entities based outside the European territory, by the authorized European representative of such legal entity.¹⁵⁵ For instance, an importer of nanoparticle substances sold by a United States corporation may request the authorized European representative of the United States corporation to declare the required detailed information on the identity of the nano-substances. In such a case, the importer may simply provide in its annual declaration the assigned declaration

151. *Id.*

152. *Id.*

153. *Id.*

154. *Id.*

155. *Id.*

number provided by the entity who sold the substance to the importer or by its authorized representative.

The declaration is electronically filed with the exception of sensitive national security defense data which is communicated via the appropriate means.

5. The Protection of the Intellectual Property

Obviously in the presence of a new, fast evolving technology the protection of intellectual property is an extremely important issue. Both the Decree and the Ministerial Order contain several provisions aiming to protect intellectual property rights.¹⁵⁶ Under the Decree, when complying with the reporting obligation, the author of the declaration should request that certain information be kept confidential in order to protect the trade secrets or the intellectual property attached to the results of the research conducted.¹⁵⁷ Each request should be well founded. With regard to information contained in a patent application, they remain confidential until the publication date of the patent.¹⁵⁸ Such publication date must be communicated to the Ministry of the Environment in the declaration of the following year.¹⁵⁹

Furthermore, some of the crucial information that must be provided under the reporting obligation as listed in the Ministerial Order is automatically deemed to be confidential information, without the need for the declarant to file a request for confidentiality. The following information is automatically deemed to be confidential information: identification of the nanoparticle substance with the exception of the chemical name,

156. Décret 2012-232 du 17 février 2012 [Decree 2012-232 of Feb. 17, 2012], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] No. 0043 [OFFICIAL GAZETTE OF FRANCE], Feb. 19, 2012, p. 2863; Ministerial Order of August 6, 2012, JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] No. 0185 [OFFICIAL GAZETTE OF FRANCE], Aug. 10, 2012, p. 2863.

157. Décret 2012-232 du 17 février 2012 [Decree 2012-232 of Feb. 17, 2012], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] No. 0043 [OFFICIAL GAZETTE OF FRANCE], Feb. 19, 2012, p. 2863.

158. *Id.*

159. *Id.*

quantity, commercial name of the mixture or the material, and identity of professional users.¹⁶⁰

For information that the declarant wishes to withhold from the public for national security reasons, it must be mentioned in the declaration.¹⁶¹ In such case, within five days from the date of filing the declaration, the declarant must submit a request to the Ministry of Defense explaining why an exemption from disclosure should be granted.¹⁶² The exemption is granted by the Ministry of Defense and communicated to both the declarant and the National Agency in charge of Food, Environmental and Occupational Safety (Agence Nationale de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail). It is to be noted that if the Ministry of Defense does not respond within a period of three months from the date of receipt of the request for exemption, such request is deemed to have been rejected.¹⁶³ A Ministerial Order will provide further information on the submission and requirements of the request for exemption from public disclosure for national security reasons.¹⁶⁴

6. What Will Happen to the Data?

The information and data received by the Ministry of the Environment will be managed by the Agency in charge of Food, Environmental and Occupational Safety, as they have expertise to process and analyze these data in the context of risks evaluation.

The Decree No. 2012-233 of February 17, 2012 provides that the National Agency in charge of Food, Environmental and Occupational Safety may, following a request of certain institutions, listed below, disclose to them the information

160. Ministerial Order of August 6, 2012, JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] No. 0185 [OFFICIAL GAZETTE OF FRANCE], Aug. 10, 2012, p. 2863.

161. Décret 2012-232 du 17 février 2012 [Decree 2012-232 of Feb. 17, 2012], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] No. 0043 [OFFICIAL GAZETTE OF FRANCE], Feb. 19, 2012, p. 2863.

162. *Id.*

163. *Id.*

164. *Id.*

received pursuant to the Decree.¹⁶⁵ The institutions listed are the French Agency of Health Products Safety (Agence Française de Sécurité Sanitaire des Produits de Santé), the National Institute of Sanitary Surveillance (Institut National de Veille Sanitaire), the National Institute of Research and Safety (Institut National de Recherche et de Sécurité), the National Institute of Industrial Environment and Risks (Institut National de l'Environnement Industriel et des Risques), as well as agencies in charge of toxicology surveillance.¹⁶⁶ These institutions and agencies will manage the data and conduct risk evaluations within their respective area of expertise. They also have to comply with data confidentiality and protection obligations.¹⁶⁷

7. Research and Development Sector, a Special Treatment

Whenever the production, importation, or distribution of a nanoparticle substance “as is,” or incorporated in a mixture in an unbound state, or of a material intended to release this substance in normal or reasonably anticipated conditions of use is accomplished in the course of a scientific research and development activity, and there is no commercialization, the reporting obligation can be limited to the identity of the declarant and the business activity involved.¹⁶⁸ Furthermore, for public research institutions, one unique declaration covering their entire research activities can be submitted. A ministerial order will specify the content and filing requirements of this unique declaration. For a research and development activity focusing on products and processes, with no commercialization, the information submitted as part of the reporting obligation is automatically deemed to be confidential information without the need for the declarant to file a request for confidentiality.

165. Décret 2012-233 du 17 février 2012 [Decree 2012-233 of Feb. 17, 2012], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] No. 0043 [OFFICIAL GAZETTE OF FRANCE], Feb. 19, 2012, p. 2865.

166. *Id.*

167. *Id.*

168. Ministerial Order of August 6, 2012, JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] No. 0185 [OFFICIAL GAZETTE OF FRANCE], Aug. 10, 2012, p. 2863.

8. Information to the Public

Subject to the confidentiality provisions of both the Decree and the Ministerial Order, information will be made available to the public in the form of a report within six months following the deadline for filing the declaration.¹⁶⁹

9. Compliance Tools and Enforcement

Following a failure to file the annual declaration with the Ministry of the Environment within the time frame provided in the Decree, or failure to submit additional information requested by the National Agency for Food, Environmental and Occupational Safety or the Ministry of the Environment, the Ministry of the Environment may order that a fine and per diem penalty be paid.¹⁷⁰ The fine shall not exceed 3,000 Euros per nanoparticle substance not reported.¹⁷¹ The penalty shall be equal to 300 Euros per day and shall commence on the day it was ordered up and until the violator fully complies with its obligations.¹⁷² These amounts are lower than traditional monetary sanctions under the French Environmental Code. These provisions relating to the fine and penalties will be effective as of July 1, 2013.¹⁷³

The Ministry of the Environment indicated that in order to verify compliance with the provisions of the Decree and Ministerial Order, they will be using several tools such as electronic verification since the annual declaration will be submitted electronically.¹⁷⁴ The authorities already have an idea

169. Décret 2012-232 du 17 février 2012 [Decree 2012-232 of Feb. 17, 2012], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] No. 0043 [OFFICIAL GAZETTE OF FRANCE], Feb. 19, 2012, p. 2863; Ministerial Order of August 6, 2012, JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] No. 0185 [OFFICIAL GAZETTE OF FRANCE], Aug. 10, 2012, p. 2863; Interview with Patricia Blanc, *supra* note 102.

170. Décret 2012-232 du 17 février 2012 [Decree 2012-232 of Feb. 17, 2012], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] No. 0043 [OFFICIAL GAZETTE OF FRANCE], Feb. 19, 2012, p. 2863.

171. *Id.*

172. *Id.*

173. *Id.*

174. Interview with Patricia Blanc, *supra* note 102.

of the market and will be able to track those companies who did not file electronically the annual declaration.¹⁷⁵ The nanotechnology industry in France is composed of big companies and small start-up companies. In between, there are very little businesses, so reviewing the size of the declarant will also give an idea of the compliance rate. Compliance will also be done through field visits; for instance, the inspectors from the Ministry of the Environment currently conduct inspections to verify compliance with REACH; they will add to their duties inspections to verify compliance under the Law, Decree, and the Ministerial Order. Also, it is expected, as such is already happening in other sectors, that competition and consumer associations and environmental groups will be watching and will alert the Ministry of the Environment of any non-compliance. Furthermore, the Ministry of the Environment and the National Agency for Food, Environmental and Occupational Safety will cross information among their different reporting programs such as REACH.

There is no doubt that during the first years of this new regulation compliance may not always be easy to achieve, and the Ministry of the Environment is fully aware of the potential obstacles; however, the fact that the program will assist in filling the knowledge gap on the characteristics, uses, and market of nanoparticle substances outweighs these potential obstacles.

III. CONCLUSION

The French regulation is a good start to collecting the information that all stakeholders agree is lacking with regard to nanotechnology and could be used as a model to implement the initial phase of a U.S. nanotechnology regulatory system. The regulation should be flexible to adjust to the fast development of nanotechnology. Section 2(a)(3) of the 21st Century Nanotechnology Research and Development Act of 2003 provides that the President shall implement the National Nanotechnology Program and one of the goals of the Program is the responsible development of nanotechnology. The lack of information and

175. *Id.*

control is an impediment to the responsible development of nanotechnology, an area in which the United States wants to maintain its leadership position. Mandating a system of collection of information, protective of intellectual property rights, using the French model and combining it with mandatory implementation of the guidelines and recommendations developed by a certain number of federal agencies such as NIOSH to ensure the safest possible workplace environment for workers handling nanomaterials (including the disposal of wastes), should be the starting point of a comprehensive federal regulatory system for nanotechnology. This system should also address the concerns of many industries regarding the cost of testing by introducing specific mechanisms of data and test sharing to reduce the cost. Adopting a product stewardship approach, research and development industries and manufacturers should design and develop products which ensure their safety from design through disposal, i.e. from cradle to grave. Another important aspect which should also be integrated in any future regulatory system for nanotechnology is labeling products containing nanomaterials. As for the debate on the release in the market place of products containing nanomaterials without having a complete knowledge of their impacts on public health, safety, and the environment, it is certainly a difficult and sensitive one. Ideally, such products should not be marketed; however, the development of our society over the centuries shows that such is usually not the road that is followed. This may also be one of the reasons technological and scientific advances have taken place. But scientific progress or technological advances should not blind us and prevent us from implementing what is already doable to protect the environment and the workplace, as well as the public at large. On the regulatory front, it is preferable to take one step at a time than do nothing. The French regulation described herein should be an example to seriously consider.