Taking a Proactive Approach Towards Responsibility: Indications of Nano Policy-Making around the World

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Abstract

In this paper, we hypothesize that the development of normative materials dealing with nanotechnology, together with certain governmental initiatives and funding allocations for projects on societal and ethical implications, could indicate the amount of action being taken in a proactive approach to the responsible development of nanotechnology around the world. We also looked at these indications of action in light of the number of reports, articles, and general agitation about the *need* to take some sort of proactive steps to see if they have influenced the level of action being taken. While very little in the way of regulation has been passed by national governments in regard to nanotech and its potential environmental, health and safety implications, a small number of government agencies, industrial organizations, and advocacy-oriented NGO's are developing normative materials that represent the first steps taken towards the responsible development of nanotechnologies.

Introduction

Since 2005, the Center for the Study of Ethics in the Professions has been collecting in the NanoEthicsBank, a publicly accessible database, materials dealing with the responsible development and use of nanotechnology. The material in this database is divided into two categories, descriptive materials, and normative materials such as codes of ethics that direct or prescribe conduct. While gathering this material for inclusion in the NanoEthicsBank, we noticed a number of trends in the types of documents being published. Between 2000 and 2006, the majority of descriptive materials found spoke generally about the possible societal and ethical effects of nanotechnology research and development, and voiced a need for an evaluative approach to be taken. After 2004, the number of normative materials, seeking to direct actions in regard to the societal implications of nanotechnology, went up considerably. This paper will first provide a summary of the findings of our research on salient materials that call attention to social and ethical implications, to the type and number of comparably salient normative materials in the NanoEthicsBank. It will finally provide a brief glimpse into the levels of funding around the world for ethical, societal, and legal implications of nanotechnology development.

Salient Materials that Call Attention to Social and Ethical Implications

Over the past three years that we have been collecting material for the NanoEthicsBank, we have noticed a distinct trend in the kinds of descriptive materials being published in the area of nanoethics. A large number of these descriptive materials are reports coming from government agencies, the insurance sector, scholarly non-governmental organizations such as the Woodrow Wilson International Center for Scholars, and more advocacy oriented non-governmental organizations (NGO's) such as Friends of the Earth and the ETC Group that call attention to the ethical and societal implications of nanotechnology, both positive and negative. Reports were considered salient when they had attracted attention or been cited in a number of other widely read reports, articles, or online publications included in the NanoEthicsBank. What emerged as a dominant issue in many of these reports is the need for attention to the potential risks of nanotechnology research and development, and an emphasis on the need for action of some kind to be taken.

Areas of Attention

Of the forty-eight reports analyzed (see Appendix I), four main themes emerged as areas meriting study and possible action. The foremost concerns in these reports were nanotechnology's implications for human health and the environment. Around 64% directly mentioned human health and safety, and 58% mentioned environmental effects (reports often mentioned both), while the majority of the remaining reports dealt less directly with these topics (reports that focused solely on one topic such as food safety, adequacy of current EHS regulations, etc.) Government reports, reports from the insurance sector, and reports by environmental NGO's focused heavily on these two areas, with the government and insurance reports often discussing concerns about workplace safety. The NGO's focused more on concerns over potential environmental pollution, the use of nanomaterials in consumer products, and at least 4 NGO reports called for either a moratorium on nanotechnology research, such as the ETC Group's report, "The Big Down" published in 2003, or called for mandatory labeling of products containing nanomaterials, as the Friends of the Earth and the International Center for Technology Assessment did in 2006 in a petition to the U.S. Food and Drug Administration.[1]

The second theme on which these reports focused was the need for government action, namely the need to study the adequacy of current risk governance and legislation (47%), the need for a strong research plan and funding for identifying potential environmental health and safety risks of nanotech

[1] "CTA and Friends of the Earth Challenge FDA to Regulate Nanoparticles at FDA Hearing." International Center for Technology Assessment Press Release. October 10, 2006. Hhttp://www.icta.org/press/release.cfm?news_id=21H.

(31%), and the need to develop a comprehensive risk framework to address these risks when identified (27%). The Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies has alone produced over twenty-five different reports and papers on these issues, many of which analyzed one aspect in detail and offered recommendations for ways to move forward.

The third area that came up frequently in a number of reports was the need for an open dialogue between all stakeholders involved in nanotechnology (38%). Reports put out by U.S. government agencies such as the EPA emphasized a dialogue between industry, academic researchers, and agency officials. In the European Union and the U.K, this open dialogue also included the public. NGO's and scholarly organizations were less focused on this issue of public involvement, though the Project on Emerging Nanotechnologies and a number of universities have published a number of surveys looking at public opinion regarding nanotechnology. This focus on public engagement seems to emphasize not only a wish to ensure the safe and ethical development of nanotechnology through including all stakeholders in decision-making processes, but also a desire for such a dialogue as a way to mitigate fears about the potential risks of nanotechnology. Fears that nanotechnology will follow the same path as genetically engineered organisms, which met a large backlash in many parts of the world, may be at least one factor behind this focus.

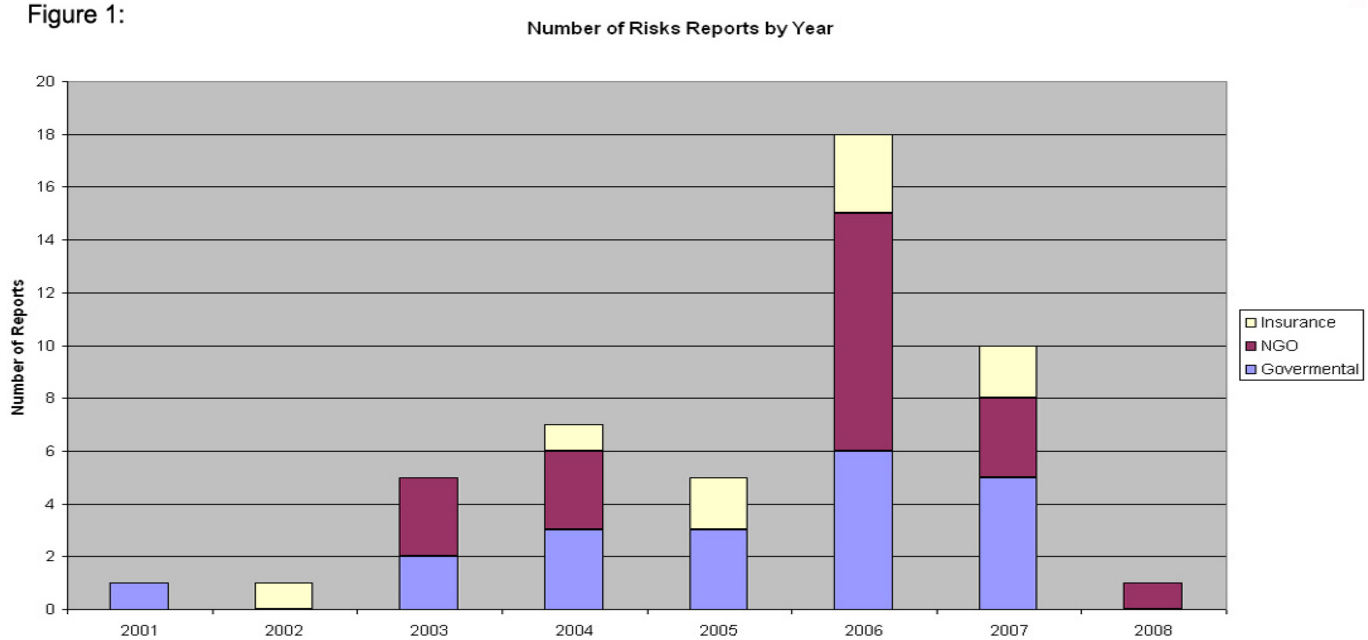
The reports from government agencies, the insurance sector, scholarly NGO's, and advocacy oriented NGO's were far less focused on other ethical issues, such as questions about human enhancement (16%), privacy (8%), and the development of a nanotechnology divide between developed and less developed areas of the world (13%). A number of specialists in ethics and science and technology studies have joined the debate surrounding nanotechnology, and have written extensively about many of these issues, but as of yet these articles are not attracting the attention of the media and government regulators as these major reports have.

Focusing of Attention on Societal and Ethical Implications

The number, location and focus of reports published by year reveals a change and probably a maturation in how these organizations understand the societal and ethical implications of nanotechnology research and development. In September 2000, the United States held a conference entitled, "Societal Implications of Nanoscience and Nanotechnology", which sought to identify some of the potential areas for research into the societal implications of nanotechnology. This conference, the first of its kind, helped begin the discussion about possible societal effects, and by the time the second conference was held in 2003, scholarship in this area had already begun. In 2004, two of the most influential reports came out from organizations located in Europe, reports that were continually referred to in subsequent U.S. and E.U. government reports and scholarly articles, “Small Matters, Many Unknowns,” by Swiss Re, and “Nanoscience and Nanotechnologies: Opportunities and Uncertainties” published by the United Kingdom’s Royal Society and Royal Academy of Engineering. That same year, “Industrial Application of Nanomaterials: Chances and Risks” was produced by the Future Technologies Division of Technologiezentrum in Germany. These European reports seem to have brought more stakeholders to the table, as it is around this period that environmental groups such as Friends of the Earth began to enlarge their advocacy efforts around nanotechnology. The reports originated from the European Union (47%), the United States (40%), Australia (4%), Canada (4%), and the international environmental group Friends of the earth (4%).

The year 2006 saw the largest number of reports published, with six of the eighteen reports coming from governmental agencies, nine from NGO’s, and two from insurance and for-profit organizations. The vast majority of these reports differ from the 2004 reports in that they deal with only one aspect of nanotechnology, such as the regulation and labeling of cosmetics containing nanoscale materials, and assessments of the adequacy of current regulation and risk assessment strategies in regard to nanotechnology. From this information, it looks as if the 2004 reports helped focus attention on some of the main questions about nanotechnology R&D. The following two years saw a focusing of attention on specific issues. By 2006, the overall understand expressed in these reports was an acknowledgement of the need for more scientific evidence about the potential environmental and health effects of engineered nanoparticles, but a clear emphasis, especially by government, scholarly organizations, and advocacy groups, on the need to do *something*, even in the face of ignorance and uncertainty.

Figure 1:



Normative Materials: Indicators of Action

As of April 2008, there have been no mandatory regulations passed by national governments that specifically address nanotechnology. The U .S. Environmental Protection Agency is attempting to use existing regulations to handle products that use silver nanoparticles, but efforts in this area have met with some criticism and confusion.[2] A number agencies in the E.U. and U.S., including the EPA and NIOSH, have or are in the process of developing research strategies for addressing potential environmental, health, and safety (EHS) risks posed by nanotechnology, as well as developing oversight frameworks for nano research and development.

Perhaps more interesting is how some local governments, NGO's and industry organizations have taken a leading role by developing codes of conduct and risk assessment schemes (such as plans that assist companies to identify the level of risk associated with a product or process utilizing engineered nanoparticles and develop ways for mitigating these risks) on their own or partnered with other organizations. The normative materials covered in this review include codes of conduct, risk assessment strategies, reporting schemes, uses of the precautionary principle, standards approved or still in the process of development by national and international standard-setting agencies, and research strategies approved by national and international governments. The following sections will give examples of the normative documents and programs we were able to locate, and analysis of the possible trends of proactive action these documents might represent.

1. Codes of Conduct

The Chemical Company BASF developed the first example of a code of conduct in 2004, which speaks both of the company's duties to workers, investors, and clients, but also towards a commitment to assist in developing relevant standards for nanotechnology as a basis future legislations.[3] This same company also helped develop the "Responsible Nanocode," which sprang from a cooperative partnership in the United Kingdom between industry and academia. The project involved BASF, the Royal Society, the University of Cardiff, TESCO, the Nanotechnology Industries Association, and Insight Investment. Begun in November of 2006 during a workshop involving seventeen European companies with an interest in nanotechnologies, the workshop participants agreed to create a voluntary code of conduct based on principles that represented the concerns of a wide variety of stakeholders. The current draft of the code lists seven principles for organizations to follow, and then

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[2] For example, see Feder, Barnaby. "New Device for Germophobes Runs into Old Law." *New York Times.* March 6, 2008. http://www.nytimes.com/2008/03/06/business/smallbusiness/06sbiz.html?scp=10&sq=Feder&st=nyt.
[3] See "BASF Code of Conduct – Nanotechnology. BASF Global 2004. Hhttp://www.corporate.basf.com/en/sustainability/dialog/politik/nanotechnologie/verhaltenskodex.htm?id=5QJSoC8AZbcp*-iH.

lists indicators of good practice that prove these principles are being followed. For example, the code calls for each company to proactively engage with its stakeholders and be responsive to their views in the development or use of nanotechnologies, and as a sign of good practice, calls for company boards' to provide, "clear disclosure of how stakeholder views have been considered and taken into account."[4] The Responsible Nanocode working group has held a public consultation on the first draft of the code, and as of February 2008 is reviewing comments received and proposing amendments to be included in the next draft of the code.

In 2007, the European Commission launched a public consultation about a proposed code of conduct nanotechnology research, as called for in the guidance document, "Nanosciences and Nanotechnologies: an Action Plan for Europe 2005-2009". In February of 2008, the "Code of Conduct for Responsible Nanoscience and Nanotechnology Research" was approved. Based on precautionary principles, this voluntary code covers seven general principles, including sustainability, precaution, inclusiveness, and accountability.[5] The main goal of this code of conduct is to help research institutes, universities, and companies in the EU ensure the safe development and use of nanotechnologies in the face of knowledge gaps and uncertainties about the future impact of these technologies on human health and the environment.

2. Risk Assessment Schemes and Development of Best Practices

Private companies, large industrial players, and NGO's have begun to try and answer the question of how to deal with the possible human health risks posed by engineered nanoparticles and at least in one instance have worked together to develop a free guidance document that helps interested companies begin to evaluate the potential risks of their nano products and processes. In June of 2005, the chemical company DuPont and Environmental Defense began developing the "Nano Risk Framework" which helps answer questions an organization should consider in developing applications using nanomaterials, including providing a way to address areas of incomplete or uncertain information using "reasonable assumptions and appropriate risk management practices."[6] The framework also includes guidance on how to communicate information and decisions to stakeholders. The freely available risk framework includes a number of case studies that have been

[4] "Responsible NanoCode Consultation Draft" 17 September 2007. Responsible Nanocode Web site Hhttp://www.responsiblenanocode.org/pages/progress/index.htmlH. Last viewed 2 April 2008. p.8.
[5] "Commission adopts code of conduct for responsible nano research." *Cordis News.* February 11, 2008 Hhttp://cordis.europa.eu/fetch?CALLER=EN_NEWS&ACTION=D&SESSION=&RCN=29114H.
[6] "Nano Risk Framework Executive Summary" June 21, 2007. Hhttp://www.nanoriskframework.com/content.cfm?contentID=6498H

developed showing how Dupont has used the Nano Risk Framework to analyze some of its own nanoparticle-containing products.

When released, the framework was criticized by other environmental and civil groups, including the ETC Group, Greenpeace, and the United Steelworkers of America, who published an open letter rejecting the framework on the grounds that historically, voluntary regulations are used to delay or prevent the adoption of more rigorous, mandatory regulations, and called the framework, "...at best, public relations campaign that detracts from urgent worldwide oversight priorities for nanotechnology."[7]

Finally, Japan is at the beginning stage of assisting nano enterprises in developing best practices for the workplace. In 2006 a research project on the proper on-site handling methods for nanotechnologies in research manufacturing was implemented, which helped produce a series of guidelines that are especially designed for nanoparticles, such as carbon nanotubes, used in industrial settings. These voluntary guidelines are being made available until further research on risk assessment methodologies has been completed and final handling methods for these nanoparticles have been compiled. [8] In a similar effort, CSEP is currently conducting a survey of companies and laboratories that work with engineered nanoparticles to gather existing examples of best practices and workplace safety guidelines.

3. Reporting Schemes

Reporting schemes that ask industry to submit information about the types and potential dangers of the nanomaterials they develop or manufacture, are one way of gathering information about the potential risks of these particles. As of April 2008, we have found one mandatory and two voluntary reporting schemes currently in existence. In December of 2006, the Berkeley City Council passed the Manufactured Nanoscale Heath and Safety Ordinance that requires, "All facilities that manufacture or use manufactured nanoparticles to submit a separate written notice of the current toxicology of the materials reported, to the extent known, and how the facility will safely handle, monitor, contain, dispose, track inventory, prevent releases, and mitigate such materials."[9] The ordinance came about after the city's hazardous waste manager, Nabil Al-Hadithy, began asking

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[7] "Civil Society-Labor Coalition Rejects Fundamentally Flawed Dupont-ED Proposed Framework." April 12, 2007. ETC Group Web site. Hhttp://www.etcgroup.org/upload/publication/610/01/coalition_letter_april07.pdfH.
[8] Ishiuzu, Saori, Mizuki Sekiya, Ken-ichi Ishibashi, Yumi Negami, and Masafumi Ata. "Toward the Responsible Innovation with Nanotechnology in Japan. *Journal of Nanoparticle Research.* 10:2 (February 2008) 248.
[9] Al-Hadithy, Nabil A. "Manufactured Nanoparticle Health and Safety Disclosure" December 5, 2006. Berkeley City Council Web site. Hhttp://www.ci.berkeley.ca.us/citycouncil/2006citycouncil/packet/120506/2006-12-05%20Item%2013%20Manufactured%20Nanoparticle%20Health%20and%20Safety%20Disclosure-Supp.pdfH.

questions about the possible safety risks of nanomaterials after Lawrence Berkeley National Lab filed an environmental impact statement in 2004 to build a "molecular foundry" to make nanoparticles. At the time of passing the ordinance, no companies in the area were covered by the new rules, and the National Laboratory was exempt, though a spokesman said they would be voluntarily submitting information.[10] The Cambridge City Council is currently considering adopting a similar plan.[11]

The U.S. and the UK have developed two voluntary reporting schemes. Britain's "Voluntary Reporting Scheme for Engineered Nanoparticles" is a temporary experiment that runs from September 2006 to September 2008. The program asks for data that can be provided on manufactured nanomaterials from anyone involved in the manufacture or use of engineered nanomaterials, or anyone involved in nanoscience research or managing wastes consisting of engineered nanoscale materials. [12] The goal of the scheme is to provide an indication of the kinds of nanomaterials currently in development and production to help inform policy-making decisions and to focus efforts and funding on areas which are relevant to the UK's current nano manufacturing and research base. As of December 2007, nine submissions have been received, 2 from academia and 7 from industry. [13] After September 2008, the reporting scheme will be subject to a six-month review by the U.K's Department for Environment, Food and Rural Affairs and a public consultation. In January of 2008 the United States Environmental Protection Agency (EPA) launched the Nanoscale Materials Stewardship Program, which "...will help provide a firmer scientific foundation for regulatory decisions by encouraging submission and development of information including risk management practices for nanoscale materials."[14] The program includes a basic program that invites participants to report available data on engineered nanoscale materials, and an in-depth program in which participants will voluntarily develop data, including testing, over a longer time frame.

4. Precautionary Principles

One area of discussion that we have been following closely since the inception of the NanoEthicsBank is the use of the precautionary principle in discussions about the regulation of

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[10] Feder, Barnaby. "Teeny-Weeny Rules for Itty-Bitty Atom Clusters" *New York Times* January 14, 2007. Hhttp://www.nytimes.com/2007/01/14/weekinreview/14feder.htmlH.
[11] Keiner, Suellen. "Room at the bottom?: potential state and local strategies for managing the risks and benefits of nanotechnology" March 2008. Woodrow Wilson International Center for Scholars Project on Emerging Nanotechnologies. Hhttp://www.nanotechproject.org/process/assets/files/6112/pen11_keiner.pdfH.
[12] "UK Voluntary Reporting Scheme for Engineered Nanoscale Materials." United Kingdom Department for Environment, Food and Rural Affairs. Hhttp://www.defra.gov.uk/ENVIRONMENT/nanotech/policy/pdf/vrs-nanoscale.pdfH p.2.
[13] Department for Environment Food and Rural Affairs. "The UK Voluntary Reporting Scheme for Engineered Nanoscale Matierials: Fifth Quarterly Report." December 2007. Hhttp://www.defra.gov.uk/environment/nanotech/pdf/vrs-5.pdfH
[14] Environmental Protection Agency "Nanoscale Materials Stewardship Program" February 21, 2008 Environmental Protection Agency Web site. Hhttp://www.epa.gov/oppt/nano/stewardship.htmH Last viewed 2 April 2008.

nanotechnology. The precautionary principle, which was most prominently mentioned in the Swiss Re report "Nanotechnologies: Small Matter, Many Unknowns" prescribes that measures should be taken to protect people and the environment at an early stage, even when there is a lack of scientific evidence demonstrating harm. The Swiss report directly calls for the use of this principle in relation to nanotechnology, stating "In view of the dangers to society that could arise out of the establishment of nanotechnology, and given the uncertainty currently prevailing in scientific circles, the precautionary principle should be applied whatever the difficulties."[15] The precautionary principle has been cited most frequently in normative materials originating from Europe, though discussions about its application in regard to nanotechnology have occurred in the U.S., Japan, and other regions.[16]

In 2004, a report entitled "Nanotechnology and Regulation within the Framework of the Precautionary Principle" was presented to the European Parliament. This report found that the Precautionary Principle for the European Union states that scientific uncertainty is no reason for inaction if there might be immense adverse effects. It suggested a number of potential actions that could be taken; and saw the regulation of chemicals and pharmaceuticals through REACH as a potential example of using the precautionary approach in the same regard as nanotechnology. [17] It is interesting to note that though the REACH regulations (which are underpinned by the precautionary principle themselves) do not specifically mention engineered nanoparticles, according to a Q&A page on REACH from the European Union web site, the European Union does see nanoparticles as falling under these regulations, and is in the midst of funding research to see if the registration and information requirements under REACH are adequate to address the potential risks form particles on a nano-scale. [18]

A few organizations have gone further, and used the precautionary principle to justify their actions in passing regulations on the use of nanomaterials. In the UK, the Soil Association, a UK environmental organization that sets standards for organic food and farming that exceed statutory organic standards, set a standard in the beginning of 2008 that bans products or ingredients produced using nanotechnology from being labeled organic. In their justification of this ban on their website,

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[15] Hett, Annabelle. "Nanotechnology: Small Matter, Many Unknowns." Swiss Re, 2004. Hhttp://www.swissre.com/resources/31598080455c7a3fb154bb80a45d76a0-Publ04_Nano_en.pdfH p. 48.
[16] For example, Ishiuzu, 253.
[17] European Parliament: "Nanotechnology and Regulation within the framework of the Precautionary Principle. Final Report for ITRE Committee of the European Parliament". Haum, Petschow, Steinfeldt, Institut für ökologische Wirstschaftforschung (IÖW) gGmbH, Berlin, 11 Feb 2004.
[18] Bowman, Diana and Geert van Calster. "Does REACH Go too Far?" *Nature Nanotechnology.* 2 (2007) 525-526. "Q & A on the New Chemicals Policy – REACH" European Commission, Enterprise and Industry. 2007. Hhttp://www.ec.europa.eu/enterprise/reach/faq_en.htmH.

they specifically state that they have applied the precautionary principle to this case due to the current lack of safety testing being done by industry and governments.[19]

4. Terminology and Standards

As of March 2008, we have located over 60 standards related to nanotechnology developed by national and international standard-setting organizations. These include terminology standards, which are essential in ensuring the clear and precise communication of nanotech's benefits and risks between scientists, policymakers, and other standards that help establish standard ways of measuring, monitoring, and labeling engineered nanoparticles. China, South Korea, and the United Kingdom have developed standards of their own, and 28 countries are working with the International Organization for Standardization (ISO) in developing international standards (and 8 countries observing).[20]

ASTM International and the British Standards Institution developed the first standards relating to nanotech, both of which defined the terminology used to described nanotechnologies and nanoscale objects. BSI passed "PAS 71 Vocabulary – Nanoparticles" in 2005, two years before approving any other standards, and ASTM International approved their very first nanotechnology-related standard, "E-2456-06 Terminology for Nanotechnology," in 2006, a year before passing two more standards in 2007. Interestingly, both BSI and ASTM have made these standards available free of charge, to help avoid confusion in dialogs about nanotechnology, or as BSI states on their web site, for "encouraging the use of a common language for nanoparticle technologies."[21] The International Standards Organization is also currently developing standards for nanotech terminology.

China was the first country to announce the development of seven standards for nanotechnology in 2004, and from 2005, the number of standards being approved has gone up steadily every year, (See figure 2) usually due to a standards setting organization releasing three or more standards at the same time. Currently 28 standards are still under development that we know of, and no doubt many more will be developed as nanotechnology research and development continues. The types of standards being developed vary from the handling and disposal of nanomaterials, to best practices for labeling products containing nanomaterials. See Appendix II for a list of all the

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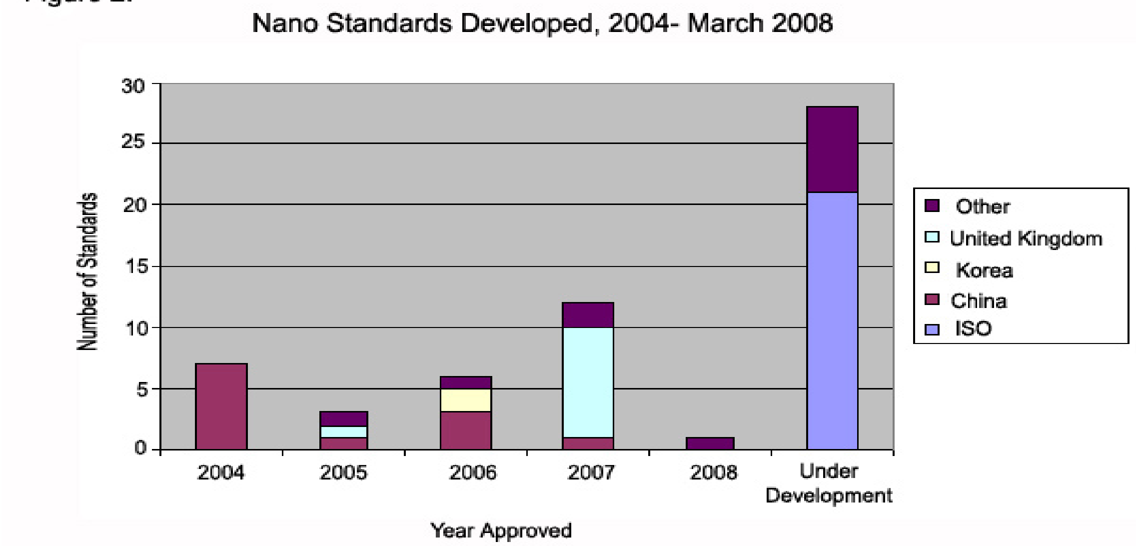
[19] "Soil Association Standards Guide, Nanotechnology" Soil Association: Our Organic Standards, 2008. Hhttp://www.soilassociation.org/web/sa/saweb.nsf/ed0930aa86103d8380256aa70054918d/444ed4dee8649ee18025739c003d0a49!OpenDocumentH.

[20] "Business Plan ISO/TC 229: Nanotechnologies" Draft version April 23, 2007 International Organization for Standardization. Hhttp://isotc.iso.org/livelink/livelink/fetch/2000/2122/4191900/4192161/TC_229_BP_2007-2008.pdf?nodeid=6356960&vernum=0H p. 6-7.

[21] British Standards Organization "Nanotechnologies." http://www.bsi-global.com/en/Standards-and-Publications/Industry-Sectors/Nanotechnologies/.

standards found. From the data collected, it looks as if standardizing terminology was the first step in this process, and only in the past two years have these organizations begun to set best practices for nanotechnology.

Figure 2:



*"Other" includes standards developed by ASTM International (10), IEEE (2), and the International Electrotechnical Commission.

5. Research Strategies

National governments have been slow to adopt nano-specific regulations; but due to the rapid release of consumer products containing nanoparticles into the marketplace and urgings of scientists, activists, and reports such as those examined in the beginning of this paper, a number of countries have developed and adopted research strategies to begin filling this knowledge gap.

Japan has made nanotechnology research and development a priority for public science funding, though it has yet to adopt a nation-wide research strategy to investigate the EHS risks of nanotechnology. In a translation of Japan's strategic plan for nanotechnology research in the "Third Basic Plan for Science and Technology (2006-2010)", one of the main focuses of this research is on the need for studies on the impact that nanotechnology has on society, as well as making standard setting for nanotechnologies a priority research goal. [22] A year before the publication of this strategy, Japan held its first comprehensive symposium on the societal impacts of nanotechnology, which led to a coordinated research project among four federal research institutes coordinated in research projects that developed recommendations regarding issues such as risk management, environmental impact, health impact, and societal, and ethical issues of nanotechnology research and development

[22] Government of Japan. "Science and Technology Basic Plan (Provisional Translation)" March 28, 2006. Hhttp://www8.cao.go.jp/cstp/english/basic/3rd-Basic-Plan-rev.pdfH. p. 65.

based on the research completed. In February of 2006, these institutes held the international symposium “Exploring the Small World: Role of Public Research Institutes” where the results of the research project were reported, and policy recommendations made.[23]

Partially spurred by the report by the *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* published by the United Kingdom’s Royal Society and Royal Academy of Engineering Royal Society, the United Kingdom’s Department of Environment, Food and Rural Affairs (DEFRA) published the report “Characterizing the Potential Risks Posed by Engineered Nanoparticles,” on 2005 that describes the agency’s research goals to help characterize the potential risks posed by engineered free nanoparticles. The yearly reports of the same name summarize the progress made on reaching these research goals, and address the recommendations made by the U.K.’s Council for Science and Technology for improving the program.[24]

Though the United State’s NNI has included funding for the ethical and societal impacts of nanotechnology R&D from as early as 2000, it took a few years for a coordinated research strategy to develop. The United States National Science and Technology Council, responding to the calls made by scholarly NGO’s such as the Woodrow Wilson Center and the triennial review of the NNI by the National Academy of Sciences for the need for more EHS research and a coordinated research plan, recently published the “Strategy for Nanotechnology-Related Environmental, Health, and Safety Research” in February of 2008. Before this, a number of federal agencies such as NIOSH and the EPA had put out intermittent reports and guidance documents detailing their own strategy for addressing EHS risks, but no detailed national plan had been released, though funding and attention to EHS risks have been part of the NNI since the beginning.

Along with the U.S. and the UK, Switzerland has produced a guidance document entitled “Risk Evaluation and Management of Synthetic Nanoparticles 2006-2009” in February of 2006. This plan proposes the development of a code of conduct for nano research, the development of standards and best practices in conjunction with international organizations, the adaptation of existing legislation to deal with nanomaterials, a plan for EHS research and funding strategies, and plans to facilitate dialogue with stakeholders.[25]

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[23] Ishiuzu, 236.
[24] DEFRA “Characterizing the Potential Risks Posed by Engineered Nanoparticles: A Second UK Government Research Report.” 2007. DEFRA web site. Hhttp://www.defra.gov.uk/environment/nanotech/research/pdf/nanoparticles-riskreport07.pdfH..
[25] “OECD Extended Steering Group Meeting on Manufactured Nanomaterials 26027 October, 2006 Item 4: Tour de Table on Current Developments in Member Countries on the Safety of Manufactured Nanomaterials: Current Developments in Switzerland.” Organization for Economic Co-Operation and Development web site. Hhttp://www.oecd.org/dataoecd/57/41/37774728.pdfH

Finally, the European Commission adopted the "Nanosciences and Nanotechnologies: an Action Plan for Europe 2005-2009" in June of 2005. This plan includes both very general goals such as developing models and standards for risk assessment and management, as well as specific actions that should be taken, such as the development of the code of conduct for nanotechnology research (as described earlier), and asking the European Group on Ethics in Science and New Technologies to carry out an ethical analysis of nanomedicine.[26] Even before the release of these two reports, the EU had funded a number of projects looking at the societal implications of nanotechnologies, including the Nanosafe project begun in April of 2003, which addressed topics of human health, dispersal into the environment, and preventative measures, and NanoSafe2, a continuation of the project that is currently underway [27].

These research strategies developed by the U.S., U.K., Switzerland, and the EU seem to be a beginning answer to concerns mentioned earlier about human health and environmental risks, the need to study the adequacy of current risk governance, and the need for a strong research plan for addressing potential EHS risks. For most of these governments, the development of a clear research agenda happened after industries located within the company began using nanotech manufacturing processes and products, and in many countries like Japan, this agenda is still in an early stage of development.

In summary, while only a handful of nations, industrial organizations, and NGO's have taken definitive steps in setting up initiatives, projects, or guidance documents that try to address the societal implications of nanotechnology, the actions of these organizations have helped focus attention on these important issues. Furthermore, national and international governments are also taking steps to establish clear research agendas to help investigate the possible health and environmental impacts of nanotechnology. Some initiatives by industry and government organizations have attracted criticism as being ineffective, but these codes of ethics, reporting schemes, risk management strategies, and research agendas are a clear indication that the concerns put forward by salient reports, such as those published by Swiss Re and the Royal Society, have had some impact. In this final section, we will summarize the funding of ELSI initiatives in the U.S. and UK, and look at the specific area of research on public engagement as an example of the types of programs that are being developed.

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[26] "Nanosciences and Nanotechnologies: An Action Plan For Europe 2005-2009: Communication from the Commission, to the Council, the European Parliament, and the Economic and Social Committee. June 7, 2005. Hftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/nano_action_plan2005_en.pdfH

[27] Ishiuzu, 235.

Public Funding of Nanotechnology ELSI Initiatives

One way to discover how much attention is being paid to the ethical and societal implications of nanotechnology is to study the amount of funds designated by countries for research into the ethical, legal, and societal implications (ELSI) of this new technology. While collecting data for this survey, we ran across a number of obstacles for getting a good international picture. Along with issues of language barriers and the public availability of documents, different countries describe and count environmental health and safety funding (EHS) and ELSI in different ways. For example, the United States classifies the portion of the budget designated for ELSI programs into two different sections, Environment, Health and Safety, and Education and Societal Dimensions. Other governments, such as the European Union only recently began publishing reports of funding levels for EHS research ad related projects, but have not specifically tracked the funding of projects that address other societal implications.[28]

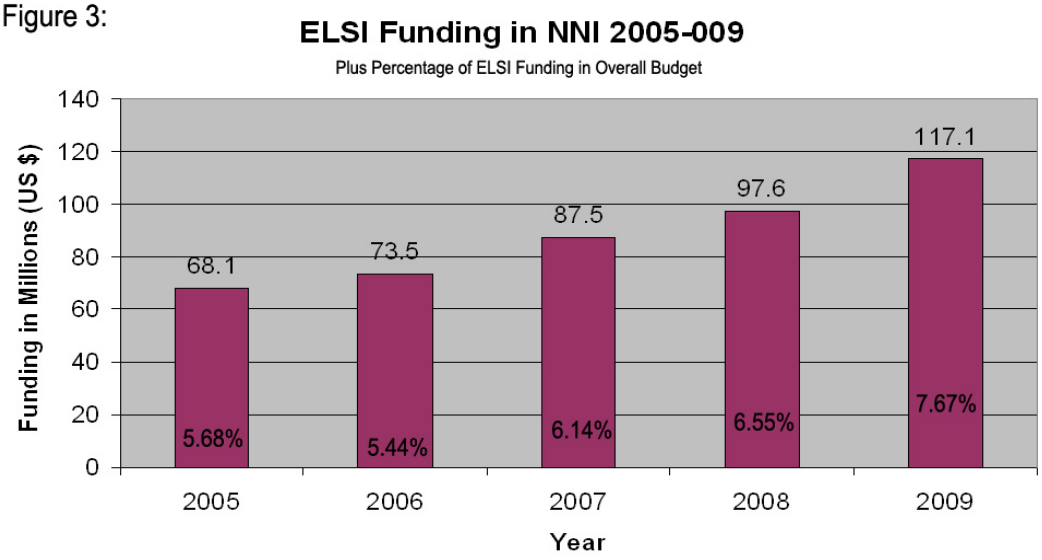
One approach to solving this issue is to create a publicly accessible database, and invite scholars, scientists, and government agencies around the world to submit reliable data about ELSI funding levels. CSEP has begun designing such a database, and has populated it with data gathered during research for the NEB. The information is accessed through an interactive map where users can click on a country to display the overall known public funding of nanotechnology research and development, the level ELSI funding, as well as a list and links to known projects or programs looking at the societal implications of nanotechnology. In the next few months, we will send out an invitation to all known international nanotechnology coordination offices and ELSI projects, inviting them to submit data for inclusion on the web site.

From the data we were able to gather, it is clear that the U.S. was the first country to include EHS and ELSI funding in their overall plan for nano development. After the workshop, "Societal Implications of Nanoscience and Nanotechnology" held in September 2000, the National Science Foundation made support for social, ethical and environmental research a priority.[29] According to an article by M.C. Roco, U.S. investment in research with societal and educational implications in FY2003 was estimated at about $30 million, and research on environmental impacts at about $50 million. This was approximately 10% of the overall budget for FY 2003.[30] The U.S. NNI budgets only begin to show a breakdown of the overall allocation of funds by area beginning in 2005. From

[28] "National Nanotechnology Initiative FY 2009 Budget and Highlights." National Nanotechnology Initiative Publications. 2009. http://www.nano.gov/NNI_FY09_budget_summary.pdf p. 2.
[29] Roco, M.C. "Broader Societal Issues of Nanotechnology." *Journal of Nanoparticle Research 5, 181-189, 2003*.P. 186. Hhttp://www.nsf.gov/crssprgm/nano/reports/BroaderSocIssue.pdfH .
[30] Roco., 186.

FY2005 to 2006, the percentage of funds dedicated to Human Health and the Environment, and Education and Societal implications dropped slightly, but since FY2006 it has been steadily rising. According to the estimated budget for FY2009, spending on the human health and the environment research saw a great increase, from $58.6 million in 2008, to $76.4 million in 2009. This count does not include funding for research in the areas of instrument research, metrology and the development of standards, which theoretically should also be counted as a type of societal and ethical implications funding. If this were included the total percentage of ELSI funding for the 2009 budget would be closer to 13% of the overall NNI budget of $1.527 billion.

Figure 3:



The European Union has also been extremely active in funding nanotechnology research, though the percentage of funding dedicated to societal and ethical implications appears to be much smaller. According to the data we could gather, €29.6 million of the total €1.429 billion of nanotechnology funding in the Research Framework Program FP6 (2002-2006) went towards research on the human health and environmental implications of nanotechnology, or about 2% of the total budget. This figure may be misleading, however, as the report this information came from only gathered information about environmental health and safety research, and relied on projects submitting information about their funding levels for inclusion in the report.[31] Along with funding from the FP6 program, member EU countries have allocated €47 million to EHS research on nanotechnology during the period 2002-2007. We hope to be able to collect a far richer set of funding data as after we have launched the public version of the ELSI funding database and begin collecting data from international governments and ELSI project leaders.

[31] See European Commission. "EU Nanotechnology R&D in the Field of Health and Environmental Impact of Nanoparticles." January 28, 2008. Hftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/final-version.pdfH .

Conclusion

A considerable amount of attention has been paid to the possible environmental and health effects of nanotechnology due to the pace of scientific innovation in the nanotechnology field, but also perhaps partially due to salient reports published by government agencies, insurance organizations, scholarly organizations, advocacy groups, and the papers of scholars. The European Unions' percentage of government funding for EHS research is much lower then United States, but countries in Europe have been quicker to begin considering adopting a more precautionary approach to nanotech development, as shown in some of the reports reviewed here. In the U.S, the focus seems to be more on ensuring a strong research strategy for studying the potential EHS implications of nanotechnology to help fill in potential gaps in knowledge before taking any major steps towards regulation. Overall, national governments seem to have taken a more wait-and-see approach, focusing efforts on EHS research, developing standards and best practices for nanotechnology, and using voluntary reporting schemes to begin collecting data about engineered nanoparticles.

In this regulatory vacuum, some industry organizations, advocacy groups, and local governments are leading the attempt to address uncertainty about the potential EHS implications by influencing major players in nanotech R&D through voluntary measures such as adopting codes of conduct for nano researchers. A much smaller number of organizations such as the Berkeley City Council and the Soil Association have passed mandatory measures as a precautionary approach to nanotech, in case negative effects may arise. Though there are over 600 different consumer products containing nanomaterials now available for sale, we are still at the very beginning of beginning to understand, much less address nanotech's potential ethical and societal implications.[32] However, with the attention that these potential implications are now receiving, we do seem to be at a very promising beginning.

[32] See the Consumer Products Industry, developed and maintained by the Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies. http://www.nanotechproject.org/inventories/consumer/.

Appendix I: Risk Reports
Government Reports

2001	U.S. National Science and Technology Council,	Societal implications of nanoscience and nanotechnology
2003	U.S. National Science and Technology Council	Nanotechnology: Societal Implications - Maximizing Benefits for Humanity
2003	U.S. National Nanotechnology Initiative	Nanotechnology and the Environment - Applications and Implications
2004	German Future Technologies Division of VDI Technologiezentrum GmbH	Industrial Application of Nanomaterials: Chances and risks
2004	U.K. Community Health and Consumer Protection	Nanotechnologies: A preliminary risk analysis
2004	U.K. Health and Safety Executive /NIOSH	Nanomaterials: A risk to health at work?
2005	European Commission Scientific Committee on Emerging and Newly Identified Health Risks	The Appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies
2005	U.S. Environmental Protection Agency	Nanotechnology White Paper External Review Draft
2005	E.U. NanoForum	Fourth Nanoforum Report: benefits, risks, ethical, legal, and social aspects of nanotechnology
2006	Australian Safety and Compensation Council	A Review of the Potential Occupational Health and Safety Implications of Nanotechnology for the Department of Employment and Workplace Relations Final Report
2006	U.K. Food Safety Agency	Draft Report of the Food Safety Agency Regulatory Review
2006	U.S. National Science and Technology Council	Environmental, Health, and Safety Research Needs for Engineered Nanoscale materials
2006	Swiss Eidgenössische Ethikkommission für die Biotechnologie im Ausserhumanbereich	Nanobiotechnologie: Ein ethische Auslegeordnung
2006	*Canada Commission de l'ethique de la science et de la technologie*	Ethics and Nanotechnologies: a basis for actions
2006	German Umwelt Bundes Amt	Nanotechnology: Opportunities and Risks for Humans and the Environment
2007	E.U. Health and Consumer Protection Directorate-General Scientific Committee on Consumer Products	Preliminary Opinion on Safety of Nanomaterials in Cosmetic Products
2007	Switzerland BAFU/BAG	Synthetische Nanomaterialien: Risikobeurteilung und Risikomanagement Grundlagenbericht zum Aktionsplan
2007	U.S. Health and Consumer Protection Directorate-General Scientific Committee on Consumer Products	Opinion on Safety of Nanomaterials in Cosmetic Products
2007	U.S. Food and Drug Administration	Nanotechnology: A report of the U.S. Food and Drug Administration Nanotechnology Task Force
2007	E.U. European Group on Ethics in Science and New Technologies to the European Union	Ethical Aspects of Nanomedicine

NGO Reports

2003	ETC Group	The Big Down: from Genomes to Atoms
2003	Greenpeace	Future Technologies, Today's Choices
2003	Wardak, Ahson ; David Rejeski (Woodrow Wilson Project on Emerging Nanotechnologies)	Nanotechnology & Regulation: a case study using the Toxic Substances Control Act (TSCA)
2004	Meridian Institute	International Dialogue on Responsible Research and Development of Nanotechnology
2004	ETC Group	Down on the Farm: The impact of nano-scale technologies on food and agriculture
2004	Royal Society ; Royal Academy of Engineering	Nanoscience and Nanotechnologies: opportunities and uncertainties
2006	Linquiti, Peter ; Adam Teepe (IFCI)	Characterizing the Environmental and Safety Implications of Nanotechnology
2006	Innovation Society	Safety, Risk and Regulation of Engineered Nanoparticles: results, trends and perspectives
2006	American Bar Association	The Adequacy of the Federal Insecticide, Fungicide, and Rodenticide Act to regulate nanotechnology-based pesticides
2006	Michelson, Evan (Woodrow Wilson Project on Emerging Nanotechnologies)	Nanotechnology Policy: An analysis of transnational governance issues facing the United States and China
2006	Friends of the Earth	Nanomaterials, Sunscreens, and Cosmetics: small ingredients, big risks
2006	Taylor, Michael (Woodrow Wilson Project on Emerging Nanotechnologies)	Regulating the Products of Nanotechnology: does the FDA have the tools it needs?
2006	Institute for Food and Agricultural Standards	Nanotechnology Standards: Report of a workshop
2006	American Bar Association	Environmental Management Systems / Innovative Regulatory Approaches
2006	ACONA (For conference)	An Uncertain Business: the technical, social, and commercial risks of nanotechnology
2007	Woodrow Wilson Project on Emerging Nanotechnologies	EPA and Nanotechnology: Oversight for the 21st Century
2007	IRGC	Nanotechnology Risk Governance
2007	Woodrow Wilson Project on Emerging Nanotechnologies	Thinking Big about Things Small: creating an effective oversight system for nanotechnology
2008	Friends of the Earth	Out of the Laboratory and on to Our Plates: nanotechnology in food and agriculture

Insurance Reports

2002	Munchener Ruck	Nanotechnology - What is in store for us?
2004	Swiss Re	Small Matter, Many Unknowns
2005	Allianz/ OECD	Small Sizes that Matter: Opportunities and Risks of Nanotechnologies
2006	Innovation Society	Nano-Regulation: a multistakeholder Dialogue approach towards a sustainable regulatory framework for nanotechnology
2006	Lux Research Inc.	Taking Action on Nanotech Environmental, Health and Safety Risks
2006	Guy Carpenter & Company Inc.; Robert Blaunstein	Nanotechnology: The plastics of the 21st century?

2007	Lloyd's of London	Nanotechnology: recent developments, risks, and opportunities
2007	Swiss Re	The Risk Governance of Nanotechnology: Recommendations for managing a global issue

Appendix II: Nanotechnology Standards

ASTM International	E2525-08 Standard Test Method for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies	Approved, 2008
ASTM International	E2526-08 Standard Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells	Approved, 2008
ASTM International	E2578-07 Standard Practice for Calculation of Mean Sizes/Diameters and Standard Deviations of Particle Size Distributions	Approved, 2007
ASTM International	ASTM E2535-07 Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings	Approved, 2007
ASTM International	E-2456-06 Terminology for Nanotechnology	Approved, 2006
ASTM International	WK10417 Standard Practice for the Preparation of Nanomaterial Samples for Characterization	Under Development
ASTM International	WK9952 Standard Practice for Measuring Length and Thickness of Carbon Nanotubes Using Atomic Force Microscopy Methods	Under Development
ASTM International	WK 9327 Standard Practice for Evaluation of Cytotoxicity of Nanoparticulate Materials on Porcine Kidney Cells	Under Development
ASTM International	WK8997 Standard Practice for Analysis of Hemolytic Properties of Nanoparticles	Under Development
ASTM International	WK8705 Measurement of particle size distribution of nanomaterials in suspension by Photon Correlation Spectroscopy	Under Development
BSI	PD 6699-1 Good Practice Guide for Specifying Manufactured Nanoparticles	Approved, 2007
BSI	PD 6699-2 Nanotechnologies Par 2 - Guide to Safe Handling and Disposal of Manufactured Nanoparticles	Approved, 2007
BSI	PAS 71 Vocabulary - Nanoparticles	Approved, 2005
BSI	PAS 136: 2007 Terminology for nanomaterials	Approved, 2007

BSI	PAS 135: 2007 Terminology for nanofabrication	Approved, 2007
BSI	PAS 134: 2007 Terminology for carbon nanostructures	Approved, 2007
BSI	PAS 133: 2007 Terminology for nanoscale measurement and instrumentation	Approved, 2007
BSI	PAS 132: 2007 Terminology for the bio-nano interface	Approved, 2007
BSI	PAS 131: 2007 Terminology for medical, health, and personal care applications of nanotechnology	Approved, 2007
BSI	PAS 130: 2007 Guidance on the labeling of manufactured nanoparticles and products containing manufactured nanoparticles	Approved, 2007
ISO	ISO/AWI TS 10797 Nanotubes -- Use of transmission electron microscopy (TEM) in walled carbon nanotubes (SWCNTs)	Under Development
ISO	ISO/AWI TS 10798 Nanotubes -- Scanning electron microscopy (SEM) and energy dispersive X-ray analysis (EDXA) in the characterization of single walled carbon nanotubes (SWCNTs)	Under Development
ISO	ISO/AWI 10801 Nanotechnologies -- Generation of silver nanoparticles for inhalation toxicity testing	Under Development
ISO	ISO/AWI 10808 Nanotechnologies -- Monitoring silver nanoparticles in inhalation exposure chambers for inhalation toxicity testing	Under Development
ISO	ISO/NP TS 10812 Nanotechnologies -- Use of Raman spectroscopy in the characterization of single-walled carbon nanotubes (SWCNTs)	Under Development
ISO	ISO/NP TS 10867 Nanotubes -- Use of NIR-Photoluminescence (NIR-PL) Spectroscopy in the characterization of single-walled carbon nanotubes (SWCNTs)	Under Development
ISO	ISO/NP TS 10868 Nanotubes - Use of UV-Vis-NIR absorption spectroscopy in the characterization of single-walled carbon nanotubes (SWCNTs)	Under Development
ISO	ISO/AWI TS 10929 Measurement methods for the characterization of multi-walled carbon nanotubes (MWCNTs)	Under Development
ISO	ISO/AWI TS 11251 Nanotechnologies -- Use of evolved gas analysis-gas chromatograph mass spectrometry (EGA-GCMS) in the characterization of single-walled carbon nanotubes (SWCNTs)	Under Development
ISO	ISO/AWI TS 11308 Nanotechnologies -- Use of thermo gravimetric analysis (TGA) in the purity evaluation of single-walled carbon nanotubes (SWCNT)	Under Development
ISO	ISO/AWI TR 11360 Nanotechnologies -- Outline of nanomaterials classification (Nano tree)	Under Development

ISO	ISO/AWI TS 11751 Terminology and definitions for carbon nanomaterials	Under Development
ISO	ISO/AWI TS 11803 Nanotechnologies -- Format for reporting the engineered nanomaterials content of products	Under Development
ISO	ISO/AWI TR 11808 Nanotechnologies -- Guide to nanoparticle measurement methods and their limitations	Under Development
ISO	ISO/AWI TR 11811 Nanotechnologies -- Guide to methods for nanotribology measurements	Under Development
ISO	ISO/NP TS 11888 Determination of mesoscopic shape factors of multiwalled carbon nanotubes (MWCNTs)	Under Development
ISO	ISO/NP 11931 Nanotechnologies -- Nano-calcium carbonate	Under Development
ISO	ISO/NP 11937 Nanotechnologies -- Nano-titanium dioxide	Under Development
ISO	ISO/NP 12025 Nanomaterials -- General framework for determining nanoparticle content in nanomaterials by generation of aerosols	Under Development
ISO	ISO/PRF TS 27687 Nanotechnologies - Terminology and definitions for nanoparticles	Under Development
ISO	ISO/NP 29701 Nanotechnologies -- Endotoxin test on nanomaterial samples for in vitro systems	Under Development
IEEE	IEEE P1650-2005 -- Test Methods for Measurement of Electrical Properties of Carbon Nanotubes	Approved, 2005
IEEE	IEEE P1690 -- Standard Methods for the Characterization of Carbon Nanotubes Used as Additives in Bulk Materials	Under Development
International Electrotechnical Commission	IEC/TC Nanotechnology Standardization for Electrical and Electronic Products and Systems	Under Development
Korean Agency for Technology and Standards	KSD2711 Measurement of ash content in the carbon nanotube soots – Thermogravimetric analysis	Approved, 2006
Korean Agency for Technology and Standards	KSD2712 Evaluation of Content of Single-Walled Carbon Nanotube using UV-VIS-NIR Absorption Spectroscopy	Approved, 2006

Standardization Administration of China	GB/T19619-2004 Terminology for nanomaterials	Approved, 2004
Standardization Administration of China	GB/T13221-2004 Nanometer powder - Determination of particle size distribution – Small angle X-ray scattering method (ISO/TS13762, Particle size analysis - Small angle x-ray scattering method, MOD)	Approved, 2004
Standardization Administration of China	GB/T19587-2004 Determination of the specific surface area of solids by gas absorption using the BET method (ISO 9277:1999, NEQ)	Approved, 2004
Standardization Administration of China	GB/T19588-2004 Nano-nickel power	Approved, 2004
Standardization Administration of China	GB/T19589-2004 Nano-zinc oxide	Approved, 2004
Standardization Administration of China	B/T19590-2004 Nano-calcium carbonate	Approved, 2004
Standardization Administration of China	GB/T19591-2004 Nano-titanium dioxide	Approved, 2004
Standardization Administration of China	GB/T19627-2005 Particle size analysis - Photon correlation spectroscopy (ISO 13321:1996,IDT)	Approved, 2005
Standardization Administration of China	GB/T 15445.2-2006 Representation of results of particle size analysis— Part 2:Calculation of average particle sizes/diameters and moments from particle size distributions (Published: 2006-02-05; implemented: 2006-08-01)	Approved, 2006
Standardization Administration of China	GB/T 15445.4-2006 Representation of results of particle size analysis— Part 2:Characterization of a classification process (Published: 2006-02-05; implemented: 2006-08-01)	Approved, 2006
Standardization Administration of China	GB/T 20307-2006 General rules for nanometer-scale length measurement by SEM (Published: 2006-07-19; implemented: 2007-02-01)	Approved, 2007
Standardization Administration of China	GB/T 20099-2006 Sample preparation dispersing procedures for powders in liquids (Published: 2006-2-5 implemented: 2006-8-1)	Approved, 2006