No. 08-26
August 2008

WORKING PAPER

LESSONS FOR NEW TECHNOLOGIES

By Gary E. Marchant

MERCATUS CENTER
GEORGE MASON UNIVERSITY

LESSONS FOR NEW TECHNOLOGIES

Gary E. Marchant, Ph.D., J.D., MPP
Lincoln Professor of Emerging Technologies, Law & Ethics
Arizona State University

Abstract

Emerging technologies such as biotechnology, nanotechnology, and several others have the potential to provide enormous economic, environmental, and health benefits. Yet, these benefits are being blocked or restricted by the discriminatory treatment and stigmatization of these technologies by regulators, sensationalized media coverage, and activist campaigns, even though these technologies are as safe, if not safer, than existing technologies. Three policy proposals are suggested to address this problem: (i) rejection of the precautionary principle; (ii) legal adoption of the principle of non-discrimination against products based on their method of production; and (iii) a voluntary government-certification program for safety testing.

LESSONS FOR NEW TECHNOLOGIES

Gary E. Marchant, Ph.D., J.D., MPP

Emerging new technologies often offer substantial economic, environmental, and health benefits to society. Yet, existing regulatory systems create impediments to the development of many new beneficial technologies by subjecting them to discriminatory regulatory burdens and pressures. This issue paper describes the discriminatory regulatory approach affecting many emerging technologies, and suggests approaches for leveling the regulatory playing field.

The Problem: Discriminatory Regulatory Burdens on Emerging Technologies

There is a growing consensus that current regulatory systems are systematically biased against new technologies. Twenty-five years ago, Peter Huber described how regulatory programs tend to disproportionately target new technologies, products, and facilities, even though these new innovations often would replace more risky older technologies, products, and facilities (Huber, 1983). On the opposite side of the political spectrum, two experts from the World Resources Institute noted that "[i]n an arena not noted for consensus, the worldwide community concerned with environmental policy is in remarkable agreement about the need for a new generation of technology," and yet bemoaned the "pervasive, implicit bias against new technology" (Heaton and Banks, 1997). The result of this bias is to suppress beneficial new technologies, to the detriment of the economy, public welfare, the environment, and public health. Since Huber first described this problem, it has only gotten worse, and is currently wreaking particularly harmful and unfair havoc on a series of beneficial new emerging technologies.

The affected technologies include several emerging technologies that have enormous potential to address many of the 21st century's most pressing problems in both the United States and globally. These new technologies include:

i. *Biotechnology:* Genetically modified (GM) foods created by modern biotechnology methods have already begun to demonstrate an almost unlimited potential to increase the availability, quality, sustainability, and safety of foods. The first generation of GM crops have not only reduced costs and increased yield, but have also produced demonstrated environmental benefits including reduced pesticide use, shifts to less environmentally harmful herbicides, less environmentally destructive tilling of soils, increased protection of water quality through reduced soil erosion and run-off, reduced greenhouse gas emissions (from less plowing and herbicide applications), and less destruction of natural habitat (by increasing yield from existing cultivated lands). For example, one recent study calculated that in the decade from 1996-2005, GM crops reduced pesticide sprayings worldwide by 493 million pounds (7 percent overall reduction), decreased the adverse environmental impacts of pesticides by 15 percent, and reduced global warming emissions by an amount equivalent to removing 4 million cars from the road for one year (Brookes and Barfoot, 2006). The second generation of GM crops now starting to be introduced promise even more significant benefits, including (i) improved shelf life and quality of fruits and vegetables; (ii) crops with improved nutritional properties (e.g., more healthy oils, more nutritious proteins); (iii) reduction or elimination of allergens and toxins in foods; (iv) functional foods containing vitamins or pharmaceuticals; (v) drought-resistant and salt-tolerant crops; and (vi) alternative sources of biofuels that do not involve sacrificing food supplies.

At the same time this technology has delivered substantial economic and environmental benefits, no known environmental or health harms have resulted from GM

crops or foods. There is a general consensus among expert scientific organizations that GM foods present no unique risks. For example, the National Research Council, research arm of the U.S. National Academy of Sciences, concluded that "the transgenic process presents no new categories of risk compared to conventional methods of crop development" (NRC, 2002).

ii. *Nanotechnology:* Perhaps the most important and promising emerging technology over the long-term is nanotechnology, the science of the very small. Hundreds of nanotechnology products are already on the market, and thousands more are in the developmental pipeline. Many of these products will provide substantial health and environmental benefits, including more effective anti-cancer agents, better technologies for hazardous waste remediation, and clean technologies such as improved solar cells, fuel cells, and emission controls. The U.S. EPA recognizes the substantial potential environmental upside of nanotechnology: "Using nanomaterials in applications that advance green chemistry and engineering environmental sensors and remediation technologies may provide us with new tools for preventing, identifying, and solving environmental problems" (U.S. EPA, 2007a). While no technology, including nanotechnology, is risk free, the scientific data available to date do not suggest that nanotechnology products and processes as a category will be inherently more risky than non-nanotechnology applications, and indeed in some cases may lower risk. A recent review of the toxicity of nanomaterials concluded: "Although it is possible that engineered NM may create toxic effects, there are currently no conclusive data or scenarios that indicate that these effects will become a major problem or that they cannot be addressed by a rational scientific approach" (Nel et al, 2006).

iii. *Food Irradiation:* Food irradiation involves the treatment of raw or processed foods with ionizing radiation to kill bacteria and other parasites that can cause food poisoning. According to a U.S. government fact sheet, "irradiation is a safe and effective

technology that can prevent many foodborne diseases" and "an overwhelming body of scientific evidence demonstrates that irradiation does not harm the nutritional value of food, nor does it make the food unsafe to eat" (CDC, 2005). The safety of food irradiation has not only been endorsed by several federal U.S. agencies, but also by the United Nations Food and Agricultural Organization (FAO), the World Health Organization (WHO), the American Medical Association (AMA) and many other expert organizations. Notwithstanding the health benefits of the technology and absence of any adverse effects on food or health, the government requires irradiated foods to carry a label indicated they have been "irradiated." Given the public's general fear of "radiation," the mandatory label and associated scare campaigns by a few activist organizations and sensationalist journalists has deterred use and consumer acceptance of the technology, despite its potential to address growing concerns about food contamination. As one dismayed, high-ranking U.S. health official remarked, "a few highly vocal opponents have cited discredited reports and repeated outlandish fears often enough to make some consumers think twice" (Mason, 1992). This irrational and counter-productive response has prompted the FDA to recently propose that many irradiated foods should be labeled as "cold pasteurized" rather than "irradiated" (FDA, 2007).

Beyond these three examples, many other emerging technologies have enormous potential and benefits, including synthetic biology, animal cloning, artificial intelligence, RFIDs, neurotechnologies, robotics, new telecommunication technologies, and the next generation of safer nuclear reactors. Notwithstanding the enormous potential benefits, as well as the significant positive environmental and health attributes, of many of these emerging technologies, they have been targeted by actual or proposed regulatory programs for selective and unjustified regulatory requirements. A critical consideration is that this regulatory scrutiny is ***not*** based on any evidence of increased risk (in fact the available evidence suggests the contrary), but rather because of a perceived public concern fueled by

campaigns by activist organizations, sensational media coverage, and in at least some cases, risk-adverse agencies. The consequence is regulation or proposed regulations based not on the products and their risks, but rather based on the process by which the products were made, even though that process is no more risky (and may be less risky) than competing or existing technology processes.

A prime example of this discriminatory dynamic is GM foods. Although no known harms to human health or the environment have resulted from the widespread use of GM crops and foods, and notwithstanding the consensus of scientific authorities that GM foods as a category present no greater risks than conventional foods, GM foods have been singled-out for unique and burdensome regulatory requirements. The United States claims to regulate biotechnology products based on the risks of the individual product rather than the process by which they were made, but the reality is quite different. All GM crops are automatically defined as plant pests by the United States Department of Agriculture (USDA), which means they require separate regulatory authorizations before they can be field-tested and grown commercially. Non-GM foods (except for those few that are actually plant pests) are subject to no similar requirement. Those GM plants that include a pest-control trait are also regulated by the U.S. Environmental Protection Agency (EPA).

The Food and Drug Administration (FDA) comes closest to adhering to the stated U.S. policy of regulating the product rather than the process when in 1992 it determined that there was no reason to treat GM foods as a category any different than non-GM foods. Nevertheless, the FDA does request that the manufacturers of all GM foods to engage in a voluntary consultation with the agency before releasing any GM food into the market, in which the FDA expects the manufacturer to produce data from a series of safety tests. No such “voluntary” consultation or data requests are made for non-GM foods. In 1993, the FDA

proposed to make the voluntary consultation for GM foods a mandatory regulatory requirement (although this proposal has not been finalized).

The European Union goes even further and expressly regulates GM foods differently and much more stringently than other foods. All foods containing GM ingredients above a 0.9% threshold are subject to strict labeling and traceability requirements. Moreover, the EU enforced a de facto moratorium on any new approvals of GM crops or foods from 1998 through 2004, which was found to violate international trade laws by a WTO dispute panel. Several individual EU countries are currently enforcing their own bans on GM foods and crops, which again were found to be unlawful by the WTO. The EU concedes it does not apply this burdensome regulatory approach to GM products because they may be more risky than non-GM products. Indeed, the EU's own scientific advisors found that "[t]he use of more precise technology and the greater regulatory scrutiny probably make (biotech crops) even safer than conventional plants and foods" (European Commission, 2001). Rather, the purported justification for this more stringent regulation is based on public opinion and the precautionary principle.

Similar discriminatory approaches have been applied or proposed for other emerging technologies. The U.S. federal government requires foods treated with irradiation to be labeled as such, even though the available evidence suggests no increased risk from such products (and again they are likely safer than non-irradiated foods). This regulatory labeling requirement has significantly suppressed use of food irradiation to the detriment of public health.

Although few jurisdictions have yet to enact binding regulations for nanotechnology, public interest organizations are ramping up calls for such regulation, and in some cases, prohibitions. For example, in July 2007, a coalition of forty-five public interest groups issued a position statement calling for a ban on commercialization of any "untested or unsafe

uses of nanomaterials and requiring product manufacturers and distributors to bear the burden of proof" (ICTA, 2007). Other activist organizations and scholars are likewise calling for moratoria on nanotechnology based on the precautionary principle, just as they did for GM foods a decade earlier.

If these new emerging technologies promise not only economic but also environmental and health benefits, why are they being subjected to unfair and burdensome regulatory discrimination? Part of the response may be the exotic, unfamiliar nature of many new emerging technologies. Research on public risk perception suggests that the public is more frightened by less familiar and complex technologies such as nuclear, nano, and genetic technologies. These technologies are also subject to media sensationalism, as evidenced by the media's use of derogatory and sensational terms such as "Frankenfoods" and "grey goo" to refer to GM foods and nanotechnology, respectively. Finally, some activist groups exploit these public and media tendencies to launch campaigns against new technologies that usually elicit extensive publicity. The result of these interacting forces are "risk cascades" in which the risks of certain technologies are sensationalized and amplified, resulting in the technologies becoming stigmatized (Gregory et al., 1995; Kasperson et al., 2003).

This social dynamic puts many emerging technologies in a precarious position. One unfortunate incident or injury, which may routinely occur for many less exotic and commonly accepted technologies, could result in a massive media, public, and governmental backlash that may be far out of proportion to the actual problem, but nevertheless could bring an entire technology to a grinding halt or result in massive economic losses. Examples include the 1999 death of Jesse Gelsinger in a human gene therapy trial, and the Starlink episode in which a GM product not approved for human consumption nevertheless got into the food system (and resulted in millions of dollars of economic loss and loss of public confidence even though no actual human illness resulted). Even if government regulators are

generally reluctant to impose premature or unduly burdensome regulations on a new technology, their common sense often gets swept aside by a tsunami of media, activist, and congressional sensationalism. To avoid such reactions, it is in the interest of both industry and government to minimize the risk of such incidents.

This tendency to stigmatize emerging technologies results in regulatory double standards that are both unfair to the developers of beneficial new technologies and detrimental to public health and welfare. A couple examples of such double standards include:

1. *Herbicide-Resistant GM:* Genetic engineering has been used to make herbicide-resistant crops, but crops with a similar herbicide-resistant trait have also been produced using non-GM methods such as chemical or nuclear mutagenesis. There is no reason to believe that the GM version is any more risky than the non-GM version; in fact, because the genetic changes are much more precise, the GM version will be better characterized and less likely to carry other potentially harmful mutations that may have been created by the other methods. Yet, both the United States and European Union stringently regulate the GM version, but give the non-GM version expressing the equivalent trait a regulatory free pass, which represents "what can only be described as a culture of irrationality." (Morris, 2007).

2. *Magic Nano:* A German company recently released a new bathroom cleaning product called "Nano Magic." Within days of the product release, dozens of consumers started complaining of "inhalation injuries," and several people were hospitalized. This incident immediately generated worldwide frontpage headlines about the dangers of nanotechnology generally, with calls from some organizations to impose an immediate moratorium on all nanotechnology products. A few days later the German government announced that Magic Nano in fact contained no nanotechnology, and attention and concern

about the case immediately vanished. The injuries to the affected individuals were apparently only newsworthy if they were caused by a nanotechnology product, but not if they were caused by a non-nano product (Wilson, 2006).

Proposed Solutions

The problem of discriminatory and undue regulation of beneficial emerging technologies can and should be addressed by legislators and regulators that resist pressure to adopt premature and unwarranted regulatory requirements based on stigma and emotion rather than scientifically based risk assessment and weighing of costs and benefits of regulatory action. To that end, three specific policy options should be pursued: (i) reject the precautionary principle; (ii) establish the principle of non-discriminatory treatment in U.S. law; and (iii) create a voluntary health and safety certification program.

1. Reject the Precautionary Principle

The first and easiest step in leveling the regulatory playing field for emerging technologies is to reject incorporation of the precautionary principle into local, state, national,and international regulatory programs. Many of the most unreasonable regulations and proposals for restricting beneficial emerging technologies are based on the precautionary principle, which opens the door to regulation based not on objective scientific evidence of risk but rather on subjective and arbitrary political biases. There is no standard definition of the precautionary principle, but it is generally regarded as implementing the concept of "better safe than sorry" by requiring proponents of a technology to demonstrate its safety before it can be marketed. Notwithstanding the lack of a clear definition, the precautionary principle has been legally adopted by the European Union; the courts and legislatures of many individual nations including many European countries, Canada, Australia, and India; in

over sixty international treaties and agreements; and most recently by several U.S. local governments such as the cities of San Francisco and Seattle.

The key problem with the precautionary principle is that it is inherently arbitrary in its application. Because there is no standard definition, and no version of the precautionary principle answers central questions such as what level of risk is acceptable or what amount of evidence is necessary to trigger its application, the precautionary principle is prone to being applied based on a political, protectionist, and arbitrary basis. Although the European Commission asserted that the precautionary principle should be based on scientific risk assessment (EU Commission, 2000), the reality is that its application by the EU and others has been anything but principled and grounded in science. There are many examples of this. Invoking the precautionary principle, Norway banned corn flakes cereal because the added essential vitamins could conceivably harm susceptible individuals, Denmark banned cranberry juice drinks because the added vitamin C could harm the rare person susceptible to vitamin C, and France banned caffeinated energy drinks because the caffeine could harm pregnant women (Marchant and Mossman, 2004). Although these applications of the precautionary principle were eventually overturned by courts as lacking a shred of scientific legitimacy, they demonstrate the extremes to which the precautionary principle can and is extended.

More tragically, the precautionary principle was cited as the justification by the President of Zaire for blocking U.S. food aid that contained some genetically-engineered corn during a recent famine in his country. Such examples show how easily the precautionary principle can be manipulated into unreasonable, counter-productive, and sometimes tragic results. While the organic food industry argues with some success that the precautionary principle should be used to restrict GM foods, the fact is that all GM foods are extensively safely tested while organic foods are generally subject to no safety tests, and moreover no

GM food has ever caused any known harmful effect whereas there are several documented examples of organic foods causing death or illness (Trewavas, 2001; Marchant, 2003). While the precautionary principle probably shouldn't be used to restrict either GM foods or organic foods, if it were nevertheless to be applied, the objective evidence would suggest that it be applied to untested organic foods before being applied to GM foods. Yet, because the precautionary principle is used in practice to advance the political and social agendas of its proponents, rather than to advance public health based on scientific evidence, it is frequently applied to GM foods but not to organic foods or other "natural" risks such as herbal remedies. The arbitrary application of the precautionary principle is particularly troubling in light of recent studies showing that invoking the precautionary principle for a particular technology exacerbates, rather than ameliorates, public concern and anxiety about that technology (Wiedemann & Schutz, 2005).

The EU is pursuing an active campaign to make the precautionary principle a recognized principle of international law by inserting the principle in as many international legal documents and agreements as possible, while organized interest groups are campaigning for the domestic adoption of the principle in the U.S. at the local, state, and national levels. A key first step for fair and rational regulation of emerging technologies should therefore be to reject adoption of the precautionary principle in domestic and international regulatory programs.

2. Establishment of Principle of Non-Discrimination

A second step would be to enshrine a principle of non-discrimination in U.S. regulatory law. This principle would prohibit regulatory discrimination against a product based on the process by which it was produced, unless clear evidence exists that the method of manufacturer somehow significantly changes the likelihood that the product will be

dangerous. Under this principle, regulation would be based on the evidence of risk of the individual product, not the technology used to make the product. It would therefore establish a level playing field for similar products made using different processes or technologies.

A principle of non-discrimination would prevent the type of absurd result described above where a herbicide-resistant crop made by GM technology is subject to intensive regulation whereas a crop with the same trait made by mutagenesis or other technologies is given a regulatory free pass. Similarly, the wide variety of products made using or incorporating nanotechnology, which likely represent a broad range of risk profiles, would not all be lumped together based on the simple fact they involved nanotechnology, but again would be evaluated on a product-by-product basis under the same criteria that non-nanotechnology products are evaluated. Unjustified regulatory discrimination based on the manufacturing process unfairly burdens some technologies against others, resulting in economic inefficiencies and reduced consumer welfare as companies are pushed to substitute non-targeted technologies for superior technologies of first-choice that have been artificially stigmatized.

The discriminatory principle has legal foundations in both domestic and international law. Courts generally prohibit arbitrary discrimination by agencies—as the D.C. Circuit has held, "reasoned decision making requires treating like cases alike" (Hall v. McLaughlin, 1989). This principle would presumably prohibit an agency from regulating one product more stringently based on its method of manufacture than another product creating similar or even greater risks but made by another method. Moreover, courts have held that agencies cannot require labeling of products simply to satisfy consumer preferences and beliefs, thus rejecting claims to require labeling of milk made from cows treated with BST in the absence of any evidence of any greater risks from such products (e.g., *Int' Dairy Foods Ass'n v.*

Amestoy, 1996). These precedents could easily be extended to prohibit discrimination against particular methods of production based on consumer fiat and political pressure.

In international law, the World Trade Organization does not permit nations to discriminate against a country's products based on their method of production (described technically as "process and production methods (PPMs)") (GATT, 1947; Read, 2004). Moreover, the EU's own "Communication" on the precautionary principle states that it should be applied "to achieve an equivalent level of protection without invoking . . . the nature of the production process to apply different treatments in an arbitrary manner." (European Commission, 2000).

The non-discriminatory principle could be reinforced in U.S. law in one or more of several ways. First, Congress could enact legislation required non-discrimination against manufacturing methods, either as free standing legislation similar to other recent generic regulatory provisions such as the Information Quality Act (also known as the Data Quality Act), or as part of the reauthorization or amendment of individual regulatory statutes. Second, the White House could direct regulatory agencies to act in a non-discriminatory manner in the form of amendments to an existing or adoption of a new executive order or guidance (e.g., Executive Order 12,866). Third, courts could more expressly adopt the non-discriminatory principle in applying the "arbitrary and capricious" standard of judicial review of agency action under the Administrative Procedure Act. The federal courts have adopted similar principles in the past in fleshing out the arbitrary and capricious standard (Warren and Marchant, 1993). However enacted, consistent application and enforcement of the non-discrimination principle will go a long way towards leveling the regulatory playing field and ensuring a fairer, more reasonable regulatory system.

3. Create a Voluntary Health and Safety Testing Certification Program

Even if regulators apply a level playing field to emerging and existing technologies, the stigmatization of some new technologies by the combination of sensational media coverage, targeted campaigns by activist groups, and public opinion heuristics against novel technologies may still create overwhelming pressure for some form of oversight intervention. Public opinion polls, many independent experts, and even some industry representatives suggest that some type of meaningful government oversight is needed to build public confidence and trust in new emerging technologies (Macoubrie, 2005). If government oversight is required to provide the public confidence needed to enable beneficial new technologies to succeed, how can this be done without unfairly burdening the emerging technologies with regulatory burdens and further stigmatizing that technology?

A solution would for the federal government to offer a voluntary health and safety testing certification program. Under this proposal, a product manufacturer could voluntarily agree to undertake certain product safety testing obligations, and in return would receive a government certification that its product had been appropriately safety tested. The requirements might include: (i) conduct a specified battery of toxicity tests that would screen the product for safety without undue cost or delay; (ii) implement specified work practices and other industrial hygiene recommendations to promote safe manufacturing; and (iii) conduct post-marketing surveillance for indications of health or environmental problems after the product is commercialized.

The certification would indicate that the product has been subject to a reasonable set of government-supervised safety precautions, and thus has some assurance of safety. Of course, such a set of obligations would not prove that the product is absolutely safe, since no reasonable set of toxicity tests could ever prove complete safety (which likely does not exist for any particular product in any event). The government certification would allow the

manufacturer to promote confidence in its product by its customers, workers, stockholders, and the public, and to defend its product against unwarranted attacks by activist groups, journalist, or business competitors. For example, if an organic food interest attacked a GM food product as potentially unsafe, the GM food manufacturer could point to its safety testing certification and challenge the organic food to undertake a similar obligation. While the safety certification could conceivably be administered by an independent private entity (and there would likely be some arguments in favor of this approach), a federal government certification program would probably be preferable because of the public and media's demand for government oversight. Moreover, a governmental role would utilize existing regulatory resources and expertise in regulatory agencies rather than having to recreate such attributes in a new entity.

This voluntary safety testing certification program would be a more formalized and potentially beneficial extension of existing voluntary programs. For example, the EPA has launched a voluntary Nanoscale Materials Stewardship Program for nanotechnology, in which nanotechnology manufacturers can choose to participate by reporting data to EPA and implementing basic risk management provisions. The FDA encourages producers of GM foods to voluntarily consult with the agency prior to commercializing GM foods, in which the agency reviews a basic test of safety data generated by the company. The EPA also operates a technology verification program that certifies the environmental benefits of new technologies (EPA, 2007). These types of programs can serve as precursors for the voluntary safety testing certification program, which could be implemented either by Congress or by individual agencies.

The design of the certification testing requirements would need to be carefully balanced to provide meaningful hazard identification data while at the same time not unduly burdening or delaying the commercial launch of the product to be certified. Two recent

National Research Council reports (2007a; 2007b) have identified significant promise for new toxicogenomic and other molecular assays to provide quick, inexpensive screening tests of toxicity within the next few years. In the interim, regulatory agencies would need to define appropriate test batteries that would likely consist of in vitro assays, short-term animal studies, and computational toxicity methods such as structure activity relationships. The specific tests required would likely need to be defined based on product category, and could be consistent whenever possible with existing voluntary screening programs. For example, foods could be screened based on the safety tests typically done for new GM foods and provided to FDA as part of the voluntary consultation prior to commercialization. Chemical products could be screened using the OECD's Screening Information Data Set (SIDS) protocol. Nanotechnology products could be screened under the "in-depth" arm of EPA's voluntary Nanoscale Materials Stewardship Program. More customized screening batteries may need to be defined for products without an existing program with a defined test battery. Whatever the specific test requirements, the guiding principles should be that participation is voluntary, and the tests required for participating products are carefully selected to provide useful safety information while minimizing burdens and delays for the commercialization of the product.

Future Research

All three of the policy proposals listed above would benefit from additional research, including (i) additional empirical research on how the precautionary principle has fared in the jurisdictions in which it has been adopted; (ii) buttressing the legal support and precedents for the principle of non-discriminatory treatment of production methods in national and international law; and (iii) further development of a certification scheme taking into account evidence on how analogous certification schemes have worked in the past. In addition, some

additional useful areas of research include: (i) the role of state and local governments in the governance of emerging technologies; (ii) international mechanisms of harmonization of regulation of emerging technologies; and (iii) designing mechanisms for the sensible incorporation of social and ethical concerns into the regulation of emerging technologies.

References

Brookes, G. & Barfoot, P. (2006). Global Impact of Biotech Crops: Socio-Economic and Environmental Effects in the First Ten Years of Commercial Use. *AgbioForum* 9:139-151.

Centers for Disease Control and Prevention (2005). Food Irradiation (Oct. 11, 2005), available at http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodirradiation.htm.

European Commission (2001). A Review of Results: EC-sponsored Research on Safety of Genetically Modified Organisms. Edited by Charles Kessler and Loannis Economidis. Office for Official Publications of the European Communities, L-2985, Luxembourg. (http://europa.eu.int/comm.research/quality-of-life/gmo/).

European Commission (2000). Communication from the Commission on the Precautionary Principle, COM 1.

Food and Drug Administration (FDA) (2007). Proposed Rule: Irradiation in the Production, Processing and Handling of Food. *Federal Register* 72:16291-16306.

General Agreement on Tariffs and Trade (GATT) (1947), art. XX.

Gregory, R., Flynn, J. and Slovic, P. (1995). Technological Stigma. *American Scientist* 83:220-223.

Hall v. McLaughlin, 864 F.2d 868, 872 (D.C. Cir. 1989).

Heaton, G.R. & Banks, R.D. (1997). Toward a New Generation of Environmental Technology: the Need for Legislative Reform. *J. Industrial Ecology* 1(2): 23-32.

Huber, P. (1983). The Old-New Division in Risk Regulation. *Virginia Law Rev.* 69:1025-1106.

International Center for Technology Assessment (ICTA) et al. (2007). Principles for the Oversight of Nanotechnologies and Nanomaterials. Retrieved Sept. 29, 2007 from http://www.icta.org/doc/Principles%20for%20the%20Oversight%20of%20Nanotechnologies%20and%20Nanomaterials_final.pdf.

Int' Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996).

Kasperson, J.X., et al., (2003). The social amplification of risk: Fifteen years of research and theory (in Pidgeon, N, Kasperson, R.E., & Slovic, P. (Eds.). The social amplification of risk (Cambridge: Cambridge University Press).

Macoubrie, J. (2005). *Informed Public Perceptions of Nanotechnology and Trust in Government*. Project on Emerging Technologies, Woodrow Wilson International Center for Scholars.

Marchant, G.E. (2003). From General Policy to Legal Rule: The Aspirations and Limitations of the Precautionary Principle. *Environmental Health Perspectives* 111:1799-1803.

Marchant, G.E. & Mossman, K.L. (2004). *Arbitrary & Capricious: The Precautionary Principle in the European Union Courts.* (Washington, D.C.: AEI Press).

Mason, J.O. (1992). Food Irradiation – Promising Technology for Public Health. *Public Health Reports* 107:489-490.

Morris, S,.H. (2007). EU Biotech Crop Regulations and Environmental Risk : A Case of the Emperor's New Clothes?, *Trends in Biotech.* 25:2-6.

National Research Council (2007a). *Toxicity Testing in the 21st Century: A Vision and a Strategy*. National Academy Press: Washington, D.C.

National Research Council (2007b). Applications of Toxicogenomic Technologies to Predictive Toxicology and Risk Assessment. National Academy Press: Washington, D.C.

National Research Council (NRC) (2002). *Environmental Effects of Transgenic Plants*. National Academy Press: Washington, D.C.

Nel et al, Toxic Potential of Materials at the Nanolevel, *Science* 311:622-627 (Feb. 3, 2006)

Read R, 2004. Like Products, Health and Environmental Exceptions: The Interpretation of PPMs in Recent WTO Trade Dispute Cases. *Estey Centre Journal of International Law and Trade Policy* 5: 123-146.

Trewavas, A. (2001). Urban Myths of Organic Farming, *Nature* 410:409-410.

U.S. Environmental Protection Agency (EPA)U.S. EPA (2007a). White Paper on Nanotechnology (Feb. 2007)

U.S. Environmental Protection Agency (EPA) (2007b). EPA's Environmental Technology Verification Program, EPA/600/F-07/005, available at http://www.epa.gov/nrmrl/std/etv/pubs/600f07005.pdf

Warren, E.W. and Marchant, G.E. (1993). More Good than Harm: A First Principle for Environmental Agencies and Reviewing Courts, *Ecology L. Q.* 20:379-440.

Wiedemann, P.M. & Schutz, H. (2005). The Precautionary Principle and Risk Perception: Experimental Studies in the EMF Area. *Environmental Health Perspectives* 113:402-405.

Wilson, R.F. (2006). Nanotechnology: The Challenge of Regulating Known Unknowns. *J. Law, Medicine & Ethics* 34:704-713.