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THE TREND TOWARDS IMPLEMENTING THE PRECAUTIONARY PRINCIPLE IN US REGULATION OF NANOMATERIALS

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□ The precautionary principle provides a framework for regulating emerging technologies in general and nanomaterials in particular. It counsels action in the presence of uncertainties about risk instead of assuming that nanomaterials are safe unless proven hazardous. Nanomaterials are regulated under different statutory programs depending on whether they are drugs, pesticides or other commercial chemicals. Recent developments in the regulation of nanomaterials that are not drugs or pesticides have demonstrated a trend towards application of the precautionary principle. This is a paradigm shift away from the requirement built into past interpretations of the Toxic Substances Control Act (“TSCA”) that manufacturing, processing and use of chemical substances cannot be restricted unless the regulatory authority proves an unreasonable risk. This same paradigm shift is incorporated into recent legislative proposals to amend TSCA.

Keywords: Precautionary principle, Toxic Substances Control Act, Nanotechnology, Regulation, Law

INTRODUCTION

Like any emerging technology, nanotechnology presents challenges for regulators because commercialization has outpaced research into its possible hazards. In the United States, nanotechnology falls within one of several preexisting statutory schemes that seek to balance risk against benefits, depending on whether the nanomaterials are used as general commercial chemicals, drugs, or pesticides. To date there is no unified set of regulations that governs all manufacture, use and handling of nanomaterials regardless of their application. There is a strong and increasing public demand for legislation that is more protective of human health and the environment than the current version of the Toxic Substances Control Act (“TSCA”), which is the statute that governs the manufacture, use, and handling of nanomaterials in products and other chemical substances that are neither drugs nor pesticides. The precautionary principle is an approach to supplying the framework for enhanced regulatory oversight of nanotechnology despite the scientific uncertainty surrounding its risks, and balancing the risks that may be posed against nanotechnology’s commercial benefits. This article will explore how the precautionary principle applies to the evolving set of regulations governing nanotechnology, with a focus on TSCA.

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The precautionary approach would not be based on whether there is a hormetic or linear dose-response to nanoscale materials. Instead, it focuses on the degree of scientific uncertainty surrounding the dose-response. As a consequence, as the hormetic or linear effects of specific nanomaterials on specific organisms become better understood, the scientific consensus can be used to enable more fine-tuned regulation based on experimental results rather than the broad policy dictates of the precautionary principle.

RISK VERSUS BENEFIT IN ENVIRONMENTAL REGULATION

Environmental disasters almost always result in broad introspection concerning how to balance the risks of using technologies against the potential benefits of using those technologies. The April 20, 2010 explosion of the Deepwater Horizon drilling rig and ensuing oil spill in the Gulf of Mexico brought an immediate focus on the regulatory and enforcement activities of the Minerals Management Service, together with the implication that stronger regulation and enforcement could have avoided the disaster (GAO 2010b; OIG 2010). Disasters that have prompted statutory and regulatory reevaluation of risk versus benefit of the underlying activity include the methyl isocyanate release in Bhopal, India in 1984, and the release of contaminants into the Rhine river in Basel, Switzerland in 1986 (Bertazzi 1999), as well as the Exxon Valdez oil spill in 1989, climate change, and exposures to bisphenol A and lead paint.

In many ways, it is easier to regulate after an environmental catastrophe. The risks and hazards are quantifiable and are no longer remote to legislators, regulators, and their constituencies. The industries that caused the problems are vilified and the societal benefits from their functions have a diminished place in the balancing of risks and benefits going forward. The legislative, regulatory, and enforcement responses seem clear in retrospect.

In comparison, balancing risks and benefits is more complex for emerging technologies such as nanotechnology because of the uncertainties presented when commercialization outpaces science's understanding of risk. The risks may seem remote to any particular individual. What percent of funding should go to research directed towards new commercial applications, and what percent should go to research on hazards and exposures? If the commercial applications are not forthcoming then the risk analysis is pointless, and if the materials cannot be handled safely then the commercial research has less relevance and less direct economic benefit, so the commercialization and risk analysis generally proceed in parallel. As a consequence, emerging technologies usually result in release into the market of products that are not fully characterized.

Nanotechnology is no exception. There were 1,015 commercial consumer products that may be based on nanotechnology as of August 2009,

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according to the Project on Emerging Nanotechnologies of the Woodrow Wilson International Center for Scholars (Project on Emerging Nanotechnologies 2010). The scientific understanding of toxicity and exposure to nanomaterials is limited (GAO 2010a).

At this relatively early stage of nanomaterial commercialization, regulations must be based on generalized principles and approaches to regulating industries where there are uncertainties about hazard, exposure, and risk. There is a spectrum of principles ranging from the extreme presumption that all nanomaterials are hazardous until proven safe, to the opposite extreme that all nanomaterials are safe until proven hazardous.

The precautionary principle is one construct that can guide regulators in this situation. It is often stated as a single definitive statement, but is in fact a spectrum of approaches that is providing a framework for regulating nanotechnology. The precautionary principle guides its adherents to reject the assumptions that all substances are safe to use in the absence of a full characterization, and to formulate a regulatory standard that acknowledges uncertainty and mandates or encourages some minimum precautions in the face of it.

For the purpose of this discussion, only a cursory definition of nanotechnology is necessary. Although there are many competing definitions, one broad formulation of the definition of nanomaterials was recently stated in a U.S. Environmental Protection Agency presentation as “[a]n ingredient that contains particles that have been intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers.” Similarly, it is sufficient to note that there are potential health concerns about exposure to nanomaterials, including the possibility that nanoscale particles may pass through cell membranes, be absorbed through skin, and cross the blood brain barrier (Jordan 2010). There is currently only limited information about the health risks posed by nanomaterials, and much remains unknown about their toxicology (DHHS 2009; Iavicoli et al 2010).

WHAT IS THE PRECAUTIONARY PRINCIPLE?

As introduced above, the precautionary principle is a broad policy statement that guides regulatory decisions in the face of scientific uncertainty concerning risk. There is no single, accepted statement of the precautionary principle, and its various formulations lead to very different regulatory results. Some of the formulations of the precautionary principle are:

- “In order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective meas-

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ures to prevent environmental degradation,” as stated in Principle 15 of the Rio Declaration, adopted at the 1992 Rio Conference (The United Nations Conference on Environment and Development 1992). Virtually the same statement has been adopted elsewhere, including in the Canadian Environmental Protection Act, 1999.

- The European Union’s (“EU”) Registration, Evaluation, Authorisation, and Restriction of Chemicals (“REACH”) law is based on “the idea that industry itself is best placed to ensure that the chemicals it manufactures and puts on the market in the EU do not adversely affect human health or the environment. This requires that industry has certain knowledge of the properties of its substances and manages potential risks.” (EC 2006; REACH 2006).
- Even TSCA, which is the subject of intense current criticism for failing to adequately protect the U.S. public, professes to apply one version of the precautionary principle when it states in Section 1 that: “It is the policy of the United States that -
“(1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures;
“(2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards” (TSCA § 2(b)).

The Rio Declaration embodies a permissive statement of the precautionary principle because it permits, but does not mandate, risk mitigation measures. Mandatory statements of the precautionary principle require risk mitigation in the face of scientific uncertainty and threats of serious and irreversible damage (Ashford 2007). Under this standard, TSCA on its surface incorporates a mandatory statement of the precautionary principle with respect to product bans and restrictions on use, processing, distribution and disposal because it requires the EPA to promulgate restrictions “if the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture ... presents ... an unreasonable risk of injury to health or the environment” (TSCA § 6(a)).

The precautionary principle is applicable only when there is scientific uncertainty. If all the risks and hazards of a particular activity are well characterized then how protective a society chooses to be is a policy decision based on myriad other factors. The precautionary principle does not dictate any particular standard of risk management, but instead supplies

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a policy that either states a preference for, or mandates, risk mitigation notwithstanding uncertainties about the risks and potential exposures (Percival 2006).

Scientific uncertainty can be broken down into several categories. Classical uncertainty is when there is a known probability distribution, and the uncertainty arises from not knowing which outcome will occur in each instance. Indeterminacy is when “we know what we don’t know,” and ignorance is when “we don’t know what we don’t know” (Ashford 2007). This is the distinction that former Secretary of Defense Donald Rumsfeld was making when he spoke of the threats of terrorism by saying “There are thing [*sic*] we know that we know. There are known unknowns. That is to say there are things that we now know we don’t know. But there are also unknown unknowns. There are things we don’t know we don’t know” (DOD 2002). He was criticized for this statement; it may be inelegant but it is fundamentally a correct statement of the three classes of uncertainties (Morris 2010).

Ignorance can be further subdivided into two types: limited ignorance when the correct questions are clear but have not yet been answered and as a result a risk is unexpected, and complete ignorance when the correct questions are inconceivable and the risks are unexpected for that reason. For example, it would be limited ignorance to refuse to perform a known test to determine if a risk may be posed, but if the risk itself was previously unknown people would be completely ignorant of it. Many types of environmental regulation encourage limited ignorance because they require either mitigation or immediate reporting of known hazards, but do not require an investigation to determine if those hazards are present. Consequently people may opt to remain ignorant, for example by not testing for the presence of contaminants known to be hazardous.

The precautionary principle can only apply to classical uncertainty, indeterminacy, and limited ignorance, because in those cases there is suspicion of a type of risk that can be identified and mitigated or a clear path to investigate whether those risks exist. If there is no reason to believe a material poses risks, that is, in the face of complete ignorance, the precautionary principle cannot supply a framework to mitigate the risk.

Applying these concepts, regulatory schemes that seek to eliminate all uncertainty do not embody the precautionary principle. Instead, they seek to regulate based on a full characterization and understanding of the substances or activities they regulate, and tend to set a high standard for public protection. Nanomaterials that are drugs are regulated under the Federal Food, Drug, and Cosmetics Act (“FFDCA”). It does not apply the precautionary principle to new drugs because it requires anyone who seeks to introduce a new drug into commerce to file an application for approval by the U.S. Food and Drug Administration (“FDA”) (FFDCA § 355(a)). The FDA can approve a new drug application only if (a) there is

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adequate testing to show whether the drug is safe or not; (b) those tests show the drug is safe for use; and (c) the FDA does not conclude from any other sources that there is insufficient information to determine that the drug is safe for use. The intent of the law is that all types of uncertainty are eliminated. Notwithstanding attempts to eliminate ignorance, the FFDCA cannot anticipate complete ignorance except to provide for product recalls when serious adverse events – which should have been predictable unless there was complete ignorance – occur. Because the FFDCA's objective is the elimination of uncertainty in new drug applications, no nanotechnology-specific regulation is required in order to mitigate the scientific uncertainties. As the FDA's Nanotechnology Task Force reported, "FDA's authority over products subject to premarket authorization is comprehensive and provides FDA with the ability to obtain detailed scientific information needed to assess the safety and, as applicable, effectiveness of products, including relevant effects of nanoscale materials" (FDA 2007).

In contrast, the FFDCA does not seek to eliminate all uncertainty in setting pesticide tolerances, which are the maximum amounts of pesticides residues that may remain in food. Pesticide tolerances are established by the EPA under the FFDCA, as modified by the Food Quality Protection Act of 1996. At least one court has agreed with the EPA that it may authorize a tolerance while in a state of partial ignorance. In the case under consideration the EPA had established a tolerance for three pesticides although developmental neurotoxicity studies had been commenced but not yet been completed (*Northwest Coalition* 2008). The EPA may only establish a tolerance at a level where "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue" (FFDCA § 346a (b)). In the case of threshold effects this standard carries a presumption that "an additional tenfold margin of safety ... shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children" (*id.*). This standard does embody the precautionary principle because it explicitly acknowledges that there may be potential uncertainties and establishes the level of risk that is presumptively acceptable.

INCONSISTENCY BETWEEN TSCA POLICY AND PRACTICE

When the precautionary principle is incorporated into policy statements, there is still wide latitude for authorizing various levels of risk taking. If action is mandated, there are regulatory decisions to be made at each step of determining what precautions to take, when to take them, and how to implement them (Ashford 2007). Determining the appropriate level of protectiveness is a political decision (Percival 2006).

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In TSCA, the regulatory decisions and statutory interpretations have been so biased that the practical effect is an inconsistency between policy and practice. While the policy statement in TSCA is a variant on the precautionary principle, the operative portions of the law require a presumption of safety if risk data is absent, which is a rejection of the precautionary principle. Two TSCA provisions illustrate this presumption of safety and consequent rejection of the precautionary principle. In the first, TSCA divides all chemicals into “new” or “existing” chemicals. Existing chemicals are on a list maintained by the EPA called the TSCA Inventory, and all other chemicals are new. Unless the EPA has issued regulations governing a particular chemical substance, all existing substances may be used by any person for any purpose without restriction. Any person who plans on manufacturing, importing or processing a new chemical must file a Premanufacture Notice (“PMN”) 90 days prior to any of those activities. The person submitting the PMN must disclose all test data and health and safety data in its possession, but is not required to undertake new studies to determine the risks posed by the substance. The PMN is generally the first notice that the EPA receives that a new chemical may be introduced into commerce, and the EPA then has several opportunities to seek additional data on it or restrict its use or handling. Typically, after the EPA’s 90 day review period the manufacturer, processor or importer must notify the EPA when its planned activities have commenced and then the EPA puts the chemical on the TSCA Inventory, conferring on it the status of an existing chemical. (TSCA § 5).

Most PMNs are submitted with very little data about the chemicals they describe; a 2003 draft study for the EPA reported that 67% of PMNs included no test data and 85% included no health data (Battelle 2003). The PMN rules encourage companies to remain in a state of partial ignorance, because if companies generate data tending to show a risk there is a likelihood that the EPA will seek to restrict the manufacture, use and handling of that chemical. In the absence of sufficient data to evaluate health and environmental effect, the EPA does not have authority to impose restrictions during the PMN process unless the EPA finds that either the chemical “may present an unreasonable risk of injury to health or the environment” or it will be made in “substantial quantities” and will result in substantial exposure to humans or the environment (TSCA § 5(e)). These requirements limit the EPA’s ability to take actions to mitigate risks in the face of uncertainty unless the person who submitted the PMN agrees to a voluntary consent order.

A second example of how TSCA does not incorporate the precautionary principle in practice comes from the statutory requirements for issuing product bans and restrictions. The EPA may ban or restrict manufacture and handling of an existing chemical that is on the Inventory only if there is “reasonable basis to conclude that the manufacture, processing,

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distribution in commerce, use, or disposal of a chemical substance ... presents or will present an unreasonable risk of injury to health or the environment" (TSCA § 6). Applying this standard in one of the more notorious and criticized court decisions on TSCA, the court in *Corrosion Proof Fittings* stated that "Congress did not enact TSCA as a zero risk statute," and struck down regulations banning uses of asbestos on several grounds. One of those grounds was that the EPA could not have made a valid determination of the unreasonableness of the risk posed by asbestos products because the EPA had not borne its burden of balancing the costs and benefits of the asbestos ban (*Corrosion Proof Fittings* 1991). Therefore, while the statute embodies a mandatory statement of the precautionary principle when it requires action if there are unreasonable risks, the interpretation of what constitutes an unreasonable risk poses high barriers to taking action to mitigate risk even for a substance such as asbestos which has well characterized risks and hazards. Notably, portions of the asbestos ban relating to products that had already been discontinued or had not yet been commercialized survived the Court's decision because a cost benefit analysis applicable to products that are not on the market is meaningless. As to these banned products, the end result was a protective approach applying the precautionary principle (Percival 2006).

TSCA'S APPLICATION TO NANOMATERIALS

Nanomaterials are regulated under TSCA in the same manner as all other chemical substances, and are not currently singled out as a group for their unique size or properties. This preexisting statutory scheme has limitations when existing chemicals are reengineered to have novel attributes. If a chemical substance is on the Inventory, then a nanomaterial with the same "molecular identity" is defined to be that existing chemical and the EPA will not currently receive any notice that a new nanomaterial will be introduced into commerce. Consequently, there will not be a premarket opportunity to regulate many nanomaterials.

The EPA issued a position paper stating that a material newly made on the nanoscale is an existing chemical only if it has the same molecular formula, structural formula, spatial arrangement of atoms and crystal lattice structure as a chemical already on the Inventory, and also is the same allotrope and is composed of the same isotopes (USEPA 2008a). EPA also clarified that each specific carbon nanotube must be on the Inventory, and industry cannot rely on the Inventory listing for carbon or other nanotubes to conclude that particular carbon nanotubes are also on the Inventory (USEPA 2008b). While these statements are likely to encompass a broader definition of "molecular identity" than permissible under the statute, they demonstrate the EPA's resolve to have an opportunity to regulate as many nanomaterials as possible under the existing statutory program.

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FUTURE DIRECTIONS UNDER TSCA

There are increasing calls for reinvigorated application of the precautionary principle to chemicals in general and nanomaterials in particular. The National Institute for Occupational Safety and Health recommended the precautionary principle's application to nanotechnology when it stated "[u]ntil further information on the possible health risks and extent of occupational exposure to nanomaterials becomes available, interim protective measures should be developed and implemented" (DHHS 2009).

Two parallel developments could ultimately result in application of the precautionary principle to nanomaterials. In 2010 legislation was introduced in Congress that would have substantially revised TSCA and given the EPA far broader authority to take action to mitigate risks from chemicals in general and nanomaterials in particular. Although neither TSCA reform bill was enacted in 2010, and prospects for formal TSCA reform appear to be remote in the short term, these legislative efforts point to the evolution of the precautionary principle in the United States.

Senator Lautenberg and Representatives Rush and Waxman introduced TSCA reform legislation in 2010 (Safe Chemicals Act of 2010; Toxic Chemicals Safety Act of 2010). Both of these bills would have moved nanotechnology regulation away from the precautionary principle and towards a policy of eliminating all uncertainty, similar to the regulatory system for new drugs. Both bills recited a policy of requiring that "all chemicals in commerce meet a risk-based safety standard that protects vulnerable and affected populations and the environment" and required companies to "provide sufficient health and environmental information for the chemical substances which they manufacture, process, or import as a condition of allowing such companies to distribute such chemicals in commerce."

Under both of the proposed TSCA bills, the EPA could determine that a nanomaterial exhibits a "characteristic" that could affect risk, and consequently categorize it as a new chemical substance even if other forms of the same chemical are on the Inventory. As in the current version of TSCA, new chemical substances would go through a premanufacture notification process, except that the proposals required development of a minimum data set to be submitted with the PMN for a new chemical. The minimum data set is a new concept for TSCA that appears to be borrowed from REACH's requirements. The minimum data set would eliminate the problem that occurs when companies opt to remain in a state of limited ignorance by failing to perform testing that would identify risks. As noted above, there are many opportunities to introduce precautionary concepts into regulation, and the EPA would have to determine what levels of uncertainty are acceptable in establishing the tests that would comprise these minimum data sets. A customized minimum data set could be established for nanomaterials.

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In both proposed versions of TSCA, the EPA would prepare a priority list of no fewer than 300 chemicals for priority evaluation against a safety standard that incorporates a “reasonable certainty of no harm.” This is virtually the same language as used in the Food Quality Protection Act of 1996, discussed above with respect to pesticide tolerances. Manufacturers and processors would have the burden of proving that their chemicals meet this standard, and if they cannot the EPA could ban or restrict the chemical. Starting with the chemicals on the priority list, the EPA would be required to evaluate all uses of commercial chemicals for compliance with the safety standard. The Senate version added that “reasonable certainty of no harm” means that there is “negligible risk of any adverse effect on the general population or a vulnerable population.”

As a practical matter, either proposed version of the TSCA reform bill would have had to incorporate elements of the precautionary principle in their implementation, or risk halting most exploitation of nanotechnology, which seems unlikely in the current economic predicament. A standard requiring proof that nanomaterials have a “reasonable certainty of no harm” or pose “negligible risks” of any adverse effects could be interpreted similarly to the “reasonable certainty that no harm will result” in the FFDCA, which does tolerate uncertainty and require action to mitigate uncertain risks. A system that seeks to eliminate all uncertainty cannot be implemented in the short term because of the long lead time for studies that would establish hazards and exposure, and the limited resources available to study the risks and exposure pathways for each potential use of each unique nanomaterial. One study estimated that it could take more than ten years to thoroughly study all existing nanomaterials if companies devoted five percent of their research and development funds to the effort (Choi et al. 2009). That study was conducted before the proposed TSCA reform bills were drafted, and could not take into account the bills’ requirement to evaluate each potential use of a chemical separately, which would increase the time and money necessary for research. Even if the “negligible risk” standard were to be enacted into law, some degree of uncertainty will have to be tolerated until the required studies are completed. The precautionary principle comes into play until the uncertainties are eliminated.

Environmental organizations and industry groups raised the safety standard and timing of safety determinations as two of the many issues that require further refinements before these stakeholders can support TSCA reform (Duvall and Wyatt 2010). These topics are at the crux of the precautionary principle, and further discussions should focus legislators and the public on whether the precautionary principle should be embraced.

At the same time as EPA is supporting TSCA reform, it has also made innovative uses of its existing statutory authority to gather information on nanomaterials and regulate them, and has announced its intent to take

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more actions in the near future (USEPA 2009a; USEPA 2009b; USEPA 2009c; USEPA 2010). If successful, these actions would reverse the historical presumption that all chemicals are safe unless proven otherwise, and would implement a presumption that risk mitigation is required for all nanomaterials. The EPA has issued rules called Significant New Use Rules for specific nanomaterials, which require the use of respirators and personal protective equipment, failing which the users must submit a notification to the EPA on the PMN form with the same data that must be submitted with a PMN. The EPA has entered into orders with the agreement of companies that submitted PMNs on nanomaterials. Each of these orders requires the company to perform a 90-day inhalation toxicity study after temporal or volume triggers have been met, and to provide workers with respirators and gloves that are impervious to nanoparticles (Gold and Warshaw 2010). These orders embody the precautionary principle because they permit the EPA to regulate without first marshalling enough data to prove that an unreasonable risk is presented.

The EPA has said that it intends to issue a Significant New Use Rule that applies generally to nanomaterials, a rule requiring companies to submit to the EPA data and studies in their possession concerning nanomaterials, and a rule requiring testing of multi-wall carbon nanotubes and nanosized clays and alumina under TSCA's test rule provisions (Jordan 2010; USEPA 2010). All of these actions are cumbersome to implement, as demonstrated by the fact that the EPA first announced the proposed test rule for multiwalled carbon nanotubes over eighteen months ago, and the proposed reporting requirements in December 2009 (USEPA 2009a; USEPA 2009c) and has not formally proposed them to date. Once these rules are formally proposed the public will have an opportunity to comment before any final rules go into effect. While the contemplated test rule and reporting rule would tend to decrease the scientific uncertainty concerning the risks of nanomaterials, the Significant New Use Rules proposed and issued to date are classical applications of the precautionary principle's injunction to take action notwithstanding uncertainty.

CONCLUSION

Chemical regulation in the United States is moving away from a presumption that risks do not warrant mitigation until they have been proven either by a disaster on the scale of the Gulf of Mexico oil spill or incontestable scientific proof. For emerging technologies such as nanotechnology US legislators and regulators are gradually embracing the precautionary principle's admonition that uncertainties should not preclude effective protections. Whether nanotechnology regulation arrives at the precautionary principle through legislative revision of the Toxic Substances Control Act, or through creative use of the regulatory options

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available to the EPA under the current law is of less consequence than the fact that this paradigm shift is taking place at all.

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