

Preliminary Cost of Compliance Analysis for the Regulation of Products that contain Nanomaterials

NRDC Health and Environment Program

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I- Introduction

Background

Many scientists view nanotechnologies as the technological revolutionary of the 21st century. Nanotechnologies are based on matter that is so small that it exists in the atomic and molecular realm. At this size, the substance's physical, chemical and biological properties frequently are different from what they were at the micrometer and larger scales. By harnessing these new properties, researchers have found that they can develop materials, devices and systems that are superior to those in use today.

Engineered nanomaterials carry a great promise for improved economic and social well-being, yet it also brings risks. Studies of the health impacts of airborne particles generally have shown that the smaller the particles, the more hazardous they become. This is due in part to the fact that, given the same mass per volume, the dose in terms of particle numbers increases as particle size decreases. As a result, toxicity standards developed for standard chemicals may prove to be highly insufficient for nanomaterials. The commercialization of nanotechnologies requires sensible management of the risk by governments.

How, or even if federal agencies will regulate the nanotechnology industry is still being debated. Existing chemical and product regulations are likely to be grossly inadequate for providing the public with assurances of safety and for providing market stability. Thus far, regulations in Europe or the United States generally have not distinguished between bulk and nanoscale materials. In addition, detection tools for routine materials are not adequate to detect nano-scale materials.

The US government has been a key driver of nanotechnology innovation through the multi-agency National Nanotechnology Initiative (NNI), with a total budget of over \$1.2 billion in FY2007, bringing the total federal investment to over \$6.5 billion since 2001 when the NNI was established to co-ordinate federal activities on nanotechnology.

Despite this, Woodrow Wilson Center reported in a 2005¹ study that funding of “highly relevant” nanotechnology risk research is just 1% of the annual NNI budget –\$11 million in 2005. Maybe even more important than the level of funding is the fact that government’s research into the environmental, safety and health implications of nanotechnologies lacks a sensible regulatory framework and actions in data collection.²

Aim

This report is a first attempt to offer a preliminary study exploring the potential social and market benefits from compliance with a sensible regulatory framework³ which aims to reduce the risks and uncertainty, and estimate the costs to implement such regulation. This analysis is specifically designed to focus on products incorporating products containing nano-engineered components from two commercial sectors; 1) cosmetics and personal care products, and 2) food storage devices. These two sectors are selected because nanomaterials used in products in these sectors are highly likely to lead to human exposure.

Uncertainty

The difficulty in conducting such an analysis arises mainly from two areas. First, is the fact that the existing data on the nano-industry is extremely limited at this time, in terms of the substance’s basic physical, chemical and biological characteristics, its potential health harm, and its market characteristics such as sales price, market share, and quantity manufactured. Secondly, the government’s regulation of nanotechnologies lacks the clearly formed strategies of traditional chemical regulations.

To be more specific, this study identified the uncertainties involved in both cost and benefit side of regulating products that contain nanomaterials. In a situation like this where the legislation has not been initiated and knowledge of the specific processes is

¹ Nanotechnology: A Research Strategy for Addressing Risk by Andrew D. Maynard. Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies.

² Nanotechnology: A Research Strategy for Addressing Risk by Andrew D. Maynard. Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies.

³ Jennifer Sass, (2006) A Rationale and Framework for US Regulation of Nanotechnologies (Draft), NRDC.

limited, ignoring the uncertainties in any regulatory analysis is almost sure to leave critical parts of the analysis incompletely examined and hence to increase the chance of generating a result that is incorrect, incomplete, or misleading. One option to this problem is to rely on default assumptions. That is, we can examine all relevant and available data first and when nano specific data are unavailable or insufficient to make robust estimates, we choose to use default assumptions, primarily from the regulation of standard chemicals, to continue in the analysis. This helps in the cost side of analysis but it is less useful in the benefit side, where uncertainties are even larger.

On the cost side, we have taken an alternative approach by assuming that the cost of regulating products containing nanomaterials is at least as much as the costs per chemical of chemical regulations. The availability of data collected for regulation of chemicals is undoubtedly better than that of products with nanomaterials, although some of the chemical data is also hard to find, such as the costs data for building up a comprehensive inventory of chemicals, as required under the Toxic Substances Control Act (TSCA). This assumption is made partially because the health harms that people care about are the same for conventional chemicals and nanomaterials, such as reproductive harm, cancer, and disease risks.

On the benefit side, the story is more complex. Basically, the benefits consist of two parts. First, benefits come from protection of public safety with compliance with a sensible regulatory framework for products containing nanomaterials. EPA usually has specific procedures to assign a monetary cost to specific diseases and sum them up as the value of the benefit when the disease has been prevented. Although it is controversial to use such a method in the public health domain, it is difficult to quantify a precise benefit and this method does provide some basic criteria to justify public policy decision making. However, even this method can be hard to implement, since specific information about the health risks associated with exposure to nanomaterials or products containing nanomaterials is extremely limited. Moreover, it would be impossible at this time to perform a probabilistic analysis without data on the frequency of occurrence of diseases or health harms, if any, associated with nanomaterials.

The second category of the benefits is composed of a wide range of additional benefits that will be enjoyed by the industry and business in complying with the

regulation. These are beyond the quantified human health benefits, and we can not yet quantify them in monetary terms. These include the potential for product liability that the company would have to pay if it were held responsible for the injuries those products cause, the adverse effect of negative public perception on a product that is suspected to be harmful or dangerous, negative public perception caste across the whole industry because of risks or suspected risks with some nanomaterials or products containing nanomaterials, and the loss to the company because of a late compliance after the products are put into production, versus earlier compliance with regulations in the research and development stage. In the absence of regulations, these problems are much more likely to occur, researchers are uncertain about how to work safely with the new nanomaterials, nano-businesses are uncertain about how to develop safe products, and public confidence in the products and the whole nanotechnology industry is in danger of being undermined.

Summary

This preliminary cost of compliance analysis identifies areas that lack economic predictability, provides a rationale for default assumptions based on the regulation of standard chemicals, and identifies data needs for a rigorous standard cost of compliance analysis consistent with the OMB guidelines for regulatory analysis. This preliminary analysis supports the need for a regulatory framework within which effective risk-based testing plays a critical role. In summary, this study identifies two major needs: Data collection and a Regulatory framework for nanotechnology risk management.

II- Market characterization

We identify three products (to be clarified) from the candidate sectors of regulation. Food storage devices typically use Nano silver as antibiotic or antibacterial to keep food fresh and longer. Anti-aging cream widely uses fullerenes as its ingredient. And zinc oxide is being used in almost all the nano-sunscreen products.

Table 1 provides the detailed description for these three products. The regulation on these products will go through the steps listed in the regulatory framework.

Table 1. Identified nano-materials for regulation in food storage and cosmetics

Product	Nanomaterial	Function of nano
Food storage, refrigerator	Nano-Silver	antibacterial to keep food fresher longer, deodorant, antibiotic
Anti-wrinkle, anti-aging creams	Nano-carbon Fullerenes	skin renewing; tissue growth and strengthening of collagen and elastin
Sunscreen	Nano Zinc oxide	protective physical barrier against sun and UV rays

It is widely recognized that the data on nanotechnology is extremely limited at this stage because government regulation of nanotechnology is in its infancy. Our response to the lack of data is to use some data, mainly the costs data, collected for regulation of chemicals to simulate that of products containing nanomaterials. This is partially because the potential harm of nanomaterials is by nature similar to that of chemicals.

III- Costs

1. Direct costs

Direct costs of regulation come mainly from the building up an inventory of nanomaterials and conducting safety testing for those materials.

1.1 Costs of collecting information for building up an inventory

The estimated costs under this category will simulate the costs of data collection for the chemical inventory required by EPA's chemical regulatory framework, the Toxic Substance Control Act (TSCA).⁴

1.2 Costs of doing independent safety testing

⁴ See the website for detailed information:
<http://www.epa.gov/opptintr/newchems/pubs/invntory.htm>

Doing independent⁵ safety testing enables us to have the adequate protection against the potential harms of nano-materials on health and environment. We adopt both the test procedures and the estimated costs from OECD's Screening Information Data Set (OECD/SIDS) for High Production Volume (HPV) chemicals⁶. EPA is focusing on Screening Information Data Set (SIDS) testing because it is comprised of a battery of tests agreed upon by the international community through the OECD, of which the United States is a member country, as appropriate for screening HPV chemical substances for toxicity and produces information. There are six basic tests which have been internationally agreed to for screening high production volume (HPV) chemicals for toxicity. The tests agreed to under the Organization for Economic Cooperation and Development's Screening Information Data Set (OECD/SIDS) program are:

- Acute toxicity.
- Repeat dose toxicity
- Developmental and reproductive toxicity.
- Genetic toxicity (gene mutations and chromosomal aberrations).
- Ecotoxicity (studies in fish, Daphnia, and algae).
- Environmental fate (including physical/chemical properties(melting point, boiling point, vapor pressure, n-octanol/water partition coefficient, and water solubility), photolysis, hydrolysis, transport/distribution, and biodegradation)

While data on the six SIDS endpoints do not fully measure a chemical's toxicity, they do provide a consistent minimum set of information that can be used to determine the relative hazards of chemicals and to judge if additional testing or assessment is necessary.

For each chemical, the basic set of six screening tests costs about \$205,000, and therefore our estimate of testing three nano-products in food storage and cosmetics is approximately \$615,000. This assumption provides an upper bound estimate of total administration costs; true costs are likely to be lower. A federally-coordinated testing

⁵ Independent testing would rigorous, credible health and safety information to the public, to industry, and to regulators. Funding would be through public and private sources. The program would be coordinated by the federal government, but the research and funds would be distributed to appropriate federal agencies and laboratories, with research results complimenting other federal initiatives.

⁶ See the website for detailed information:
<http://www.epa.gov/chemrtk/pubs/general/hazchem.htm>

program would have the burden of costs shared between the public and private sector, but managed through the federal agencies, with results publicly available.

2. Indirect costs

In this part, we examine the market effect of implementing the regulation on products containing nanomaterials. The direct costs of regulations will increase the market price of related products, and the output of the products will presumably decrease. Unfortunately the lack of data greatly limits our ability to conduct rigorous calculation on the exact magnitude of this short-run price effect, which should be based on models and existing data of the nano industry's structure, elasticity of demand for nano-products, as well as their market prices and quantities of production, etc.

Instead, we refer to the results of two analyses⁷ for chemical regulations, in which they both conclude that although there is a price effect on the market, the scale of the effect is actually too small to have a major impact. Based on the similarity between chemical regulations and the regulation of products containing nanomaterials, the small this suggests a similarly negligible effect on the nanotechnology market due to the price increase.

3. Other economic costs

In addition to direct and indirect costs, entities subject to the proposed test rule will also incur expenses associated with the administration of the testing program itself. Administrative activities include "reporting activities," such as preparing letters of intent, study plans, exemption requests, progress reports, and final reports, and "other activities," such monitoring tests under progress, developing cost-sharing agreements, and auditing of laboratories for compliance with EPA's Good Laboratory Practice (GLP) standards.

3.1 Administrative costs

⁷ The two studies refer to: The true cost of REACH by Frank Ackerman and Rachel Massey (2004), Global Development and Environment Institute, Tufts University. And Economic Analysis for the proposed section 4 Test Rule for HPV Chemicals by EPA's Economic and Policy Analysis Branch (2000).

Prior studies typically calculated administrative costs by assuming them to be equal to 25 percent of laboratory costs. This assumption was based on a survey that examined laboratory and administrative costs incurred in response to several previous HPV rules⁸ (D’Ruiz and Riordan, 1988).

However, the recent economic study of EPA for the new HPV rule assumes that total administrative costs equal 100 percent of laboratory costs because laboratory costs of the basic tests proposed under the current HPV rule are significantly lower than the laboratory costs of the more complex tests required by the earlier rules. Yet the administrative requirements (e.g., letters of intent, final reports, etc.) of the HPV rule are similar to the administrative requirements of earlier rules. Thus, the ratio between administration costs and laboratory costs is expected to be greater than 25 percent for the HPV rule. Thus, total administrative costs are assumed to equal \$615,000. These costs are assumed to be incurred through reporting and other administrative activities.

3.2 Export notification costs (to be determined)

To conduct a detailed analysis of the impact of export notifications requires data on the identity and/or number of exporters and the identity and/or number of countries to which each regulated product is exported. While data on aggregate export volumes for various products can be found in U.S. Department of Commerce publications, detailed data identifying exporters and destination countries for regulated nano products are not readily available from secondary data sources. Therefore, it is difficult to estimate the number of export notifications that would be triggered by the promulgation of regulations for products containing nanomaterials.

Given these data limitations, the cost of export notifications for this rule has been estimated using an alternative estimation procedure adopted in EPA’s study⁹. This

⁸ The assumption was based on a survey that examined lab and administrative costs incurred in response to several test rules at EPA. D’Ruiz and Riordan, (1988) a survey that examined lab and administrative costs incurred in response to several test rules at EPA

⁹ Economic Analysis for the proposed section 4 Test Rule for HPV Chemicals. EPA’s Economic and Policy Analysis Branch (2000), Economic Analysis for the proposed section 4 Test Rule for HPV Chemicals.

analysis, therefore, assumes that there will also be 65 export notifications per product subject to the proposed regulation.

According to the same study, accounting for labor and shipping costs, the total cost of preparing and submitting an export notification is estimated to range from \$19.09/notice to \$83.38/notice. For each nano-containing product that is regulated, assuming that 65 notifications will be submitted for each product, it is estimated that the total cost of export notifications triggered by the proposed rule per product is in the range between \$1,240 and \$6,420.

4. Net present value of costs

The costs of regulating a product containing nanomaterials is measured by the flow of costs associated with the product over time, including direct, indirect, and other economic costs. The steps of regulation include some one-time effort such as testing which helps to develop basic toxicological data as a precondition for continuing sale of the affected product. The regulation also includes maintenance of the inventory, administrative efforts, and following the track of the export of the product. These are not based on one year's results, but rather on the total earnings stream associated, and this should be appropriately discounted over time.

In order to develop a net present value analysis of regulation costs, we adopt standard values used in EPA's studies for the economic life of the chemical and discount rate for chemicals. The Office of Management and Budget's (OMB's) economic analysis guidance recommends that analysts use the opportunity cost of capital for discounting in economic analyses of regulations (OMB, 1992). The discount rate reflecting the opportunity cost of capital, as specified by OMB Circular A-94, is estimated to be 7 percent. This represents the average rate of return on low-yielding capital investments, such as housing, and the returns on high-yielding investments, such as corporate capital. The life of the chemical is assumed to be 15 years. The one-time testing costs are thus annualized over a 15-year period using a 7 percent discount rate. There are two formulas used in the calculation of present value, the first one is used when there is a one time future investment and the second is for continuous annual investment through a number of years.

The standard present value formula for a future investment cost is given by:

$$PV = I \cdot (1/1+i)^n$$

Where PV is the present value, I is the amount of the future investment, i is the discount rate and n is the number of years.

The formula for present value of annuities is:

$$PV = A \cdot (1 - (1+i)^{-n})/i$$

Where A equals the annual amount, i is the discount rate, and n is the useful life of the investment. This or a similar calculation needs to be done once the necessary data is available.

IV- Benefits

Product liability: Asbestos case and its compensation

Asbestos liability is considered an alert for potential risks to human health and the environment, in part because of toxicity tests demonstrating the extreme toxicity of inhaled nanocarbon particles, including the induction of progressive fibrosis in the lungs, similar to asbestos and other inhaled fibers. As with asbestos, the health hazards of nanomaterials are likely to be long-lasting and possibly deadly. Lloyds of London, a major insurance agency, posted a news release on its website in June, 2006 alerting its clients of the risks associated with insuring nanotechnologies, and in particular quoting another insurer, Swiss Re, that, "... some nanotubes, are similar in form and size to asbestos fibers...there are indications that certain nanomaterials are potential health hazards... the danger is most probably of a chronic nature and it could be some time before it manifests itself"¹⁰.

¹⁰ Lloyd's of London. Does size really matter? June 19, 2006.
http://www.lloyds.com/News_Centre/Features_from_Lloyds/Does_size_really_matter.htm

A RAND Corporation's report¹¹ on compensation and costs of asbestos litigation shows that the compensation for the tort liability of asbestos is extremely high. Here is a summary of the compensation:

- A total of \$54 billion has already been paid out for victims of asbestos.
- Transaction costs have consumed more than half of total spending.
- About 65 percent of compensation has gone to nonmalignant claimants, with no or limited measurable health impacts.
- Compensation for mesothelioma claims, a disease specific to asbestos, has risen sharply since 1993.
- Estimates of the number of people who will file claims in the future—and the costs of those claims—vary widely, but they are all extremely high. All accounts agree that, at best, only about half the final number of claimants has come forward. At worst, only one-fifth of all claimants have filed claims to date. Estimates of the total costs of all claims range from \$200 to \$265 billion.

V- Sensitivity and uncertainty analysis

An uncertainty and sensitivity analysis must be conducted. A sensitivity analysis evaluates the effects of changes in input values or assumptions on a model's results. Uncertainty analysis investigates the effects of database uncertainties, uncertainty associated with model parameter assumptions, uncertainty regarding appropriate application of the model, and other potential sources of error in the model. Thorough documentation must be provided of the underlying assumptions that are used to conduct the cost compliance analysis, and that are used to define the parameters of the analysis. The parameters are terms in the analysis that are fixed, but can be changed in different analyses to conduct sensitivity analysis or calibrate the model.

VI- Conclusion/implication and future improvement

The need to make EPA regulatory decisions as transparent and to allow others to reproduce EPA analyses is essential to elevating the public confidence in EPA analyses.

¹¹ Rand Corporation's report (2001) Asbestos' Compensation and Litigation Costs http://www.rand.org/pubs/documented_briefings/2005/DB397.pdf

All analyses used to inform regulatory decisions should be accompanied by comprehensive, publicly available documentation that describes the conceptual and theoretical basis for the analysis, the process used to evaluate the model, and access to input and output data such that the public can replicate results derived from the model.