Review of the OSHA Framework for Oversight of Occupational Environments

Jae-Young Choi and Gurumurthy Ramachandran

Nanotechnology is a collection of different technologies and approaches dealing with manipulating matter with dimensions on the nanometer scale.[1] The growth of nanotechnology has been rapid in recent years and encompasses a range of industries including pharmaceuticals, chemicals, robotics, medicine, agriculture, electronics, national defense, fiber optics, and energy.[2] Nanoparticles with shapes, morphologies, and chemical compositions engineered for specific functions and applications are now common. While estimates of the numbers of new types of nanoparticles being produced in academic and industrial labs that combine these different characteristics are uncertain, it is likely that they run into the hundreds.

Investments in Nanotechnology

In the United States, almost all of the 425 manufacturing, applications, and equipment companies that make up the U.S. nanotechnology industry today were launched prior to emerging nanotechnology economic development efforts and have generated nearly 23,000 new jobs.[3] Based on this promise, there has been significant investment in this technology by governments and industry worldwide. It is estimated that worldwide funding for nanotechnology R&D was $11.8 billion in 2006 and came mainly from three sources: governments ($5.79 billion), corporations ($5.34 billion), and venture capitalists ($699 million).[4] The United States provides about 37 percent of the total funding. The U.S. government invested $1.78 billion on nanotechnology in 2006, representing about 30 percent of worldwide government spending of $5.79 billion.[5] U.S. corporations accounted for 37 percent of worldwide corporate spending. While corporate and venture capital funding has been dominated by electronics and information technology (about 54 and 42 percent respectively), manufacturing and materials development have accounted for substantial portions as well (about 29 and 26 percent respectively). Companies have devoted substantial funding to developing new nanomaterials (nanoparticles, nanotubes, nanoporous materials) and nano-intermediates (composites and coatings).

Similar to its previous projection in 2004, Lux Research announced that more than $50 billion in nano-enabled products will be sold worldwide in 2006 — up 65 percent from 2005. As of March 2006, an

Jae-Young Choi *is a Ph.D. student in the Division of Health Policy and Management at the School of Public Health at the University of Minnesota.* **Gurumurthy Ramachandran, Ph.D.,** *is a Professor in the Division of Environmental Health Science at the School of Public Health at the University of Minnesota.*

online inventory of manufacturer-identified nanotech goods identified 475 consumer products using nanotechnology.[6] The National Science Foundation in 2001 estimated a global market for nanotechnological products of $1 trillion for 2015.[7] Lux Research forecasted in 2007 that $2.6 trillion in global manufactured goods will incorporate nanotech by 2014.[8] This will comprise 4 percent of manufacturing and materials output, 50 percent of electronics and IT output, and 16 percent of manufactured goods in health care and life sciences.[9] This represents an increase of products incorporating nanotech from about 0.5 to 15 percent of all manufacturing output.

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Potential Occupational Health Implications

It is estimated that about two million new workers will be exposed to engineered nanoparticles (<100 nm) over the next decade.[10] Consumer products that contain nanoparticles are also becoming more commonplace, and it is only a matter of time before a significant proportion of the population will use or come into contact with products containing nanoparticles. However, the most significant exposures and risks will be in the occupational arena.

Despite the large investments in nanotechnology, corresponding investments in studying the health and safety aspects of this technology and its products have been minimal. For example, compared to the approximately 30,000 papers published on nanotechnology in 2005, only about 64 papers on health and safety were published in the same year, increasing to 110 in 2006.[11] Most of these papers deal with only a few nanomaterials (e.g., ceramic nanoparticles) and describe toxicity through inhalation or in vitro studies.

The number of companies that used nanotechnology to perform R&D was estimated to be about 441 in 2003, constituting 26 percent in the total nanotechnology industry. Out of 441 companies manufacturing nanoparticles, approximately 50 percent are considered to be small sized companies (5-249 employees). Most innovations in nanotechnology will likely emerge from research groups and firms that are small businesses and startups and will consequently be more sensitive to signaling from regulatory bodies.[12] We can consider primary production of nanomaterials as being the sector containing the most exposed workers. We have compiled a database of U.S. nanomaterial companies and analyzed the firms' profiles and financial information using several sources: Nanomaterial Database, corporate annual reports, and the Nanotech Report, 5th edition.[13] This database includes 53 firms that are publicly traded companies and 276 privately owned firms. We can also obtain a rough estimate of the number of nanomaterials currently in production from Nanomaterial Database provided by Nanowerk LLC, which lists 265 nanomaterials in nine categories. The database includes only nanoparticles that can be identified using a search of manufacturers' websites that provide detailed particle descriptions. Of the 190 nanoparticle manufacturers identified, roughly two-thirds provide particle descriptions and hence are included in the database.[14] Consequently, the number of nanoparticles should be seen as a lower bound. It is widely expected that the number of nanomaterials in production will grow rapidly over the next decade.

In the United States, regulation of the risks associated with nanotechnology is primarily the responsibility of the Occupational Safety and Health Administration (OSHA) for occupational risks under the OSH Act. Yet, there are substantial limitations to the oversight capabilities of OSHA. A series of court rulings has resulted in the burden of health risk assessment for any substance being placed on the agency without the budgetary means to carry out the mandate.[15] This has led to a standard-setting process that is so slow that thousands of chemicals have no defined occupational exposure limits. It is predicted that any new nanomaterial would likely meet the same fate.[16] While it is well recognized that health risks from exposure to nanoparticles are poorly understood and need to be quantified,[17] nanomaterial production and use are effectively unregulated in the workplace and in the environment.[18]

This paper is part of a larger effort to evaluate oversight models for nanotechnology in several areas including gene therapy, drugs and devices, genetically engineered organisms, and chemicals in the workplace. In order to probe relationships between features of oversight systems and important outcomes of them in future work, we categorized criteria into four groups: (1) those associated with the initial development of the system (e.g., establishment of policies, procedures, or regulations); (2) the attributes of the system (e.g., how the system operates for particular processes or decisions); (3) the outcomes of the system (e.g., social, economic, cultural, health, environmental, and consumer impacts); (4) and the evolution of the system (e.g., changes to the development, attributes, or outcomes over time). A previous study developed a set of 28 criteria from an initial set of 66 criteria.[19] We employed several methods to devise these evaluative criteria, including review of the relevant literature, historical analysis, group consensus, and quantitative expert and stakeholder elicitation. Criteria were developed with consideration to law, economics, social science, ethical, health, and environmental implications. The Generic Expert Elicitation Survey used for all case studies is presented in Appendix A of Jordan Paradise et al.'s article in this symposium (hereinafter "Generic Survey"). This study's survey instrument is a minor variant of the Generic Survey. The purpose of this study is to assess the oversight system for chemicals in the workplace employing the previously developed a set of criteria. The eventual goal of this study is to use the lessons of this case study to inform the development of a robust oversight system for nanotechnology.

Methods

The Experts

A group of 27 experts was identified, consisting of representatives from industry, academia, and the highest levels of federal agencies (National Institute of Occupational Safety and Health and OSHA). Table 1 describes the characteristics of the experts. The academic experts were from the following backgrounds: occupational hygiene, health policy, occupational medicine, and risk assessment. Experts from industry were from medium and large companies. The third category included experts from state and federal occupational agencies. Since there was only one respondent from a labor union, this person was grouped with the government category.

The experts were selected using standard criteria to qualify as "experts," including substantive contributions to the scientific literature,[20] status in the scientific community, membership on editorial committees of key journals,[21] membership on advisory boards, and peer nomination.[22] By seeking out experts from academia, industry, government, and labor, we attempted to get a variety and balance of institutional perspectives, and also to minimize sample selection bias.

The experts were contacted by telephone, and the nature of the study and the reason for the expert elicitation were described. Respondents could submit completed surveys online, by fax, or by postal mail. Reminder emails were sent out over the course of four months. No incentive was offered to survey respondents. All surveys were accompanied by an informational sheet detailing the background of the project and an address to return the completed survey. The information sheet informed respondents that return of the completed survey implied consent for the data in it to be used for the project, resultant professional publications and conference presentations. All returned surveys were anonymous unless the participant chose to include personal details. Data collection began in November 2007 and ceased in February 2008.

The Survey

In order to evaluate relationships between features of the OSHA oversight system and important outcomes, we categorized criteria into three groups: (1) those associated with the initial development of the system (e.g., establishment of policies, procedures, or regulations); (2) the attributes of the system (e.g., how the system operates for particular processes or decisions); (3) and the outcomes of the system (e.g., social, economic, cultural, health, environmental, and consumer impacts). It is possible that criteria within and among categories might be correlated with each other. In later statistical analysis, the outcome variables are treated as dependent variables while the development and attribute criteria are treated as independent variables.

As previously described, a set of 28 criteria from an initial set of 66 criteria was developed and used for the survey.[23] The Generic Expert Elicitation Survey used for all case studies is presented in Appendix A of Jordan Paradise et al.'s article symposium. The survey questionnaire to evaluate oversight systems is based, in part, upon multi-criteria decision analysis (MCDA) described by Belton and Stewart as "an umbrella term to describe a collection of formal approaches, which seek to take explicit account of multiple criteria in helping individuals or groups explore decisions that matter."[24] MCDA has inherent properties that make it appealing and pragmatic: (1) it seeks to take explicit account of multiple, conflicting criteria; (2) it helps to structure the management problem; (3) it provides a model that can serve as a focus for discussion; and (4) it offers a process that leads to rational, justifiable, and explainable decisions.[25] MCDA has been used recently to evaluate strategies for risk management (e.g., remediating environmental hazards such as oil spills).[26] We used MCDA to develop the criteria that the experts evaluated in the questionnaire.

For the elicitation, we asked each expert to evaluate the oversight system in terms of each criterion. The members were asked to rank how the oversight system for workplace chemicals performed, on a scale from 0 to 100 with the option of referring to qualitative descriptions of different probability levels. These levels included Certain (100); Near Certain (80-99); Probable, Likely, We Believe (60-80); Even Chance (40-60); Less than an Even Chance (20-40); Improbably, Probably Not, Unlikely, Near Impossibility (1-20); and Impossible (0).

Statistical Analysis

The quantitative data retrieved from the survey were entered in Microsoft Excel. The analysis of expert scores for the criteria was performed using correlation analysis (SAS : PROC CORR), univariate analysis (SAS : PROC NPAR1WAY : Mann-Whitney-Wilcoxon/ Kruskall-Wallis), Common Factor Analysis (PROC FACTOR), and linear least square regression (PROC REG). Statistical analysis was performed using SAS v.9.1 (SAS Institute, Cary NC, 2002).

We used the Kruskall-Wallis test to compare the three groups: academia, industry, and government/ labor. If a significant difference was detected with Kruskall-Wallis test, pairs of groups were then compared using the Bonferroni (Dunn) t-tests. Common Factor Analysis was employed to describe the interrelationships between multiple variables. This is a multivariable analytic technique that uses existing variables to create a new set of variables called "factors."[27] The extent of variation between variables in each factor is expressed by eigenvalues. If there is a strong relationship between variables, the first few factors explain a high proportion of the total variance and the last few factors contain very little additional information.[28] Because of the small subject to item ratio (*N:p*), we imposed a conservative criterion of retaining only criteria with loading above 0.50 or below -0.50. "PROC FACTOR" procedure with orthogonal "VARIMAX" rotation was used for subsequent factor analysis. Components with eigenvalues less than one account for less variance than the original variable, and so are of little use. Hence, only components with eigenvalues greater than 1.0 were included. As shown below, it seemed appropriate to extract four factors in the present study. The factor analysis model is:

$$z_j = a_{j1}F_1 + a_{j2}F_2 + \cdots + a_{jn}F_m + u_j$$

where z_j is the jth original variable, j=1,...p, p is the number of original variables, a_{j1}, a_{j2}..., a_{jn} are factor loadings, F_1, F_2,..., F_m are the new factors, n the number of factors, and u_j the residual error related to z_j. For the analysis, we reduced the number of criteria from 21 to 13 because we have a small sample size that does not allow this study to contain many variables. To determine the number of latent factors, we used both Kaiser criterion (Eigenvalue >1) (Kaiser, 1960) and scree-plot test.[29] Finally, F_m retained factors were subjected to linear least square regression in order to determine any significant association ($p < 0.05$, 2-tailed) with each of the four outcome variables.

Results

The response rate achieved by this survey was 74 percent (20 out of 27). Figure 1 summarizes the respondent information. There was no discernable difference between respondents and non-respondents with respect to the profession and institution. Institutions of the respondents are evenly distributed. For further statistical analysis, we combined the consultants and industry experts. Likewise, the experts from government (state and federal) and labor groups were combined into one category. Education levels of the respondents in the survey in all categories are uniformly high.

Figure 1

Characteristics of Experts (n=20)	No. (%)
Profession / Expertise	12
Science	5
Public Policy	4
Industrial Hygiene / Occupational Hygiene	3
Public Health / Epidemiology	3
Medicine	1
Bioethics	2
Toxicology	1
Institution	
Academic	5 (25%)
Industry	7 (35%)
Government	7 (35%)
Labor	1 (5%)
Education	
Bachelor	1 (5%)
Master	4 (20%)
Doctorate	15 (75%)

Variability in Scores of Criteria

Figure 2 summarizes the responses to the questions, which scored the experts' beliefs regarding the performance of the OSHA chemical oversight system in the United States with respect to each criterion on a scale of 0-100.

We examined the degree of dispersion in terms of standard deviation and inter-quartile range (75th-25th percentiles). There is significant variability among respondents' judgments for most criteria. The average standard deviation of the 25 criteria is 24.4 and the average inter-quartile range is 35.6. Overall, high variability of expert opinions is seen for the following criteria: clarity of technological subject matter (D2) (s.d. = 28.4), informed consent (A20) (s.d. = 28.7), and legal grounding (D4) (s.d. = 29.0). Ecological impact (O25) (75th-25th=50), empirical basis (D5) (75th-25th=50), treatment of intellectual property (A14) (75th-25th=50), and public input (A17) (75th-25th=50) showed wide inter-quartile ranges. Among these criteria, experts believed that legal cases were most influential in affecting the shape of the oversight framework (average = 63.3). Informed consent (A20), ecological impact (O25), and treatment of intellectual property (A14) were ranked relatively low by experts with large dispersion.

Figure 2 can be used to examine criteria that are scored high or low, that may indicate success or failure of the oversight system. While these cut-offs are necessarily arbitrary, we assumed that scores above 60 were high (i.e., success), scores between 50 and 60 were moderate, and scores below 50 were low. Based on mean scores, 17 out of 25 (68 percent) criteria had a score below 50, which implies a negative perception of the performance of the workplace chemicals oversight system for most criteria. Since this category was so large, we selected a smaller subset of these, i.e., scores less than 40, as "failures" on which to focus our discussion. Of the 17 criteria, 10 were scored below 40 and seven were scored between 40 and 50.

Experts believed that the influence of lawsuits to shape the initial development of the oversight system for chemicals in the workplace was strong (D4, mean=63.3). The experts also agreed that there is little ambiguity about what the agencies can or cannot do (A8, mean=63.7). In addition, empirical basis for both development and attributes (D5, mean = 55.0; A9, mean = 57.6), and public input for the attributes (A17, mean = 54.5) were considered to be moderate. With regard to the outcome criteria, while research and innovation (O23, mean = 52.3) was considered to be moderate, the other outcome criteria, public confidence (O22, mean=40.5), health and safety (O24,

Figure 2

Summary of Responses to Survey Questions by All Respondents and by Expert Group (Academia N=7, Industry N=7, Government N=6)

Category		Questions	N	Mean	Std Dev	Percentile			*Academy*			*Industry*			*Government*		
						25th	75th	75th-25th	Mean	Std Dev	75th-25th	Mean	Std Dev	75th-25th	Mean	Std Dev	75th-25th
Development	D1	D-Impetus	20	26.3	20.2	12.5	32.5	20	24.3	16.4	25	28.6	28.9	20	25.9	14.3	15
	D2	D-Clarity of technological subject matter	17	50.3	28.4	20	75	55	58.6	23.9	35	51.3	37.1	57.5	40	28.9	50
	D3	D-Public input	20	43.2	19.6	35	50	15	41.1	14.2	15	50.4	24.1	17	37.2	19.9	28
	D4	D-Legal case	20	63.3	29.0	47.5	80	32.5	82.9	9.1	15	63.6	23.8	35	40	35.2	70
	D5	D-Empirical basis	20	55.0	26.8	30	80	50	50	25.2	40	66	27.6	30	48.3	28.4	55
	D6	D-Transparency	20	44.3	26.6	20	67.5	47.5	40.7	23.9	45	58.6	28.5	50	31.7	23.2	30
	D7	D-Financial Resources	17	29.8	23.1	10	50	40	22.9	17	30	41.8	31.9	51.5	30	23.7	50
Attributes	A8	A-Legal grounding	20	63.7	22.4	50	85	35	61.1	21.2	25	67.9	20.8	30	61.7	28.4	55
	A9	A-Empirical basis	20	57.6	26.3	45	75	30	61.4	24.6	25	63.9	29.3	25	45.8	24.9	35
	A10	A-Data requirements and stringency	19	36.9	18.2	22	50	28	38.3	18.9	16	43.3	14.5	28	28.2	20.7	37
	A11	A-Treatment of uncertainty	19	40.5	23.7	20	50	30	47.5	16.7	20	45	30.8	60	28.3	18.3	20
	A12	A-Compliance and enforcement	20	38.8	24.8	20	50	30	41.4	25.4	50	49.3	26.5	50	23.3	16.3	30
	A13	A-Incentives	20	33.0	22.5	10	46.5	36.5	21.3	24.6	32	45.1	23.1	38	32.3	12.6	15
	A14	A-Treatment of intellectual property	19	44.7	26.9	20	70	50	51.7	33.1	60	47.9	28.6	50	34.2	18	30
	A15	A-Flexibility	20	31.0	21.9	20	45	25	16.4	8.52	10	42.9	27.9	50	34.2	16.9	30
	A16	A-Capacity	20	24.1	21.8	10	40	30	6.42	4.8	10	42.9	22.1	40	22.7	16.3	30
	A17	A-Public input	20	54.5	27.2	30	80	50	65.7	29.4	50	47.9	23.2	50	49.2	29.4	50
	A18	A-Transparency	19	39.2	24.6	20	63	43	38.7	21.9	37	42.8	27.7	47	36	28.4	43
	A19	A-Conflict of interest	18	51.2	28.1	30	70	40	48.3	25.6	40	63.7	18.4	15	37	38.7	55
	A20	A-Informed consent	19	32.4	28.7	10	55	45	20	17.6	10	45	38.8	70	30	26.6	50
	A21	A-Post marketing	15	24.8	24.5	10	35	25	16.2	11.1	10	34	40	57	25.8	22	40
Outcomes	O22	O-Public confidence	20	40.5	19.2	25	54	29	32.9	14.9	30	50.9	18.9	30	37.2	21.3	43
	O23	O-Research and innovation	20	52.3	24.7	45	67.5	22.5	44.3	28.2	30	60.7	21.7	20	51.7	24.8	30
	O24	O-Health and safety	19	42.9	22.8	30	60	30	36.3	18.9	20	48.3	19.9	33	43.2	30.7	61
	O25	O-Ecological impact	18	41.3	26.8	10	60	50	21.7	16.3	30	52.1	14.9	10	38.8	38.8	71
		Mean		42.4	24.4			35.6	39.6	19.7	28.4	50.2	26.0	38.6	36.5	24.3	40.9
		Median		41.3	24.6			32.5	40.7	18.9	30.0	48.3	26.5	38.0	36.0	23.7	40.0

mean = 42.9), and ecological impact (O25, mean = 41.3), were considered to be somewhat low, i.e., negative impacts.

Agreement among Experts

A high degree of consensus of expert opinion, measured by standard deviation, was found for the following criteria: data requirement and stringency (A10), public confidence (O22), public input (D3), and impetus (D1). In addition to these four criteria, research and innovation (O23) and post-marketing review (A21) showed narrow inter-quartile ranges. Notably, except for the research and innovation criterion (O23), all of the outcome criteria were scored low.

In Figure 2, the average standard deviations of the responses for different types of experts are 19.7 for respondents from academia, 26.0 from industry, and 24.3 from government and labor. The academia group showed an overall higher level of consensus than the other two groups. Specifically, the academia group showed a considerable level of agreement in terms of capacity (A16), flexibility (A15), legal grounding (D4), and post-marketing (A21), while showing high levels of disagreement in terms of treatment of intellectual property (A14), public input (A17), research and innovation (O23), and conflict of interest (A19). The industry group in our sample showed a high level of agreement in terms of data requirement and stringency (A10), ecological impact (O25), and attention to conflict of interest (A19), but low levels of consensus in terms of informed consent (A20), clarity of technological subject matter (D2), financial resources (D7), and treatment of uncertainty (A11). Finally, the government/labor group showed high levels of agreement in terms of incentive (A13), impetus (D1), compliance and enforcement (A12), and capacity (A16), but low levels of consensus in terms of ecological impact (O25), attention to conflict of interest (A19), and legal grounding (D4). Notably, capacity (A16) had high agreement from both the academic group and government/labor group, whereas the industry group showed somewhat low level of consensus with moderate average scores.

Figure 3 shows the results of Kruskal-Wallis tests for significant differences in score between the three types of expert groups in our sample. There was a statistical difference between the three groups for the following three criteria: capacity (p = 0.007), flexibility (p = 0.05), and ecological impact (p = 0.05). The mean scores for all three criteria were higher in the respondents from industry than for those from academia (p < 0.05) (Bonferroni t-tests). The mean score for flexibility was higher in the respondents from industry than for those from academia (p > 0.10) (Bonferroni t-tests). Interestingly, the mean score for the ecological impact was also higher in the respondents from industry than for those from their academic counterparts (p > 0.10) (Bonferroni t-tests).

Figure 3

Results of Kruskal-Wallis Test for Significant Differences between Academia, Industry, and Government/Labor Experts for Each Criterion

Variable	Variable Description	χ^2	DF	Pr
d1	D-Impetus	0.048	2	0.98
d2	D-Clarity of technological subject matter	1.35	2	0.51
d3	D-Public input	2.42	2	0.30
d4	D-Legal case	5.35	2	0.70
d5	D-Empirical basis	1.83	2	0.40
d6	D-Transparency	25.63	2	0.27
d7	D-Financial Resources	1.49	2	0.48
a8	A-Legal grounding	0.41	2	0.81
a9	A-Empirical basis	2.41	2	0.30
a10	A-Data requirements and stringency	1.68	2	0.43
a11	A-Treatment of uncertainty	2.5	2	0.29
a12	A-Compliance and enforcement	3.78	2	0.15
a13	A-Incentives	3.63	2	0.16
a14	A-Treatment of intellectual property	0.99	2	0.61
a15	A-Flexibility	5.82	2	**0.05** *
a16	A-Capacity	10.1	2	**0.007** ***
a17	A-Public input	1.85	2	0.40
a18	A-Transparency	0.3	2	0.86
a19	A-Conflict of interest	2.03	2	0.36
a20	A-Informed consent	1.59	2	0.45
a21	A-Post marketing	0.39	2	0.82
o22	O-Public confidence	3.68	2	0.16
o23	O-Research and innovation	1.68	2	0.43
o24	O-Health and safety	0.78	2	0.68
o25	O-Ecological impact	5.93	2	**0.05** *

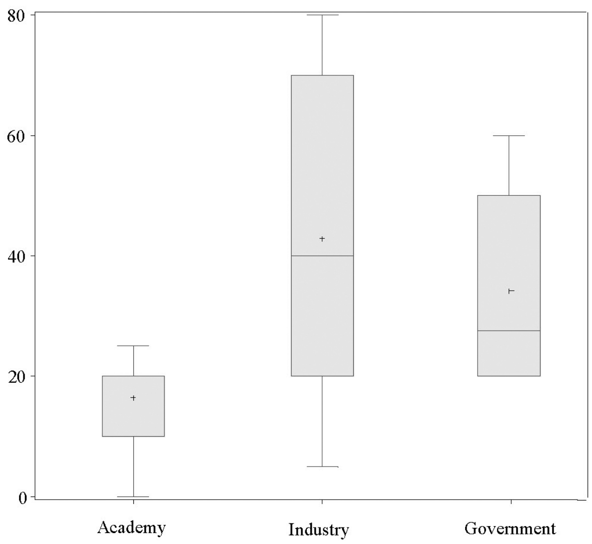
Exploratory Correlation Analysis

We performed an exploratory correlation analysis on the relationship between development, attribute, and outcome criteria (Figure 5). Not surprisingly, most criteria having a high degree of variability in expert opinion measured by standard deviation and inter-quartile range — e.g., clarity of technological subject matter (D2), legal grounding (D4), public input (A17), transparency (A18), and capacity (A16) — do not have statistically significant correlations with other cri-

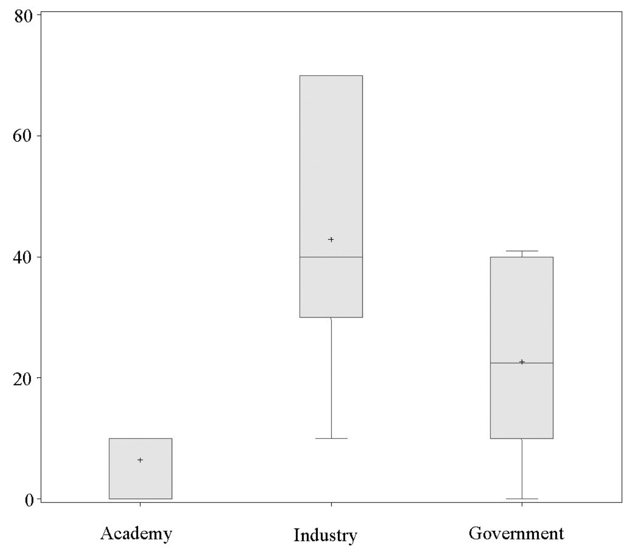
Figure 4

Mean Score of the Criteria That Showed Significant Differences between the Three Groups of Experts

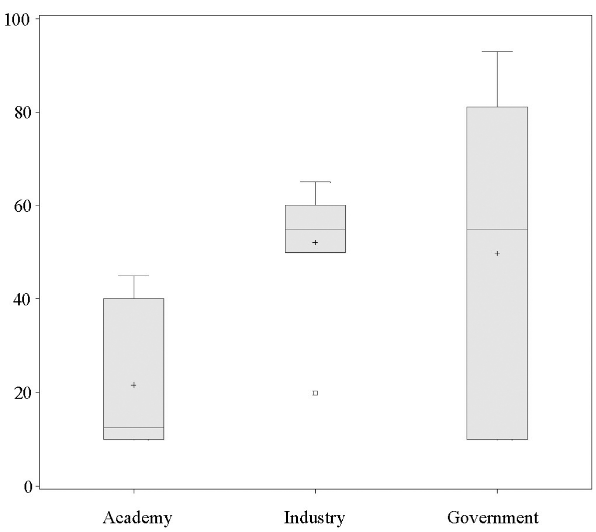
A15 = Flexibility [1]



A16 = Capacity [2]



O25 = Ecological Impact [3]



1. There was a significant difference between groups in the sample for the flexibility criterion (p = 0.05) (Kruskal-Wallis). The mean score was higher in the respondents from industry than those from academy (p > 0.10) (Bonferroni t-test).

2. There was difference between groups in the sample for the capacity criterion (p = 0.007) (Kruskal-Wallis). The mean score was higher in the respondents from industry than those from academy (p > 0.05) (Bonferroni t-test).

3. There was difference between groups in the sample for the ecological impact criterion (p = 0.05) (Kruskal-Wallis). The mean score was higher in the respondents from industry than those from academy (p > 0.10) (Bonferroni t-test).

teria, except for legal grounding (A8). The strongest correlations were seen between transparency (D6) and treatment of intellectual property (A14) (r = 0.80), public confidence (O22) and health and safety impact (O24) (r = 0.77), and public confidence (O22) and ecological impacts (O25) (r = 0.77). Considering the importance of the four outcome criteria as dependent variables, we probed development and attribute criteria that were significantly correlated with other criteria. Strong correlations were seen between research and innovation (O23) and post-marketing review (A21) (r = 0.76), and between health and safety impact (O24) and treatment of intellectual property (A14) (r = 0.71). Several weaker but still significant relationships were observed between public confidence (O22) and incentives (A13) (r = 0.62), flexibility (A15) (r = 0.65), informed consent (A20) (r = 0.64), and post-marketing review (A21) (r = 0.63). Health and safety impacts (O24) also had weaker relationships with public input (D3) (r = 0.61), transparency (D6) (r = 0.60), conflict of interest (A19) (r = 0.62), informed consent (A20) (r = 0.65), and post-marketing review (r = 0.72). Another interesting finding is that strong correlations were observed within the constellation of outcome criteria. For example, public confidence (O22) was correlated significantly with health and safety impact (O24) (r = 0.70) and with ecological impact (O25) (r = 0.77). In addition, health and safety impact (O24) was correlated significantly with ecological impact (O25) (r = 0.77).

Factor Analysis

We also performed factor analysis to identify the relationships between multiple criteria. Figure 6 presents the results of the factor analysis. Even though the Kaiser criterion (i.e., retain only factors with eigenvalues greater than one) suggested that four factors can be retained for this analysis, given the small sample size and scree-plot test, we conservatively retained only three factors. The first factor was formed by A-Flexibility, D-Impetus, A-Capacity, A-Incentives, and D-Public input (these had loadings >0.50) and 36 percent of the variance in the data seems to be explained by the first factor. The second factor was formed by A-Transparency, A-Public input, A-Legal Grounding, D-Transparency, and D-Empirical basis and 19 percent of the variance in the data can be explained by the second factor. The third factor was formed by A-Data requirements and stringency, A-Compliance and enforcement, and D-Legal grounding, and 13 percent of the variance in the data can be explained by the third factor. This model explains 70 percent of the total variance.

Linear least square regression was used to determine the association between four outcome criteria and the extracted factors (Figure 7). Only one of the retained factors showed a significant relationship ($p < 0.05$) with all outcome criteria in the multivariate assessment. Both factor-1 and factor-2 have statistically significant associations with outcome criteria of the public confidence ($p < 0.05$, respectively). Further, we found a marginally significant association of factor-1 with Research and Innovation ($p < 0.10$) and factor-1 and factor-2 with health and safety ($p < 0.10$),

Results from factor analysis are somewhat hard to interpret, and labeling the latent factors is also chal-

Figure 5

Pearson Correlation Coefficients between Pairs of Criteria

Only criteria with correlation coefficients greater than 0.6 and significance at the 0.0001 level are shown.

	d1	d2	d3	d4	d5	d6	d7	a8	a9	a10	a11	a12	a13	a14	a15	a16	a17	a18	a19	a20	a21	o22	o23	o24	o25	Variable Description
d1			○																							D-Impetus
d2																										D-Clarity of technological subject matter
d3							◙													○	○			○		D-Public input
d4																										D-Legal case
d5						◙	◙		◙		○							○								D-Empirical basis
d6											○	○		◙				◙	○	◙	○			○		D-Transparency
d7									○		◙		○							○	○					D-Financial Resources
a8																										A-Legal grounding
a9											◙										○					A-Empirical basis
a10												◙														A-Data requirements and stringency
a11																		◙			○					A-Treatment of uncertainty
a12													○	○						○						A-Compliance and enforcement
a13															○					◙		○				A-Incentives
a14																								◙		A-Treatment of intellectual property
a15																◙						○				A-Flexibility
a16																										A-Capacity
a17																										A-Public input
a18																										A-Transparency
a19																								○		A-Conflict of interest
a20																					◙	○		○		A-Informed consent
a21																						○	◙	○		A-Post marketing
o22																								◙	◙	O-Public confidence
o23																								○		O-Research and innovation
o24																									◙	O-Health and safety
o25																										O-Ecological impact

○: Criteria for which correlation estimate between criteria is greater of equal than 0.60

◙: Criteria for which correlation estimate between criteria is not only greater of equal than 0.60 but also statistically significant at the < 0.0001 level.

Figure 6

Results of Factor Analysis After "Varimax" Rotation

Only factors with eigenvalues > 1 are shown. The bold numbers represent the loadings of the retained criteria that are greater than 0.50.

Rotated Factor Pattern (Standardized Regression Coefficients)

Criteria	Factor1	Factor2	Factor3
A-Flexibility	**0.916**	-0.03	-0.195
D-Impetus	**0.794**	-0.064	0.026
A-Capacity	**0.748**	-0.167	-0.291
A-Incentives	**0.687**	0.145	0.252
D-Public input	**0.522**	0.203	0.344
A-Transparency	0.016	**0.943**	-0.283
A-Public input	-0.106	**0.822**	-0.002
A-Legal Grounding	-0.365	**0.79**	-0.118
D-Transparency	0.29	**0.735**	0.109
Empirical basis	0.218	**0.699**	0.192
A-Data requirements & stringency	-0.106	-0.267	**0.893**
A-Compliance & enforcement	0.344	0.04	**0.775**
D-Legal case	-0.534	0.0091	**0.689**
Eigenvalue	4.66	2.52	1.87
Cumulative proportion	0.36	0.55	0.7

lenging. Figure 8 summarizes the result of factor analysis and retained factor regression. Results from the retained factor regression indicate that development and attribute criteria in our study may be determinants of outcome criteria. We believe the regulatory adequacy is clearly dependent on the outcome criteria — public confidence, research and innovation, and health and safety, and the set of outcome criteria in the study are proxies for a good regulatory framework.

Discussion

The most striking finding is that experts in our sample tend to believe that the current oversight system for chemicals in the workplace is neither adequate nor effective. About 17 (or 70 percent) of the 25 criteria were scored below 50 out of 100. The mean score of the 25 criteria across all experts is 42.4 and median is 41.3 out of 100.

It is very likely that the performance of the OSHA oversight system for nanomaterials will be equally inadequate. It is therefore important to consider alternative approaches that may show better performance in terms of the efficiency (using least resources) and effectiveness (extent of coverage of new nanomaterials) of producing information essential for risk assessment.

The questionnaire was designed such that, in most but not all instances, a higher score corresponds to a normatively better attribute or outcome. However, in some cases a lower score is better. While none of the criteria were scored above 70 out of 100, most criteria (17 out of 25) were scored below 50 out of 100. For more in-depth discussion of the results, we chose the "strengths" and "weaknesses" based upon the mean scores for each criterion, where means >60 out of 100 (n = 3) were labeled as strengths and means <40 (n = 11) were categorized as weaknesses. In addition, given the importance of the outcome criteria, we also conducted a comprehensive literature review of the criteria. We summarize below the strengths and weaknesses of the oversight system for the chemicals in the workplace, based on the mean scores for each criterion. Many of these are specifically discussed in subsequent sections.

Strengths of the Oversight System for Chemicals in the Workplaces:

1. the clarity of the statutes or rules for implementing the specific decisions within the oversight framework and achieving its goals (Legal grounding–A8); and
2. the amount and quality of evidence used for particular approvals (Empirical basis–A9).

Weaknesses of the Oversight System for Chemicals in the Workplaces:

1. the reactive development of the oversight system (Impetus–D1);
2. lack of flexibility in unique or urgent situations (Flexibility–A15);
3. inadequate financial resources in the development of the oversight system (Financial Resources–D7) and inadequate resources, including expertise, personnel, or financial, to appropriately handle decisions (Capacity–A16);
4. inadequate incentive for compliance with system requirements (Incentives–A13);
5. minimal data requirements on health effects from companies. (Data requirements and stringency–A10). Insufficient compliance and enforcement. (Compliance and enforcement–A12);
6. lack of transparency as an attribute of the system. (Transparency–A18); and
7. the oversight system has a moderately low impact on worker health and safety (Health and Safety–O24).

Figure 7
Results of Retained Factors Regression
The independent variables are the three factors determined by factor analysis, and the dependent variables are the four outcome variables.

Variable	Parameter Estimate (SE),	p Value
	Public Confidence (N=19)	
Intercept	41.63 (3.2)	0.00
Factor 1	8.89 (3.49)	0.02
Factor 2	8.43 (3.51)	0.03
Factor 3	0.75 (3.53)	0.84
	Research and Innovation (N=19)	
Intercept	53.42 (5.29)	0.00
Factor 1	10.82 (5.78)	0.08
Factor 2	6.54 (5.82)	0.28
Factor 3	-4.17 (5.84)	0.49
	Health and Safety Impact (N=18)	
Intercept	43.67 (4.5)	0.00
Factor 1	8.89 (3.49)	0.11
Factor 2	10.25 (3.51)	0.08
Factor 3	-0.10 (3.53)	0.98
	Ecological Impact (N=17)	
Intercept	42.62 (6.05)	0.00
Factor 1	11.9 (6.27)	0.08
Factor 2	7.02 (6.49)	0.30
Factor 3	-6.85 (6.30)	0.30

The following sections discuss selected results from the analysis of expert opinion in terms of past studies in the peer-reviewed literature.

Impetus (D1)
This criterion addresses whether the reasons for developing the original framework for the oversight system were proactive (continuous rating scale: 0=reactive, 100=proactive). Experts believed that the reasons for developing the system were reactive with considerable consensus (mean = 26.3). After a series of environmental and occupational tragedies such as the mine explosion in Farmington and the explosion of an oil rig off the Santa Barbara coast in 1968, environment protection and occupational safety rose to the top of the domestic policy agenda. The OSH Act was passed in 1970 with the objective of protecting workers' health in occupational settings.[30] During congressional hearings on the bill leading to the act, it was noted that 14,500 persons were killed each year from industrial accidents and during the four years prior to the act, meaning that more Americans were killed on the job than in the Vietnam War.[31]

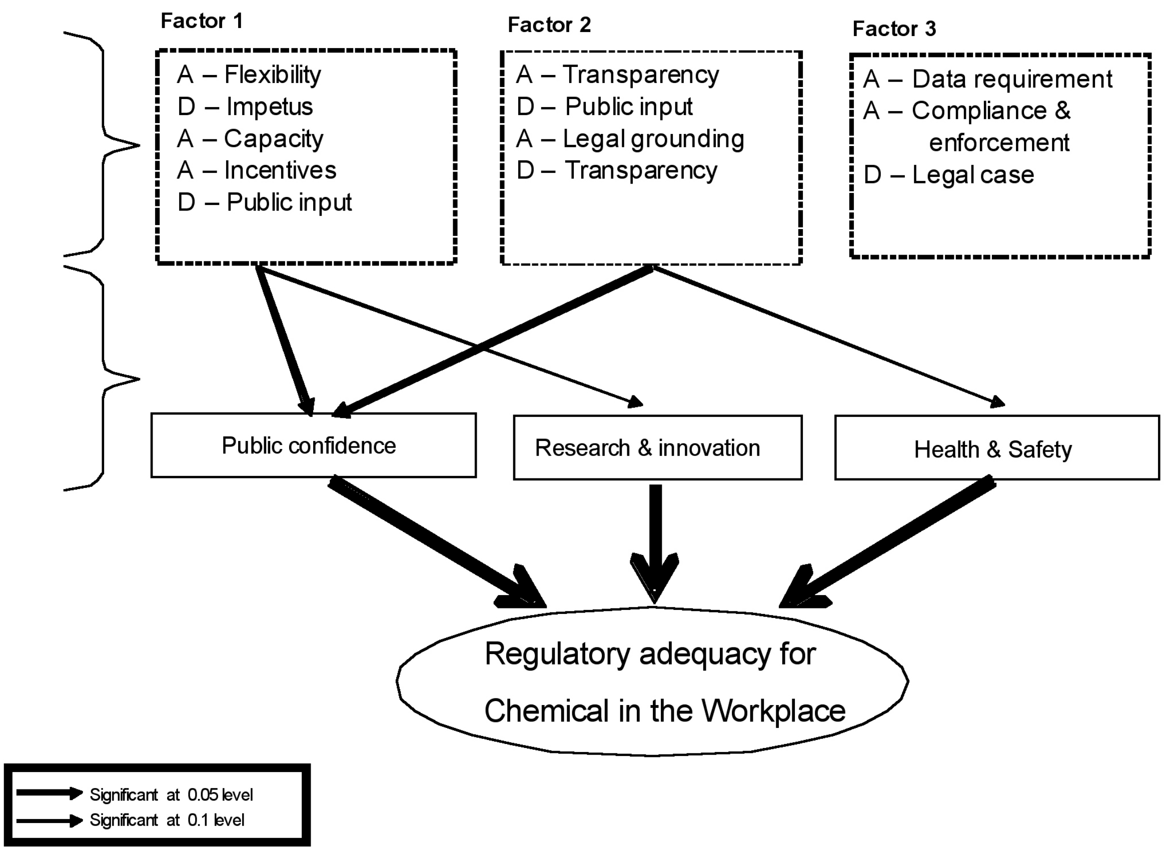
Flexibility (A15)
This criterion related to whether the system had the flexibility in unique or urgent situations or when new information came to light (continuous rating scale: 0=low, 100=high). Experts assigned a low average score to this attribute (mean=31). Their response is consistent with much of the literature. It is often argued that OSHA inspectors are constrained to go "by the book," with limited flexibility to tackle safety problems not explicitly covered in regulations.[32] For example, even though there is compelling scientific evidence linking occupational exposure to diacetyl with bronchiolitis obliterans – a rare, debilitating and sometimes fatal lung disease – OSHA officials have taken the position that hazards for which there is no applicable OSHA standard "do not fall within OSHA's jurisdiction."[33]

When faced with a hazard for which no standard has been set, OSHA has the authority, under Section 6(c) of the OSH Act, to issue an emergency temporary standard (ETS) if "employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards," and that "such emergency standard is necessary to protect employees from such danger." However, since its inception, OSHA has issued only nine emergency temporary standards under Section 6(c) of the OSH Act.[34] During the last two decades, OSHA has not issued any ETSs. Rather than setting ETSs, OSHA has proceeded directly to establishing permanent standards for toxic substances.

Capacity (A16)
This criterion was structured in terms of whether the OSHA oversight system has the expertise, personnel, or financial resources to appropriately handle decisions (continuous rating scale: 0=inadequate, 100=adequate). Experts gave this criterion the lowest score among all the criteria. They seem to consider it as the biggest failure of the oversight system (mean=24.1). It is important to note that, as discussed earlier, the mean score was higher in the experts from industry than those from academia ($p < 0.05$) (Bonferroni t-tests). This response is consistent with published literature.

The agency's actual budget totaled $485 million in FY 2007. However, inflation-adjusted budget has remained roughly constant until since FY 2000. Since then OSHA's inflation-adjusted budget has been cut every year. In terms of staffing, FTEs have declined gradually since 2001. For FY 2007, OSHA had a staff of only 2,092. This is approximately 240 fewer FTEs

Figure 8
Scheme of Regulatory Adequacy Based on Factor Analysis and Regression



than in 2001, almost 820 fewer than in 1980, and 270 fewer than in 1975.

Furthermore, establishments covered per OSHA FTE more than doubled between 1975 (1,621) and 2007 (3,882), and employees covered per OSHA FTE have more than doubled between 1975 (59,589) and 2007 (27,845). OSHA's actual budget rose 65.8 percent between 1990 and 2002, but this is far lower than the 92.3 percent average growth in discretionary spending by all non-defense agencies.[35] Judging from the experts' perception of capacity, the capacity of the OSHA oversight system to fulfill its mission has been questionable for some time.

Incentives (A13)
This criterion was structured in terms of whether the oversight system provides the incentives for compliance with requirements (continuous rating scale: 0=few, 100=many). Experts believed that the system provided limited incentives (mean=33.3). Shapiro and Rabinowitz noted that OSHA enforcement creates fewer incentives for compliance than enforcement by other agencies for two reasons.[36] First, OSHA is less likely to detect rule violations than other agencies because it has fewer inspectors. The Mine Safety and Health Administration (MSHA), for example, has jurisdiction over even fewer employers than OSHA, but it has about two hundred more inspectors than OSHA. Given the status of OSHA's current capacity, it would take OSHA 133 years to inspect each workplace once.[37] Second, after OSHA detects violations, it is more limited than other agencies in its ability to assess large fines. Obviously, both reasons are directly related with the capacity we discussed above. Company size seems to be related to the level of compliance. Seligman et al. found that OSHA recordkeeping was the worst for small firms (11-99 employees) and best for large firms (500+ employees).[38] Shapiro and Rabinowitz explain the relationship between company size and regulatory compliance as follows:

> The incentives identified are stronger for large firms and may not exist for small business. First, smaller business lacks the economies of scale available to large firms in the use of abatement technologies. Since the likelihood that a firm will

undertake abatement is a function of its abatement costs, higher compliance costs make it less likely that small firms will take preventative actions. Second, workers compensation premiums for small employers are not experience rated because they have too few employees. Third, small firms are less likely to act virtuously in response to social attitudes than larger companies because they are in a weaker business position. Finally, small firms may lack resources to employ professionals who may have internalized safety norms.[39]

Data Requirements and Stringency (A10) / Compliance and Enforcement (A12)

The criterion "A10-Data requirements and stringency" addresses whether programs and procedures are in place to ensure compliance with the oversight process and in the cases where there is a lack of compliance, whether there are consequences and corrections (continuous rating scale: 0=weak 100=strong). The criterion "A12-Compliance and enforcement" addresses whether empirical studies desired by the overseers are submitted to them and whether there is adequate authority for action in the case of noncompliance. Experts believed that data requirements and stringency are minimal, with the greatest consensus measured by standard deviation among criteria (mean=36.9, standard deviation=18.2). For criteria of compliance and enforcement, our experts also believed that there is little compliance or enforcement (mean=38.8, standard deviation=24.8). A wealth of empirical studies show links between OSHA enforcement and compliance.[40] Using data from 1973 to 1983, Viscusi found that OSHA inspections significantly reduce injuries.[41] Using 77 sources of Biological Oxygen Demand (BOD) from EPA Permit Compliance System (PCS) database, Magat and Viscusi found that inspections and enforcement actions have a strong effect on both pollution levels and rate of compliance with the permit levels.[42] Using data from individual steel plants, Gray and Deily found greater enforcement leads to greater compliance.[43] LaPlante and Rilstone also found that both inspections and the threat (perceived probability) of an inspection have a strong deterrent effect on pollution emissions.[44] Using the OSHA Integrated Management Information System covering 1980-1989, a recent study by Deily and Gray also found that steel plant-level compliance is affected by enforcement pressure.[45] Further, the study found that recent enforcement pressure is associated with greater current compliance.

One of the ways OSHA enforces safety in workplaces is by "establishing requirements for injury and illness recordkeeping by employers, and for employer monitoring of certain occupational illnesses."[46] However, empirical research by Seligman et al. and Leigh, Marcin, and Miller found that a substantial proportion of employers do not maintain OSHA 200 logs (currently OSHA 300 logs).[47] Further, when OSHA discovers a violation, it often settles it for only a small fraction of the assessed amount.[48] For example, two striking citations of 1986, against the Union Carbide Corporation for $1.37 million and Chrysler for $910,000, were settled for less than a third of the original amounts.[49] Given consistency in the literature over the data requirements and stringency, and compliance and enforcement, the judgments of our expert panel seem reasonable.

Transparency (A18)

This criterion addressed whether interested parties can obtain information about decisions that are being made within the oversight framework (continuous rating scale: 0=low, 100=high). Experts responded that the system has a moderate problem with transparency (mean=39.2). Some commentary argues that OSHA struggles with transparency in how it conducts risk assessments for hazardous chemicals.[50] However, Seminario notes that "OSHA's standard setting process is open and accessible and provides many opportunities for involvement by all interested parties."[51] Furthermore, she noted that the OSHA standards development process is one of the most open and accessible processes in the federal government." In fact, during its 37-year history, OSHA has completed only 31 toxic materials.[52] In the last 10 years, OSHA has only set one standard for a (hexavalent chromium [Cr VI]). A recent debate on use of non-consensus standards for workplace health and safety was centered on transparency. Some argued that the transparency in the rulemaking process is not ensured in that standard-setting bodies do not allow for stakeholder input. Some have criticized that "the OSH Act and other federal laws encourage agencies to use consensus standards, but unfortunately do not expressly prohibit their use of non-consensus organizations (NCOs) that, like, ACGIH, adopt standards under a veil of secrecy."[53] Section 3(9) of the OSH Act defines the term "national consensus standard" as any occupational safety and health standard or modification thereof which (1) has been adopted and promulgated by a nationally recognized standards-producing organization under procedures whereby it can be determined by the Secretary that persons interested and affected by the scope or provisions of the standard have reached substantial agreement on its adoption; (2) was formulated in a manner which afforded an opportunity for diverse views to be considered; and (3) has been designated as such a standard by the Secretary, after consultation with other appropriate federal agencies.

Morris argues that "the problem is not that private organizations like ACGIH produce standards but that those standards sometimes become ossified through their adoption by government agencies, limiting the incentive to produce competing standards that could develop new solutions."[54] Given the controversy over the issue of transparency, the response from he expert panel seems reasonable.

Public Confidence (O22)

This criterion addressed whether there is general public confidence in the OSHA oversight system (continuous rating scale: 0=low, 100=high). Experts agreed that the level of public confidence in the oversight system is moderately low (mean=40.5). This criterion had one of the lowest standard deviations among the criteria, which means a high degree of consensus (standard deviation =19.2). To the best of our knowledge, studies regarding public confidence in the oversight system for chemical in the workplace are not available in the peer-reviewed literature. However, a recent study by Macoubrie is suggestive.[55] The study evaluated whether low trust in government to manage nanotechnology-related risks is related to any of the following political entities and regulatory agencies: the Food and Drug Administration, Occupational Health and Safety Administration, Centers for Disease Control, Consumer Product Safety Commission, Environmental Protection Agency, United States Department of Agriculture, Congress, and the White House. While 40 percent of the respondents disagreed or strongly disagreed that OSHA could effectively manage the risks, 46 percent of them agreed or strongly agreed with the proposition. Not surprisingly, Congress and the White House received the highest level of distrust at 63 percent and 56 percent, respectively. Macoubrie suggests that trust in regulatory agencies may be a sign of past history with the agencies.[56] Though the findings of the study cannot directly be compared with our study, the level of the public confidence assessed in both studies appears similar.

Health and Safety (O24)

This criterion assesses whether the oversight system leads to beneficial impacts on workers' and the public's health and safety (continuous rating scale: 0=negative, 100=positive). Experts judged the impact of the oversight system on health and safety impact to be moderately low (mean=42.9). Many empirical studies have examined the impact of OSHA on health and safety, largely focusing on the inspections and enforcement. In 2000, OSHA reported that "workplace injury and illness rates declined for the seventh straight year-nearly a 30 percent drop since 1992."[57] Furthermore, the Survey of Occupational Injuries (SOI) shows that injuries have gradually declined in the United States since the early 1990s.[58] However, Friedman and Forst found that 83 percent of the reported decrease in occupational injuries and illnesses in the U.S. from 1992 to 2003 was attributed to the change in OSHA recordkeeping rules and only 17 percent was attributed to an actual decrease in morbidity.[59] A recent work by Gray and Mendeloff studied the effects of OSHA inspections on manufacturing injuries from 1979 to 1998. They found that OSHA inspections imposing penalties reduced lost-workday injuries by 19 percent from 1979 to 1985. However, this effect fell to 11 percent from 1987 to 1991 and to a statistically insignificant one percent between 1992 and 1998.[60] The authors concluded that OSHA inspections do not seem to affect restricted work activity injuries. Another study found that enforcement inspections are significantly associated with decreasing compensable workers compensation claims rate.[61]

Earlier studies have shown somewhat inconsistent findings. An industrial-level work by Mendeloff found that only 19 percent of workplace injuries could have been prevented by a fully effective government safety program.[62] Bartel and Thomas similarly found that if all firms moved into complete compliance, then injury rates would fall only by 9.8 percent.[63] However, studies by Viscusi,[64] Smith,[65] McCaffery,[66] and Ruser and Smith[67] found little evidence of an effect of OSHA on injury rates.

Though it is true that OSHA has been successful in reducing exposure to widely recognized chemical hazards and has unquestionably saved thousand of lives, there are huge gaps in OSHA standards that play a pivotal role in ensuring workers' health and safety. There are OSHA standards for fewer than 193, or approximately 7 percent, of the approximately 2,943 chemicals characterized by the EPA as High Production Volume. OSHA currently enforces permissible exposure limits for only about 500 chemicals, and even these limits are mostly outdated.[68] Shapiro and McGarity noted that "OSHA has either no worker protection standards or inadequate standards for more than one-half of the 110 chemicals used in work places that the National Cancer Institute (NCI) regards as confirmed or suspected carcinogens."[69]

The Center for Occupational and Environmental Health, University of California, reported that in 2004, more than 208,000 California workers were diagnosed with fatal, preventable chronic diseases — such as cancer, chronic obstructive pulmonary disease (COPD), asthma, and pneumoconiosis — that were attributable to chemical exposures in the workplace.[70] An additional 4,400 died as a consequence of those diseases in 2004. The authors noted that occupational diseases resulting from chemical exposures are highly preventable. Though the report has limited external validity, we may cautiously extrapolate the results to estimate states-wide burden of occupational diseases resulting from chemical exposures from the study. Given the somewhat negative impact of the oversight system on workers' health and safety and actual burden of occupational disease, the experts' opinion on this criterion seems reasonable.

We interpreted the survey results with great caution and avoided reaching decisive conclusions from statistical results. Instead, we believe this study presents several methodological directions for future studies.

Research and Innovation (O25)
This criterion addresses whether the oversight system has encouraged more research and innovation (continuous rating scale: 0=negative, 100=positive). Experts believed that the extent to which the system has led to more research and innovation is moderate (mean=52.3). Although there is a wealth of prior literature on the influence of environmental regulation on technological innovation, few studies have examined the impact of the occupational health and safety regulation on research and technological innovation.

Conclusions

Limitations of the Study
Before discussing the conclusions of this study, it is appropriate to acknowledge the limitations of the study. A limitation of this study was its small sample size (n=20). Of those 20 respondents, not all answered every question. Our sample was non-randomly selected, which could have caused an unknown amount of selection bias. For those reasons, we interpreted the survey results with great caution and avoided reaching decisive conclusions from statistical results. Instead, we believe this study presents several methodological directions for future studies.

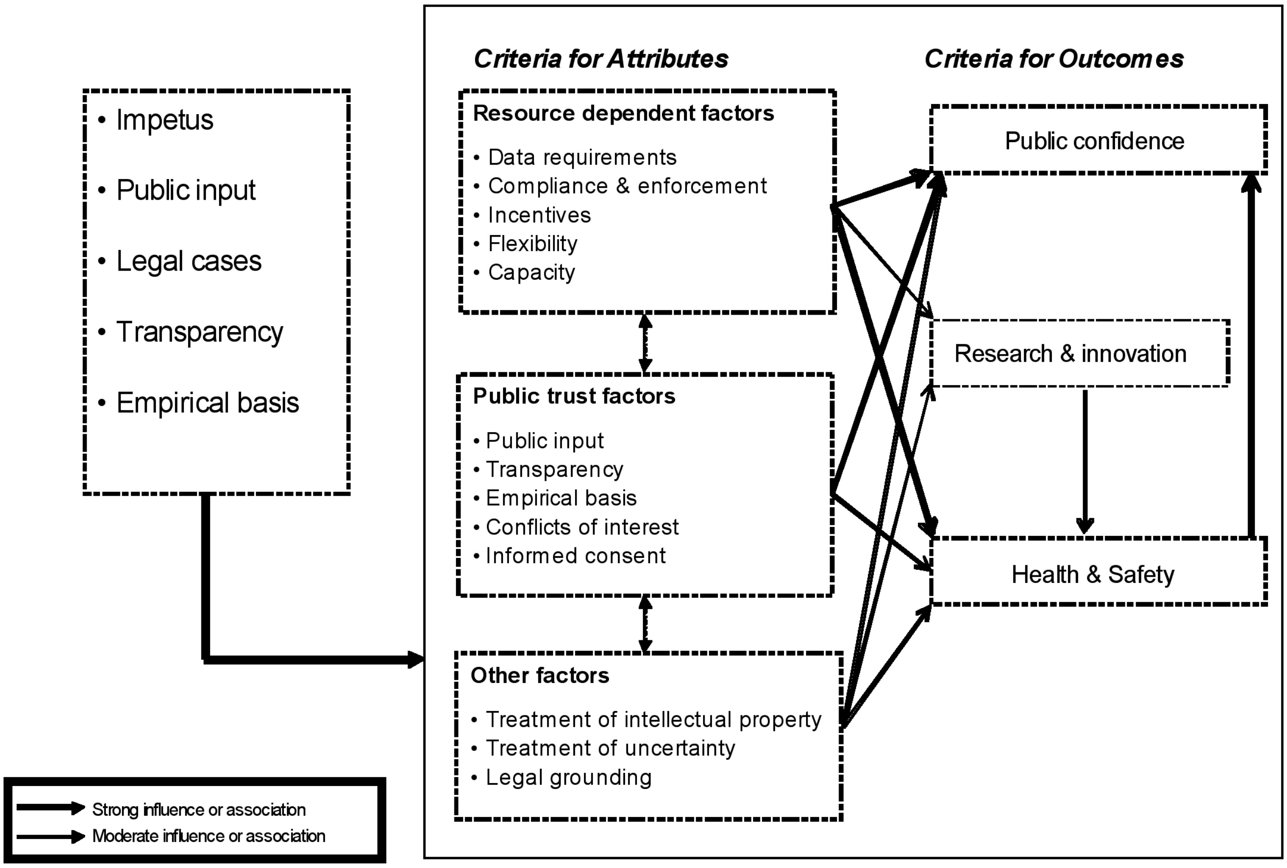
Our findings, particularly from factor analysis and attained factor regression, should be interpreted with caution. It may be possible that some experts might have assigned a score of 50 out of 100 for a particular question (i.e., regressed to the mean) when they did not have relevant knowledge or were not sure, rather than skipping the question. Furthermore, retained factor regression results may potentially contain several sources of bias such as omitted variable bias or simultaneous equation bias.

Another source of the limitation in the survey instrument is that it does not specify a time frame for the development of the oversight system. Thus, while some experts may consider the first 10 years from inception of OSHA as the development phase, others may have a smaller window. In addition to the development criteria, we defined the attribute categories as: "The attribute criteria apply to the process, whether formal or informal, of making decisions about specific chemicals, products or other specific ways in which the framework is implemented." Again, the interpretation of the time frame is subjective.

Lessons for Nanotechnology
There were significant systematic differences among the experts regarding the criteria. There was a statistical difference between the three groups for the criteria of capacity, flexibility, and ecological impact. This is, in part, because of heterogeneity in the group. The experts responded to each question from their own perspectives, reflecting their varied backgrounds. Among three groups of experts, the government/labor group had far more negative attitudes toward the oversight system than had the other two groups. The industry experts had generally more positive attitudes toward the oversight system than had the other two groups.

Based on the expert survey results, factor analysis, retained factor regression, and literature review, we developed an influence diagram. (See Figure 9.) The influence diagram may be viewed as a conceptual model that needs to be empirically tested by future studies. Criteria for development of the oversight system seem to have influenced the attribute and outcome criteria either directly or indirectly. Three general factors can be identified: resource-dependent attributes, public trust attributes, and other attributes. Most experts agreed that the oversight system does not have sufficient resources to appropriately achieve its mission. Lack of capacity may hinder providing incentives for compliance with regulations. We may postulate that lack of incentive is a product of enforcement and compliance, capacity, and data requirements and stringency. These attributes can be labeled as a group of resource-dependent factors. The resource-dependent factors have a strong influence on the outcome

Figure 9
Influence Diagram of Oversight System for Chemicals in the Workplaces



criteria of public confidence and health and safety, respectively. Results from factor analysis seem to support this postulation. "Public Trust" attributes consist of public input, transparency, empirical basis, conflict of interest, and informed consent. Arguably, a common theme of those criteria is the level of trust engendered by the regulatory system in the public. "Other factors" consists of treatment of intellectual property, treatment of uncertainty, and legal grounding. Though moderate, it may influence outcome criteria as well. Outcome criteria also interact with each other. Better workplace environments through research and innovation unquestionably benefit not only the employers but also employees' health and safety in the workplace. Health and safety of the employees directly influences public attitudes toward the regulatory system. We believe our hypothesized influence diagram will provide future studies useful hypotheses that are worth testing.

The most striking finding is that experts in our sample tend to believe that the current oversight system for chemicals in the workplace is not adequate and effective. About 17 (or 70 percent) of the 25 criteria were scored below 50 out of 100. The mean score of the 25 criteria across all experts is 42.4 and median is 41.3 out of 100.

It is, therefore, very likely that the performance of the OSHA oversight system for nanomaterials will be equally inadequate. It is important to consider alternative approaches that may show better performance in terms of the efficiency (using least resources) and effectiveness (extent of coverage of new nanomaterials) of producing information essential for risk assessment.

There are several alternative approaches that we draw on. Choi et al. have proposed an alternative oversight system drawing inspiration from the new REACH program recently promulgated in the European Union (EU) as well as Proposition 65 in the state of California.[71] This approach places the burden on *firms* to provide relevant exposure and toxicity information (like Proposition 65 does) while simultaneously using a tiered toxicity testing strategy to most efficiently and effectively use scarce resources (like REACH does). Tiered strategies begin with an initial screening tier comprised of relatively simple and inexpensive tests; the outcomes of simple tests are used to prioritize substances for further, more resource-intensive and complex testing with increasing degrees of selectivity for adverse effect.[72] Assessing whether such a system might be able to fill the enormous data gap for untested nanoparticles requires that we understand how costly it is likely to be, especially if the burden of providing environmental health and safety data falls on industry. Jae-Young Choi et al. show for the United States that costs for testing existing nanoparticles range from $249 million for optimistic assumptions about nanoparticle hazards to $1.18 billion for a more comprehensive precautionary approach.[73]

At current levels of R&D spending, the time taken to complete testing is likely to be very high if all nanomaterials are to be thoroughly tested. These results support a tiered risk-assessment strategy similar to the EU's REACH legislation for regulating toxic chemicals.

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