Environmental Science & Technology

Policy Analysis

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Integrating Legal Liabilities in Nanomanufacturing Risk Management

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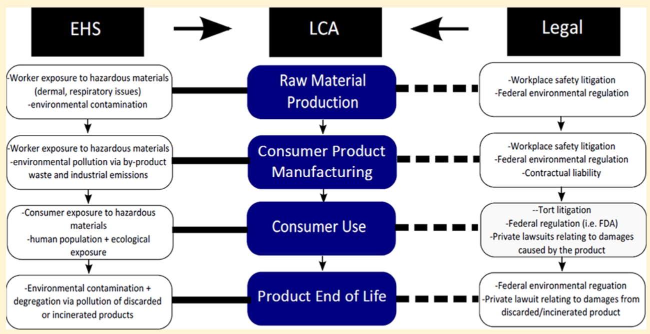
S *Supporting Information*

ABSTRACT: Among other things, the wide-scale development and use of nanomaterials is expected to produce costly regulatory and civil liabilities for nanomanufacturers due to lingering uncertainties, unanticipated effects, and potential toxicity. The life-cycle environmental, health, and safety (EHS) risks of nanomaterials are currently being studied, but the corresponding legal risks have not been systematically addressed. With the aid of a systematic approach that holistically evaluates and accounts for uncertainties about the inherent properties of nanomaterials, it is possible to provide an order of magnitude estimate of liability risks from regulatory and litigious sources based on current knowledge. In this work, we present a conceptual framework for integrating estimated legal liabilities with EHS risks across nanomaterial life-cycle stages using empirical knowledge in the field, scientific and legal judgment, probabilistic risk assessment, and multicriteria decision analysis. Such estimates will provide investors and operators with a basis to compare different technologies and practices and will also inform regulatory and legislative bodies in determining standards that balance risks with technical advancement. We illustrate the framework through the hypothetical case of a manufacturer of nanoscale titanium dioxide and use the resulting expected legal costs to evaluate alternative risk-management actions.



■ INTRODUCTION

The rise in prevalence of nanomaterials in human activity directly corresponds with an increased effort to identify and mitigate the possible risks associated with nanoenabled consumer products.[1] With the growing interest in nanotechnology commercialization, U.S. Government institutions throughout the National Nanotechnology Initiative (NNI) have advocated for thorough analyses of nanomaterial environmental health and safety (EHS) risks across life-cycle stages to help producers, regulators, and consumers better understand the potential toxic and pollutant risks associated with nanomaterial production and use.[2,3] Since traditional approaches to life-cycle assessment (LCA) are appropriate with respect to only some environmental forms of risks, risk practitioners have recently proposed several different extensions to LCA that incorporate a more complete account of EHS risks.[4−7]

Nanomaterial life-cycle EHS risks are beginning to be investigated, but little has been done to incorporate the potential legal liabilities associated with these EHS risks and other aspects of nanomanufacturing into a broader approach for nanomaterials risk management.[8] Although nanomaterials and nanoenabled products are subject to few nanospecific laws or legal precedents, the U.S. Environmental Protection Agency (USEPA) has begun to regulate certain nanoscale materials in earnest under the *Toxic Substances Control Act*[9] and the European Community's requirements for the *Registration, Evaluation, Authorisation and Restriction of Chemical substances* (REACH) contemplate similar widespread management.[10] However, many still debate the adequacy of existing legislation to govern the nanomaterials industry [11] and this lack of clear definition of the legal system further obfuscates the already uncertain choice of production and risk-mitigation strategies based on uncertain EHS risks. In addition, the trend in legal decisions regarding civil liabilities has progressed toward the imposition of greater responsibility on the party that had greater knowledge and control of a new product, which could lead to higher penalties for the manufacturer in the event of harm or loss resulting from the high uncertainties, unanticipated effects, or potential toxicity associated with many nanomaterials.[12] Moreover, the wide array of applications where nanomaterials could potentially be used significantly affects the number of ways in which manufacturers may be subject to such liabilities.[13] With holistic risk mitigation based on a thorough understanding of both legal liabilities and physical EHS risks, nanomaterial producers can operate within a more certain and potentially less costly environment, avoiding some physical and

Received: January 25, 2012
Revised: May 22, 2012
Accepted: June 20, 2012
Published: June 20, 2012

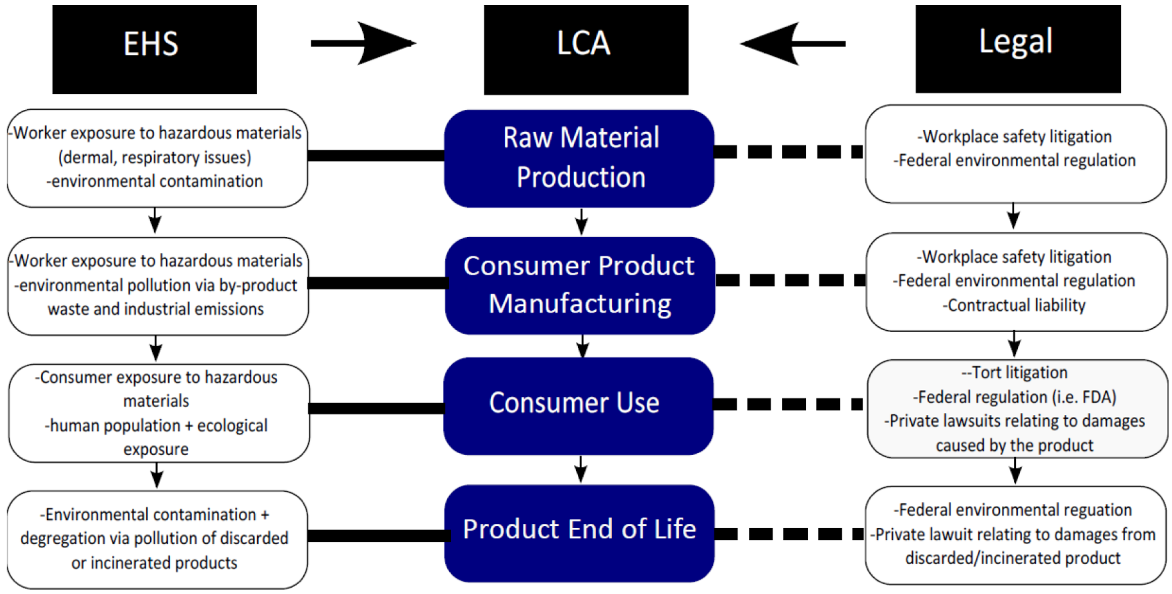


Figure 1. A framework for nanolegal life-cycle assessment showing the proposed integration of legal and EHS life-cycle risks for nanomaterials. Example risks are shown in the white boxes (EHS risks on the left, legal risks on the right) for four example life-cycle stages common to product manufacturing (blue boxes, center of the diagram; see Supporting Information for a description of each stage).

legal damages that could limit successful product commercialization and impede the growth of an industry anticipated to be valued in the billions or trillions of dollars in the coming decades.[14−16] By analogy, when asbestos was introduced as a cost-effective construction material, early warnings of possible toxic behavior were never fully investigated because the benefits were apparently higher. The resulting $80 billion litigation was perhaps a consequence of failing to fully consider possible legal liabilities in the initial decision analyses.[13]

To overcome this informational gap, we propose using a legal LCA *alongside* a comprehensive EHS LCA by merging EHS data, scientific and legal judgment, and knowledge of relevant regulatory and civil laws to monetize the range of liabilities potential encountered in nanomanufacturing and to integrate these costs in a comprehensive approach for risk management (Figure 1). Here, practitioners use historical cases, knowledge of material properties, and expert judgment to identify potential legal risks at each life-cycle stage arising from regulatory structures and rulings, national and international public law, tort and contract private law, and equity/restitution precedents to quantify release or exposure scenarios that might lead to undesirable outcomes. In the case of the European REACH requirements, much of the requisite life-cycle exposure information is already being collected for chemical registration.[17] The likelihoods of each scenario, and fines given those scenarios, are estimated by the experts as probability distributions, and Monte Carlo simulations calculate the total expected monetary damages a manufacturer might incur from various material, product, manufacturing, and risk-management choices. EHS risks are similarly assessed using standard risk-analysis techniques. These EHS risks and legal liabilities, measured in different units and arising from different sources, can be combined through utility functions and aggregated across life-cycle stages using Multi-Criteria Decision Analysis (MCDA).[18] Here, decision makers choose between operational alternatives by relatively scoring and trading off each type of contribution to overall risk. In this framework, already successfully applied to integrate EHS risks with manufacturing criteria,[19] expected legal costs can be considered as another of the many risk metrics already being integrated by the MCDA to guide comprehensive risk-management decisions. While we are not aware of a similar framework being implemented by a manufacturer in practice, risk and decision techniques have been shown to impact agent behavior, especially in cases where the agent actively sought the analysis or when the analysis was directly relevant to the agent.[20]

To demonstrate the novel components of the proposed framework, we model a scenario where a hypothetical manufacturer of nanoscale titanium dioxide (nano-TiO_2) based topical sunscreen is interested in comparing expected legal costs across risk-management strategies involving installation of various monitoring and safety equipment. The nano-TiO_2 manufacturing processes details, potential hazard events, pathways for emissions, and exposure and insights on standard monitoring and safety equipment are derived from the literature. Possible releases to air and water from normal operations, accidental spillage, and equipment cleaning are probabilistically modeled and combined with expert judgments of likely regulatory fines, given those releases, to estimate legal liabilities from relevant regulations, which are ultimately used to compare the cost effectiveness of the proposed risk-management strategies. While not included in this example, which aims to succinctly demonstrate the novel components of the framework, other legal liabilities can be included by following similar processes.

METHODS AND CASE STUDY

General Framework for Identifying and Quantifying Nanomaterial Legal and EHS Risks. To the extent that distinct scenarios can be estimated as having probabilities or probability distributions of occurring and leading to regulatory or civil penalties, settlements, or fees, these legal risks can be calculated and monetized in terms of expected cost. For each scenario, *i*, leading to potential liability, legal experts estimate the cost should the liability be incurred. This can be based on past legal decisions, best professional legal judgment, etc., and may include high uncertainty. The probability, *p*, of each scenario

dx.doi.org/10.1021/es3003266 | Environ. Sci. Technol. 2012, 46, 7955−7962

occurring and leading to legal action is also estimated and applied via the standard risk equation:[21]

$$\text{risk} = p(\text{unfavorable event})*\text{consequence of unfavorable event} \quad (1)$$

where the summation of expected legal costs for all liability scenarios within a single life-cycle stage, j, for a single product or alternative, k, yields the total expected legal cost for that stage:

$$\text{legal cost}_{j,k} = \Sigma_i p(\text{scenario}_{i,j,k})*(\text{legal cost}_{i,j,k}|\text{scenario}_{i,j,k}) \quad (2)$$

These expected consequences and legal costs can be either deterministic or probabilistic, and the resulting legal costs can be used to directly compare processes or alternatives within a life cycle stage or aggregated with other anticipated production and O&M costs and summed across life-cycle stages to select the total least-cost process or product alternative:

$$\text{total cost of least} - \text{cost alternative} = \min_k \Sigma_j, \ (\text{legal cost}_{j,k} + \text{prod cost}_{j,k} + \text{O\&M cost}_{j,k}) \quad (3)$$

A simultaneous EHS life-cycle analysis follows similar steps to anticipate EHS risks. However, instead of being monetized, each risk is calculated in its own specific units or scored on an ordinal scale. For each alternative, these risks can be summed across all outcomes, l, measured in the same units:

$$\text{score}_{j,k,l,} = \Sigma_i p(\text{scenario}_{i,j,k})*(\text{score}_{i,j,k,l}|\text{scenario}_{i,j,k}) \quad (4)$$

(See the Supporting Information for a discussion of potential types of legal and EHS risks and metrics for their measurement and scoring.)

General Framework for Integrating Legal and EHS Risks Across Life-Cycle Stages. An MCDA model integrates the nanomaterial costs and risks in eqs 2–4 through utility scores elicited from the decision makers or stakeholders. These scores relate the desirability of each individual cost or risk to the total range of costs or risks encountered among all alternatives.[18] This quantifies the relative utility of each outcome for each alternative in each life-cycle stage and, in aggregate, provides a composite measure of the overall desirability of each operational alternative:

$$\text{utility}_{j,k} = \Sigma_l \text{ utility}(\text{score}_{j,k,l}|\text{range of scores}_l) \quad (5)$$

(where one iteration of $\text{score}_{j,k,l}$ would be $\text{legal cost}_{j,k}$ + $\text{O\&M cost}_{j,k}$). The optimal decision among alternatives across the entire life cycle is then given by the following:

$$\text{utility of optimal production plan} = \max_k \sum_j, \text{ utility}_{j,k} \quad (6)$$

Case study: Simulation of hourly concentrations of nano-TiO_2 in ambient air and exhaust-air and effluent-water waste streams. We use a Probabilistic Risk Analysis (PRA) model to estimate the probabilities (see eq 2) of nanomaterial environmental releases that can potentially trigger regulatory liabilities during product manufacturing for a hypothetical producer of nano-TiO_2 based sunscreen. PRA provides a useful conceptual basis for understanding how various parameters affect the imposition of regulatory liabilities and supports calculation of order of magnitude estimates of these liabilities. Owing to the emerging nature of nanoscale materials, detailed quantitative data on manufacturing processes, actual release scenarios, safety measures, permissible emission limits, and factors that determine overall liability are very limited. Even given this limitation, PRA can be used with reasonable estimates and analytical insights obtained from expert judgment in lieu of empirical data.[22,23]

To develop the PRA model used in this study, we start by considering four steps comprising the manufacturing life-cycle stage for nano-TiO_2 based topical sunscreens, as motivated by a case study by the USEPA:[24]

(1) Raw Materials Storage & Handling:
(2) Surface Treatment
(3) Dispersion
(4) Packaging

For each of these steps, the case study also recognizes three possible pathways for of the environmental release of nano-TiO_2 [24] (see the Supporting Information for discussion of their relative likelihoods):

(1) Nano-TiO_2 release from normal operations
(2) Nano-TiO_2 release from accidental spillage
(3) Nano-TiO_2 release from equipment cleaning

Qualitative judgments form an initial basis for obtaining detailed quantitative values for each manufacturing stage, release event and pathway (s,e,p) combination. The model requires that an expert provide a probabilistic estimation of two values for each s,e,p combination:

(1) Amount of nano-TiO_2 released, in milligrams/hour: $A_{s,e,p}$
(2) Time period for which the release is expected to last, in hours: $T_{s,e,p}$

The sample probabilistic inputs used in this case study are for the first step of the manufacturing life-cycle stage (Table 1; see Supporting Information Table S1 for a summary of qualitative judgments of relative likelihood for the remaining steps in the manufacturing life-cycle stage.)

Three other parameters are also required for calculating the concentrations of nano-TiO_2 in ambient (indoor) air and in the exhaust-air and effluent-water streams, with values derived from manufacturing process details or elicited from relevant expert. These are as follows:

(1) Indoor air volume of the manufacturing facility (m^3): V;
(2) Hourly air exchange rate efficiency (fraction of air volume exchanged): R;
(3) Hourly effluent water volume (m^3): W.

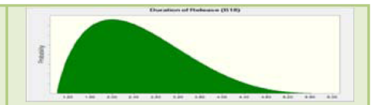
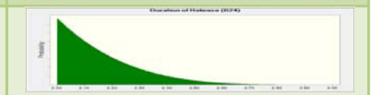
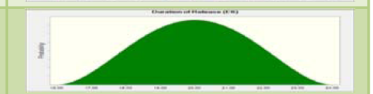
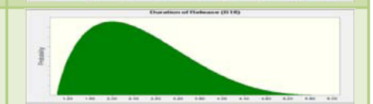
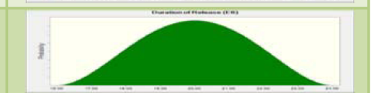
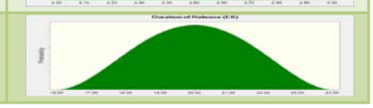
On the basis of these parameters, the model calculates the total hourly concentrations of nano-TiO_2 in ambient, exhaust air, and effluent water. The calculations assume that nano-TiO_2 diffuses completely with the medium and that the complete indoor air volume is exchanged with an efficiency R.

Hourly release ($A_{s,e,p}$) of nano-TiO_2 is simulated for each combination of s, e, p over a day. The simulation limits the number of hours for a given combination of s, e, p to the simulated value of the time period for which the release lasts ($T_{s,e,p}$). For example, if the time period is 8 h, the hourly amounts of nano-TiO_2 released are simulated over a randomly chosen 8 h. Thus:

$$\text{if } A^t_{s,e,p} > 0, \text{ then } I^t = 1, \text{ where } t \text{ is the hour and } I \text{ is a binary release variable} \quad (7)$$

$$\text{if } A^t_{s,e,p} = 0, \text{ then } I^t = 0 \quad (8)$$

Table 1. Sample Quantified PRA Model Inputs for the Raw-Materials-Storage-and-Handling Step of the Manufacturing Life-Cycle Stage of a Hypothetical Nano-TiO_2 Based Topical Sunscreen Producer

Raw Materials Storage and Handling	**Operations**	**Air**	**Amount (mg/Hour)**	
			Time Period (Hours)	
		Water	Amount (mg/Hour)	
			Time Period (Hours)	
	Accident	Air	Amount (mg/Hour)	
			Time Period (Hours)	
		Water	Amount (mg/Hour)	
			Time Period (Hours)	
	Equipment Cleaning	Air	Amount (mg/Hour)	
			Time Period (Hours)	
		Water	Amount (mg/Hour)	
			Time Period (Hours)	

$$T_{s,e,p} = \Sigma_{t=1}^{24} I^t \quad (9)$$

The total hourly ambient air concentration is calculated as follows:

$$C^t = (C^{t-1})(1 - R) + (\Sigma_s \Sigma_e A^t_{s,e,p=\mathrm{Air}})/V, \text{ where } C^t \text{ is ambient concentration at time } t \quad (10)$$

Similarly, the hourly exhaust air concentration is calculated as follows:

$$E^t = RC^{t-1}, \text{ where } E^t \text{ is the exhaust concentration at time } t \quad (11)$$

And the hourly effluent water concentration is calculated as follows:

$$L^t = (\Sigma_s \Sigma_e A^t_{s,e,p=\mathrm{Water}})/W, \text{ where } L^t \text{ is the effluent water concentration at time } t \quad (12)$$

Case Study: Simulation of Monetized Liabilities from Three Relevant Regulations. The next step is to determine the permissible regulatory limits for each of these concentrations. Often, regulatory limits consist of hourly concentrations and a number of permissible hours.[8,25] To violate this type of regulatory scheme, the ambient concentrations will have to be higher than the permissible limits for a duration that is greater than the permissible number of hours. In the event that this occurs and a statute is violated, SV, certain liability costs, LC, are imposed on the manufacturer. Given the uncertainty surrounding regulation of nanomaterials, we demonstrate this approach using expert judgments for both the permissible concentration, PD, and permissible duration, PD, of three relevant statutory areas:

(1) Occupational Health and Safety Administration (OSHA) regulations (assumed relevant for ambient air concentrations only)
(2) Clean Air Act (CAA)
(3) Clean Water Act (CWA)

Although the PHC, PD, and LC values for the three regulations for this study (Table 2) are hypothetical, they can be elicited from an expert. Even if the estimation of these values

dx.doi.org/10.1021/es3003266 | Environ. Sci. Technol. 2012, 46, 7955−7962

Table 2. PHC, PD, and LC Values for the Study

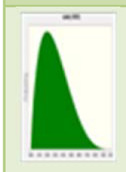
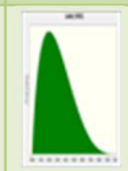
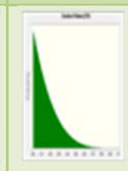
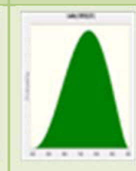
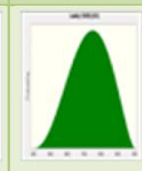
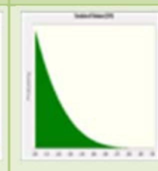
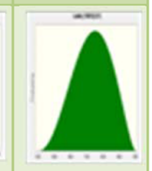
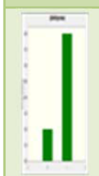
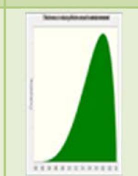
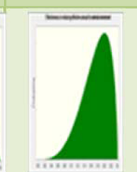
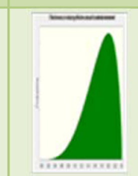
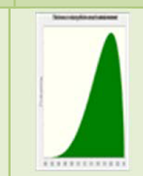
OSHA			CAA			CWA		
PHC (mg/Hr)	PD (Hrs)	LC (1000$)	PHC (mg/Hr)	PD (Hrs)	LC (1000$)	PHC (mg/Hr)	PD (Hrs)	LC (1000$)
								
Min: 0.1 Likely: 0.5 Max:7.0	Min: 1 Likely: 3 Max:8	Min: 100 Likely: 120 Max:200	Min: 0.5 Likely: 1.0 Max:2.0	Min: 2 Likely: 4 Max:8	Min: 40 Likely: 75 Max:100	Min: 0.5 Likely: 1.0 Max: 3.0	Min: 2 Likely: 3 Max:4	Min: 40 Likely: 75 Max:100

Table 3. Parameters for Modeling the Effectiveness of Various Safety Measures

ME			PPE		EACE		EWCE	
p(Id.)	Efficiency	Annual O&M Cost (1000$)	Efficiency	Annual O&M Cost (1000$)	Efficiency	Annual O&M Cost (1000$)	Efficiency	Annual O&M Cost (1000$)
								
p(Id) =0.8	Min: 0.3 Likely:0.5 Max:0.6	Min: 5 Likely:9 Max:12	Min:0.2 Likely:0.3 Max:0.4	Min:10 Likely:15 Max: 20	Min: 0.2 Likely:0.4 Max:0.5	Min: 10 Likely: 20 Max: 25	Min:0.2 Likely:0.4 Max:0.45	Min:10 Likely: 15 Max:20

is difficult and initially cannot be done with certainty, the quantitative incorporation of legal information in risk management represents an improvement over management without this information. In estimating these values, the expert may be guided by the chemical and physical properties of nano-TiO_2, empirical evidence of harmful effects of nano-TiO_2, the extent of violation, the foreseeability of the violation, any economic burden on the manufacturer, and results of prior cases, etc. (See the Supporting Information for a model that uses these data to estimate regulatory violations based on environmental releases.)

To determine the liability costs from each of the regulations the model calculates the following:

$$\text{if } C^t \geq \text{PHC}_{\text{OSHA}}, \text{ then } I^t_{\text{OSHA}} = 1 \quad (13)$$

$$\text{if } C^t < \text{PHC}_{\text{OSHA}}, \text{ then } I^t_{\text{OSHA}} = 0 \quad (14)$$

$$\text{if } \Sigma^{24}_{t=1} I^t_{\text{OSHA}} \geq \text{PD}_{\text{OSHA}}, \text{ then } \text{SV}_{\text{OSHA}} = 1 \quad (15)$$

$$\text{if } \Sigma^{24}_{t=1} I^t_{\text{OSHA}} < \text{PD}_{\text{OSHA}}, \text{ then } \text{SV}_{\text{OSHA}} = 0 \quad (16)$$

$$\text{if} E^t \geq \text{PHC}_{\text{CAA}}, \text{ then } I^t_{\text{CAA}} = 1 \quad (17)$$

$$\text{if } E^t < \text{PHC}_{\text{CAA}}, \text{ then } I^t_{\text{CAA}} = 0 \quad (18)$$

$$\text{if } \Sigma^{24}_{t=1} I^t_{\text{CAA}} \geq \text{PD}_{\text{CAA}}, \text{ then } \text{SV}_{\text{CAA}} = 1 \quad (19)$$

$$\text{if } \Sigma^{24}_{t=1} I^t_{\text{CAA}} < \text{PD}_{\text{CAA}}, \text{ then } \text{SV}_{\text{CAA}} = 0 \quad (20)$$

$$\text{if } L^t \geq \text{PHC}_{\text{CWA}}, \text{ then } I^t_{\text{CWA}} = 1 \quad (21)$$

$$\text{if } L^t < \text{PHC}_{\text{CWA}}, \text{ then } I^t_{\text{CWA}} = 0 \quad (22)$$

$$\text{if } \Sigma^{24}_{t=1} I^t_{\text{CWA}} \geq \text{PD}_{\text{CWA}}, \text{ then } \text{SV}_{\text{CWA}} = 1 \quad (23)$$

$$\text{if } \Sigma^{24}_{t=1} I^t_{\text{CWA}} < \text{PD}_{\text{CWA}}, \text{ then } \text{SV}_{\text{CWA}} = 0 \quad (24)$$

The overall expected liability (EC) is then:

$$\text{EC} = \text{LC}_{\text{OSHA}} * \text{SV}_{\text{OSHA}} + \text{LC}_{\text{CAA}} * \text{SV}_{\text{CAA}} + \text{LC}_{\text{CWA}} * \text{SV}_{\text{CWA}} \quad (25)$$

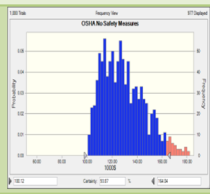
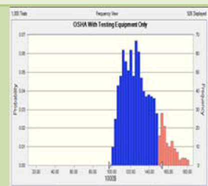
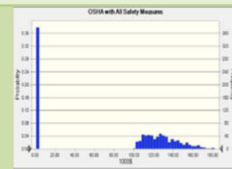
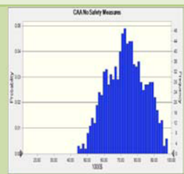
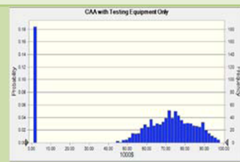
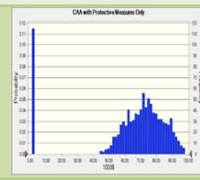
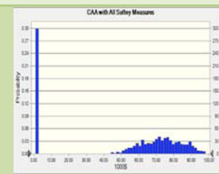
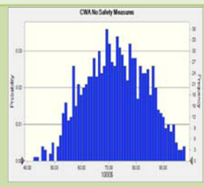
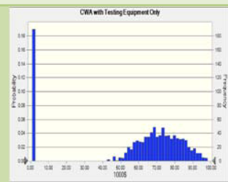
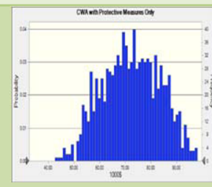
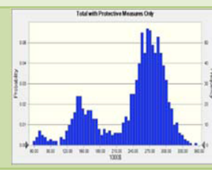
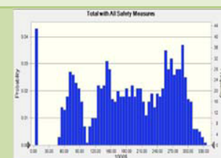
Note that these distributions and calculations are based on the premise that the manufacturing setup is not equipped with any safety or protective measures. Thus, the expected liability value obtained in eq 25 is a baseline value.

In addition, we estimate the efficiency and annual O&M cost of Testing & Monitoring Equipment (ME), Personal Protective Equipment (PPE), Exhaust Air Cleaning Equipment (EACE), and Effluent Water Cleaning Equipment (EWCE) (Table 3; see Supporting Information for descriptions).[24,26] Under normal operating conditions, monitoring equipment is assumed to reduce the duration of a release by an efficiency parameter due to earlier release identification, and safety equipment is similarly assumed to similarly reduce the release's concentration.

Thus, for all cases except accidental release, we replace $T_{s,e,p}$ in eq 9 by $T_{s,e,p} * p(Id) * \text{efficiency}_{\text{ME}}$. Similarly, to model the effects of PPE, we replace C^t in eqs 13 and 14 by $C^t * \text{efficiency}_{\text{PPE}}$. The benefit of using EACE is modeled by substituting E^t in eqs 17 and 18 by $E^t * \text{efficiency}_{\text{EACE}}$. The benefit of using EWCE is modeled by substituting L^t in eqs 21 and 22 by

dx.doi.org/10.1021/es3003266 | Environ. Sci. Technol. 2012, 46, 7955−7962

Table 4. Expected Monetized Regulatory Liabilities from the Manufacturing Life-Cycle Stage of a Hypothetical Producer of Nano-TiO_2 Based Topical Sunscreen[a]

	No Equipment	Monitoring Equipment	Safety Equipment	Both Monitoring and Safety Equipment
OSHA				
	Expected Value: $126,000 p(OSHA Liability < $100,000)=0.03	Expected Value: $119,000 p(OSHA Liability < $100,000) = 0.08	Expected Value: $100,000 p(OSHA Liability < 100,000) = 0.38	Expected Value = $80,000 p(OSHA Liability < $100,000) = 0.5
CAA				
	Expected Value: $69,000 p(CAA Liability < $100,00) = 1.0	Expected Value: $59,000 p(CAA Liability < $100,000) = 1.0	Expected Value: $64,000 p(CAA Liability < $100,000) = 1.0	Expected Value: $51,000 p(CAA Liability < $100,000) =1.0
CWA				
	Expected Value: $72,000 p(CWA Liability < $100,000) = 1.0	Expected Value: $58,000 p(CWA Liability < $100,000) = 1.0	Expected Value: $71,000 p(CWA Liability < $100,000) = 1.0	Expected Value: $51,000 p(CWA Liability < $100,000) = 1.0
Total				
	Expected Value: $267,000 p(Total Liability <$100,000) = 0.02	Expected Value: $238,000 p(Total Liability < $100,000) = 0.07	Expected Value: $237,000 p(Total Liability < $100,000) = 0.1	Expected Value: $184,000 p(Total Liability < $100,000) = 0.29

[a]Monetized legal liabilities come from three relevant EHS regulations, shown separately and in total, and are compared under four different risk-mitigation strategies. The probability of the regulatory liabilities amounting to less than one-hundred thousand dollars is specifically shown.

L^t * efficiency$_{EWCE}$, where:

- p(Id) = probability of identification of release;
- efficiency$_{ME}$ = efficiency of ME in reducing the duration of release;
- efficiency$_{EACE}$ = efficiency of EACE in reducing the amount of nano-TiO_2 in exhaust air;
- efficiency$_{EWCE}$ = efficiency of EWCE in reducing the amount of nano-TiO_2 in effluent water.

Upon making these changes, eq 25 gives the expected liability with all safety measures. To estimate the expected liability with only one of the safety measures, the model changes only the values relevant to that equipment and eq 25 will calculate the expected liability with the safety measure(s) under consideration.

RESULTS AND DISCUSSION

Here, hypothetical estimates of manufacturing details have been presented that in practice would be informed by discussions with organizational decision makers and scientific and legal experts. Nanomaterial releases and corresponding legal liabilities are randomly simulated from the aforementioned probability distributions for each relevant statute and are combined to estimate the expected legal cost of the no-action case and of each alternative risk-management strategy under consideration.

To complete the analysis, this process could be expanded to similarly calculate various civil liabilities, replicated across all life-cycle stages and integrated with life-cycle EHS risks through utility functions to find the lowest-total-cost and most-EHS-friendly nanomanufacturing process or risk-management plan across a product's entire life cycle.

The results (Table 4) show potential liabilities for this manufacturer from the different regulations ranging between \$3000 and \$360 000, with average expected liabilities of between \$180 000 and \$270 000 with various risk-mitigation measures. These results indicate that investment in safety equipment may provide better protection against OSHA liabilities while investment in monitoring equipment may provide better protection against CWA liabilities. Likelihood estimates of the probability of expected liabilities not exceeding \$100 000 are also shown (Table 4). (See Supporting Table S2 of the Supporting Information for a cost-benefit analysis of the three proposed types of equipment investment).

It is possible to attribute the total emissions in a given pathway (e.g., air emissions, Figure 2) to different steps or events in the manufacturing process. This can help a plant operator to focus on preventing events most responsible for the offending emissions or to focus on particular steps in the manufacturing process that are more likely to cause regulatory violations.

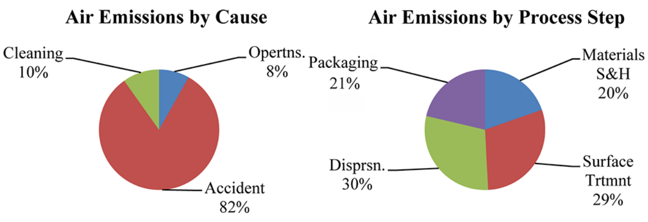


Figure 2. Contributions to air emissions by causing event and step in the manufacturing process.

A sensitivity analysis can also help assess the robustness of the model and provide additional insights for management in terms of identifying parameters most affecting expected liability. In our case, the total expected liability is most sensitive to the probability of identifying the release (see Supporting Figure S2 of the Supporting Information). Over the range of this parameter's values, the total expected liability varies by 60%. Thus, it may be useful to also guide investment toward means of determining a narrower range of this variable's values. Sensitivity analyses can provide guidance for both value of information and value of control studies.[27,28]

The development of a risk-management system that integrates legal and EHS risks across all life cycle stages can provide valuable insight for nanomanufacturers seeking to identify low-risk, high-reward operational strategies in complex and uncertain regulatory and operating environments. The combined basis of this approach in risk analysis and MCDA is well suited for emerging materials and processes, as reasonable estimates and analytical insights can be obtained thorough expert judgment and used in combination with or in lieu of empirical data.[23,29,30] This offers the decision maker an opportunity to obtain an a priori understanding of the order-of-magnitude quantified risk profiles associated with different manufacturing and risk-mitigation strategies. Adopting this type of this framework will require significant change in the way legal risks are currently perceived in the nanotechnology field, now predominantly defined in terms of EHS issues alone. It is our belief that the industry can benefit from systematically quantifying and integrating nanomanufacturing legal risks that may otherwise take an ad-hoc role in determining production decisions.

■ ASSOCIATED CONTENT

Supporting Information

Additional equations, data and discussion. This material is available free of charge via the Internet at http://pubs.acs.org.

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Notes

The authors declare no competing financial interest.

■ ACKNOWLEDGMENTS

This effort was sponsored through the ERDC Nanotechnology Focus Area. Permission was granted by the USACE Chief of Engineers to publish this material.

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