

Managing Your Environmental, Health & Safety Risk: A Guide for Nano Companies and their Insurers

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ABSTRACT

Nanotechnology companies are facing increasing scrutiny as federal and state agencies adopt regulations and propose recommended workplace practices and exposure standards. In addition, more studies are being released that indicate that some nanomaterials present the potential for environmental and health impacts. These companies and their insurers are looking for tools to ensure that nanomaterials do not follow the same litigation and liability path experienced with materials such as asbestos.

This paper presents three approaches to risk evaluation, highlights the current status of regulatory actions that establish applicable standards against which nanomaterials operations will be judged, and provides a system that can be implemented by companies and their insurers to assess, address and manage potential environmental, health and safety risks associated with nanomaterials operations.

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1 EVALUATING RISKS

Nanomaterials companies and their insurers can approach the evaluation of relevant environmental, health and safety risks associated with nanomaterials operations by choosing risk avoidance; utilizing risk management; or incurring risk inadvertently.

1.1 Risk Avoidance

First, these companies may choose risk avoidance. Under this approach, a nanomaterials company or its insurer may choose to refrain from conducting or insuring certain forms of operations or operations that involve certain types of nanomaterials.

An insurer may make a broader risk avoidance decision by deciding to excluded nanomaterials operations from coverage under its policies. In September 2008, the Insurance Services Office issued a model Nanotubes and Nanotechnology Exclusion.[1] This exclusion has not been widely adopted by insurers but on September 24, 2008, one insurer did issue such an exclusion.[2]

The company explained, “reports have raised concerns regarding health risks from workers that may be inhaling carbon nanotubes during the manufacture of certain products. The carbon nanotubes resemble asbestos fibers in appearance, raising the concern that they may cause illness similar to that linked to asbestos.”[3] The company based its decision on

the “unknown and unquantifiable” risks associated with carbon nanotubes.[4]

Risk avoidance decisions, however, must be based on a reasonable evaluation of the relevant risks associated with a particular company’s operations or with nanotechnology in general. Failure to do so could result in missing an opportunity to insure portions of an industry that has been predicted to account for \$2.4 trillion in revenues by 2015.[5] The framework for such an evaluation is discussed below.

1.2 Risk Management

Other companies and insurers may utilize risk management with respect to nanomaterials operations. A company may choose to evaluate the risks associated with its operations, determine the viable protective measures that are available to address these risks, make appropriate decisions as to which of these measures to implement and under what conditions to do so, and document its risk evaluation process. In conducting such a risk evaluation process, a company can appropriately manage its risks and ensure its compliance with applicable environmental, health and safety requirements.[6]

Insurers can also conduct such a risk evaluation process. However, such a process can be time and resource-intensive. As a result, insurers may choose to require its potential insured to develop and provide documentation regarding the company’s risk evaluation process. Again, the framework for such an evaluation is discussed below. An insurer may also require the company to engage the services of a third-party consultant with expertise in nanotechnology risk analysis to assist in developing and conducting the risk analysis. Based on a review of such documentation, an insurer can make an appropriate decision as to whether to provide insurance and at what cost.

1.3 Inadvertently Incurring Risk

Companies and insurers that fail to pursue either a risk avoidance or a risk management approach with respect to nanomaterials operations may find that, by default, they have adopted the third and least desirable approach to addressing potential environmental, health and safety risks associated with nanomaterials operations – inadvertently incurring that risk.

Companies may find themselves in this situation by failing to adequately consider that their operations are creating or handling materials that do not occur naturally, that the nanomaterials or the chemicals used to create them have potentially hazardous properties; and that their workers have

higher potential exposures than would the general public. These exposures can occur during research and development, manufacturing and waste disposal activities. Risks can be presented based on whether the operations utilize unbound nanomaterials as compared to materials in solution. A company's knowledge differences as compared to other similar operations can present a risk, particularly in light of the fact that there are an increasing number of studies that report potential effects of exposure to nanomaterials. A company's failure to identify and consider risks that are relevant to its operations will prevent the company from having adequate information with which to make appropriate decisions on the protective measures that are appropriate for its operations.

An insurer may also inadvertently incur risk by failing to identify those that it insures that are engaged in nanomaterials operations. Even insurers that are aware of an insured's nanomaterials operations may have failed to consider the specific nanomaterials and hazardous substances that are used by the insured, their characteristics, relevant scientific studies, exposure risks, potential release points, the company's compliance with applicable environmental, health, and safety requirements, the selection and use of feasible protective measures, and the existence and adequacy of standard operating procedures to prevent and respond to upsets. An insurer's failure to consider these risks can cause it to inadvertently incur risk that it could otherwise avoid or manage.

2 APPLICABLE REGULATIONS

While there are not environmental, health and safety regulations specifically focused on nanomaterials operations, it does not follow that such operations are not subject to environmental, health and safety regulations. Federal, state and local regulations place compliance obligations on such operations.

2.1 OSHA Requirements

Under the Occupational Safety and Health Act (the "OSH Act") and the regulations promulgated by the Occupational Safety and Health Administration ("OSHA") under the authority of the OSH Act, companies engaged in nanomaterials operations are subject to general and specific requirements. Relevant requirements include the OSH Act's general duty clause ("General Duty Clause") and special duty clause ("Special Duty Clause").

The General Duty Clause imposes on an employer a duty to provide each of its employees "a place of employment ... free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees." [7] A company must show that it had in place measures for recognizing and correcting hazards which a reasonably prudent employer, similarly situated, would adopt. The question of whether a hazard is recognized goes to the knowledge of the employer, or in the absence of actual knowledge, to the standard of knowledge in the industry. At the same time, an employer cannot ignore the presence of an

obviously hazardous condition by asserting that its industry is ignorant of such hazards. [8]

In addition to the general duty placed on employers to provide a safe workplace, the OSH Act imposes a specific obligation to comply with all occupational safety and health standards promulgated under the OSH Act (the "Special Duty Clause"). [9] Although there are not occupational safety and health standards specifically designed to address potential risks from handling nanomaterials, employers should be aware of OSHA regulations that are generally applicable to manufacturing, processing, distribution or disposal operations which may have nano-specific implications. Among these include hazard communication; [10]; and the use of engineering controls, administrative controls and personal protective equipment. [11]

Failure to comply with the General Duty Clause or the Special Duty Clause can result in significant consequences, including administrative or civil penalties. The failure can also expose an entity to liability for any personal injuries that may be attributable to the failure. A company with nanomaterials operations will be well-served by conducting a survey of the applicable information that is available regarding the behavior of the particular nanomaterials, the toxicological effects associated with exposure to the materials, and any engineering controls, administrative controls, and personal protective equipment that can be utilized to address any hazards that the materials may present.

2.2 EPA Requirements

Environmental requirements that are potentially applicable to nanomaterials operations have been established under the Toxic Substances Control Act ("TSCA"), the Resource Conservation and Recovery Act, the Comprehensive Environmental Response, Compensation and Liability Act, the Clean Water Act, the Clean Air Act, the Federal Insecticide, Fungicide and Rodenticide Act and the regulations promulgated under the authority of these statutes. The Environmental Protection Agency ("EPA") has begun to more aggressively pursue regulatory action directly affecting nanomaterials operations. Of most significance perhaps is EPA's proposed TSCA rule developments that would address pre-notification requirements; the required submittal of production volume, methods of manufacture and processing, exposure and release information, and available health and safety data; and the testing for certain nanomaterials already in commerce.

2.3 Draft Recommended Exposure Limits

In November 2010, the National Institute for Occupational Safety and Health ("NIOSH") issued draft recommended exposure limits ("REL") for Carbon Nanotubes ("CNTs") and Nanofibers ("CNFs"). Relying on several animal studies that "consistently show that relatively low mass doses of CNT are associated with early-stage adverse lung effects in rats and mice," including pulmonary inflammation and fibrosis, NIOSH proposed a REL of 7 $\mu\text{g}/\text{m}^3$ elemental carbon as an 8-hour time-weighted average respirable mass airborne concentration. [12] This proposal

follows a similar draft related to occupational exposure to titanium dioxide (TiO₂) which was drafted in 2005, was subjected to peer review in 2006, and is currently under further development.[13]

Although the REL is proposed to be set at the lowest airborne CNT and CNF concentration that can be accurately measured by NIOSH procedures, this level is above that at which NIOSH suggests that an excess risk of adverse lung effects is predicted. Therefore, in addition to proposing an REL, NIOSH is suggesting certain recommended practices for employers and employees to further minimize exposure to airborne concentrations of CNT and CNF.

Although NIOSH's proposals are only in draft form, companies handling CNTs, CNFs, or TiO₂ should be aware of the proposed RELs and should document the steps it has taken to ensure that these limits are met. Companies handling CNTs and CNFs should review the proposed work practices, document the review, and implement the work practices that are applicable and appropriate for their operations. Although the RELs are only proposed, it is likely that potential litigants would point to these RELs and NIOSH's recommended work practices in order to establish liability. Insurers should also consult with their insureds to ensure that the insureds have properly documented their response to NIOSH's recommendations.

2.4 State Requirements

At the state level, regulatory activities have also increased. California has been the most active, demonstrated by requests for information to nanomaterials manufacturers regarding Carbon Nanotubes, Nano Silver, Nano Zero Valent Iron, Nano Cerium Oxide, Nano Titanium Dioxide, Nano Zinc Oxide, and Quantum Dots. The notices, sent by the California Department of Toxic Substances Control, required companies to share health and safety information.

2.5 Company and Insurer Responses

Nanomaterials manufacturers and processors should assess their operations to ensure compliance with regulatory obligations in light of these increased efforts to regulate nanomaterials at the federal and state level. Performing this evaluation under an applicable audit statute or policy will enable an entity to identify potential environmental issues, while limiting potential liability for penalties and protecting confidential business information.

The increased regulatory activity amplifies the importance that insurers identify their insureds that are involved in nanomaterials operations. Failure to comply with regulatory requirements can lead to increased potential liability. Insurers should develop a game plan for evaluating the risk that they are incurring as a result of their insured's nanomaterials operations. In addition, insurers should implement a systematic, iterative approach to managing their risk in this arena. An iterative approach is necessary because: nanomaterials operations are increasing in number, scope and complexity; regulations are increasing; and our knowledge of

the potential effects of these operations and viable protective measures is constantly growing.

3 EVALUATION PROCESS

The OSH Act's General Duty Clause requires employers to have in place measures for recognizing and correcting hazards which a reasonably prudent employer, similarly situated, would adopt. OSHA's regulations require hazard identification and communication. As a result, a company engaged in nanomaterials operations is required to have and implement a process to identify any hazards that may be present as a result of the operations. To demonstrate compliance with these requirements, it is critical that the company's review and analysis be documented.

Insurers also have an interest in ensuring that such an evaluation has been conducted. Through this risk evaluation process, hazards can be identified and appropriate protective measures can be implemented. Through such a process, potential liability can be minimized.

Nanomaterials operations present some unique challenges in developing an appropriate risk evaluation process. It is helpful to view the development of such a process from the perspective of the company and the insurer.

3.1 Company Perspective

A company manufacturing, processing, distributing, or disposing of nanomaterials can develop an appropriate risk evaluation process by taking the following steps:

- Determine what nanomaterials are used or are present at the facility. This step is particularly important for facilities that are downstream of the nanomaterials manufacturing facility.
- Determine the composition, characteristics, concentrations, volume, and properties of the nanomaterials, and identify any exposure pathways. Research and testing by internal and external scientists may be appropriate.
- Review existing scientific studies relevant to the specific nanomaterials in use, as well as those that have similar compositions characteristics, properties and exposure pathways. As part of this review, survey facilities engaged in similar operations to determine potential risks those facilities have identified.
- Determine the potential exposure risks associated with the nanomaterials that are being handled.
- Analyze the facility's processes to determine the potential points of releases, discharges or emissions. The facility should consider material receipt and unpacking; manufacturing and finishing processes; lab operations; storage, packaging and shipping; waste management; maintenance and housekeeping; and potential upset events.
- Identify the local, state and federal regulatory requirements applicable to the facility's operations.

- Identify, evaluate and implement available and appropriate engineering controls, administrative controls and personal protective equipment that can address potential releases of, or exposures to the nanomaterials in use at the facility. As part of this process, survey facilities engaged in similar operations to identify any protective measures that are in use.
- Establish or review standard operating procedures to ensure compliance with regulatory requirements and the appropriate and effective use of the engineering controls, administrative controls and personal protective equipment, and to prevent upset events; and to respond to such events, should they occur.
- Communicate to the employees the results of the risk evaluation and the standard operating procedures to be used to minimize the risks identified. Develop and provide training to the employees. Employees should be trained prior to their initial assignment to a nanomaterials work area. The training should be repeated on a periodic basis.
- Conduct periodic audits of the facility's operations to test its regulatory compliance and the appropriate and effective use of the engineering controls, administrative controls and personal protective equipment. The audits should be performed under available state or federal audit programs and policies, or under the attorney-client privilege.
- Establish or review the facility's records retention policy and system to ensure that appropriate documentation is maintained to demonstrate that the facility has appropriately identified and addressed the potential risks from its nanomaterials operations.
- Develop a system to periodically review the analysis set forth above to ensure that the information is current and that the decision-making is valid and appropriately documented.

3.2 Insurer Perspective

An insurer will not have the time or resources to conduct a review such as is described above. Instead, an insurer should develop and implement a process through which it identifies the insureds that are involved in nanomaterials operations and ensures that, for each identified insured, an appropriate risk evaluation process has been implemented.

Insurers can utilize such a process to evaluate the insured's knowledge of its processes and procedures; its potential risks; the regulatory standards that are applicable to its operations; and the viable protective measures that can be implemented to address any identified risks. In addition, it is critical for the insurer to confirm that the insured has appropriately documented its risk evaluation and that the evaluation is up-to-date.

An insurer may also choose to require that the evaluation be subject to an independent review by a qualified third-party. Such a review can provide additional assurance that potential

risks have been appropriately identified and addressed. Third-party verification can also increase the credibility of the analysis in the event that the company's evaluation is challenged in the context of litigation.

CONCLUSION

This paper has discussed three approaches to risk evaluation, highlighted the current status of regulatory actions that establish applicable standards against which nanomaterials operations will be judged, and provided a system that can be implemented by companies, and reviewed by their insurers, on an on-going basis to ensure continuing compliance with applicable environmental, health and safety requirements. These same steps can assist in limiting potential liability and in preventing incidents that could seriously damage the viability of a specific company and the nanotechnology industry as a whole.

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