Commentary: Oversight of Engineered Nanomaterials in the Workplace

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lobal investment in nanotechnology research and development over the past few years has stimulated the manufacture of an increasing number of commercial products based on engineered nanomaterials. The Project on Emerging Nanotechnologies Consumer Products Inventory listed over 800 products claimed by the manufacturer to be based on nanotechnology in January 2009.¹ However, this inventory only represents a portion of the commercial and consumer products currently available that rely on nanotechnology in some form. While estimates vary, Lux Research suggest that the global market for nanotechnology-enabled products in 2007 was worth \$147 billion, and is projected to grow to \$3.1 trillion by 2015.2 Many of the products in development and commercial production use nanotechnology to enhance existing technologies. Increasingly though, new products are being conceived and developed that depend to a far greater degree on novel materials and functionality that arise from nanotechnology.

The growth in nanotechnology-enabled commercial products is inevitably leading to a range of new materials being produced, handled, and used in the workplace. Some of these materials, such as nanotitanium dioxide, nano-zinc oxide, and nano-carbon black, are nanoscale versions of substances that have been in commerce for many years. Others are substances which have been in use for some time, but which have been engineered in new ways to enhance or change the way they behave. Examples in this category would include materials such as metal and metal oxide nanoparticles with altered surface compositions and chemistries. This category would also include metamaterials, where material functionality derives from precisely engineered repeating structure at the nanoscale rather than directly from chemical composition. A third category encompasses new materials, for which there are no direct antecedents - materials such as carbon nanotubes, which were discovered less than 20 years ago,³ and are only just beginning to be used commercially.

Across these categories of nanomaterials, advances in science, technology, and nanoscale engineering are leading to sophisticated interfacing between non-living and living systems — so-called nanobiotechnology. These developments are influencing new classes of drugs and medical devices that blur the distinction between chemical and physical agents in the body.⁴

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The resulting diversity of potential nano-engineered materials is extensive, and covers novel advances in

tute for Occupational Safety and Health [NIOSH]) were asked to complete a questionnaire designed to provide insight into the development, attributes, and outcomes of the current workplace safety oversight framework. By employing this approach, the authors aimed to systematically explore the current oversight framework in light of multiple, sometimes conflicting,

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composition, structure, and functionality. Yet a common attribute is that they are typically designed with a functionality that is dependent on physical form and chemical composition at the nanometer scale.7 This functionality may depend solely on an increased ability to incorporate the nanoscale form of a material into a product. It may rely on enhanced material characteristics when engineered at the nanoscale such as an increase in available surface area. Or it may derive from step-wise changes in behavior that emerge at the nanoscale, such as particle size-determined fluorescence in semiconductor quantum dots. In each case, the potential for the material to cause harm if human exposure occurs may also be associated with the structure and chemistry of the substance at the nanoscale.8

If engineered nanomaterials are to be used safely within the workplace, this possibility for nanostructure-related health risks needs to be explored and, where necessary, addressed.⁹ Information is needed on where existing approaches to ensuring safety cover new nanomaterials adequately, and where new approaches should be developed. In this context, there is a need to assess the robustness of the existing oversight framework and its ability to respond to new challenges. This is the central focus of the paper by Jae-Young Choi and Gurumurthy Ramachandran,¹⁰ on which this commentary is based.

In "Review of the OSHA Framework for Oversight of Occupational Environments," Choi and Ramachandran¹¹ use expert opinion combined with a variant of Multi-Criteria Decision Analysis (MCDA) to assess the strengths and weaknesses of the U.S. Occupational Safety and Health Administration's (OSHA) oversight. Twenty-seven experts from industry, academia, and government(specifically, OSHA and the National Insticriteria, and develop a "process that leads to rational, justifiable, and explainable decisions."¹²

The statistical analysis of the questionnaire returns by Choi and Ramachandran is extensive, and while the relatively small pool of experts used led to statistical uncertainty in many areas, the authors were able to extract a number of trends from the data. Nevertheless, as Choi and Ramachandran acknowledge, the small number of respondents limited the study. Experts participating in the study were not randomly selected, which could conceivably have led to selection bias. Different sectors were not equally represented – for instance, there was only one expert representing labor directly. And not every expert answered every question on the questionnaire. For these reasons, the authors "interpreted the survey results with great caution and avoided reaching decisive conclusions." Rather, they suggest that the study presents several methodological directions for future studies. They do nevertheless identify 12 characteristics of the current U.S. federal oversight system for chemicals in the workplace from the study that the expert opinion and associated MCDA highlighted as potentially important. In exploring the validity of these characteristics, the authors discussed evidence in the peer review literature supporting the expert assessment.

The result of the study is a clear and systematic perspective on current federal workplace oversight for conventional chemicals. The overall finding of Choi and Ramachandran was that "experts in our sample tend to believe that the current oversight system for chemicals in the workplace is not adequate and effective." However, the authors stop short of examining in-depth what this finding might mean to the growing use of nanotechnology — and engineered nanomaterials in particular — in the workplace. Building on the Choi and Ramachandran study, this commentary considers each of the 12 identified characteristics of the current U.S. federal oversight system in light of new and novel materials being introduced into the workplace.

Identified Strengths in the Oversight System for Chemicals in the Workplace

The Clarity of the Statutes or Rules for Implementing the Specific Decisions within the Oversight Framework and Achieving Its Goals

On balance, experts in the Choi and Ramachandran study indicated that there was relatively little ambiguity over what OSHA can and cannot do as far as conventional occupational hazards are concerned. This consensus does not in itself suggest that the agency's legal grounding is robust — merely that it is clear. Nevertheless, it does suggest that there is a firm foundation for evaluating how the existing framework applies to engineered nanomaterials.

In carrying out such an evaluation, there are two considerations that are paramount — assessing the extent to which existing regulations and guidance apply directly to engineered nanomaterials, and assessing where engineered nanomaterials might exhibit novel behaviors that render existing regulations and guidance inadequate.

The OSH Act of 1970¹³ is, in the main, concerned with actions that reduce or remove the likelihood of injury or death in the workplace. Section 5(a)(1) of the Act — often referred to as the General Duty Clause requires that an employer "shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees." This clause provides for broad and unequivocal authority that covers emerging technologies, including nanotechnology, as much as existing technologies. The emphasis is on the potential to cause harm, not the means by which that harm might come about. However, it provides little insight into how harm might be avoided where the agents of harm present new or unusual risks.

OSHA has published a list of standards within the OSHA Act of 1970 that may be applicable to situations where employees are exposed to nanomaterials.¹⁴ These include recording and reporting occupational illnesses and injuries,¹⁵ personal protective equipment, general requirements,¹⁶ eye and face protection,¹⁷ respiratory protection,¹⁸ hand protection,¹⁹ sanitation,²⁰ hazard communication,²¹ and occupational exposure to hazardous chemicals in laboratories.²² These standards address mode of action, and are relevant to scenarios where exposure to nanomaterials might occur — through inhalation, ocular, or dermal routes. However, they do not provide clear guidance on actions to take where nanomaterials might present a different risk than their chemical makeup might suggest.

Other organizations have begun to address the issue of how to work safely with nanomaterials in the workplace. For instance, NIOSH has issued guidance on this matter,²³ and the International Standards Organization (ISO)²⁴ has published a technical report on nanomaterials and occupational health that draws on the NIOSH document. The standards organizations BSI²⁵ and ASTM International²⁶ have also issued guidance documents on specific aspects of working safely with nanomaterials in the workplace.

Nevertheless, these documents generally acknowledge that there is insufficient information to make firm judgments on working safely with some emerging nanomaterials, and that more research and understanding is needed. Thus while the statutes and rules of OSHA are clear, their implementation to nanotechnology overall, and nanomaterials in particular, remains far from clear.

The Amount and Quality of Evidence Used for Particular Approvals

Experts in the Choi and Ramachandran study generally agreed that the OSHA framework for oversight of occupational environments is evidence based. This is a positive attribute for addressing existing occupational hazards, although as Choi and Ramachandran point out, a series of court rulings "have led to a standard setting process that is so slow that thousands of chemicals have no defined occupational exposure limits." Thus while the agency is seen as positively embracing data-driven decisions, the speed with which it assimilates and applies new data on engineered nanomaterials, based on past performance, is likely to be slow. This presents serious limitations to the agency's ability to respond to an increasing number of nanomaterials being introduced into commerce, where small variations in nanostructure for a given substance may lead to significant changes in risk profile.

Weaknesses of the Oversight System for Chemicals in the Workplace

The Development of the Oversight System as Reactive Experts in the Choi and Ramachandran study indicated with considerable consensus that the impetus for developing the original OSHA framework was reactive. This is borne out through Choi and Ramachandran's examination of events leading up to the passing of the OSH Act of 1970.

Whether this indicates a weakness in the system for nanotechnology, however, is not immediately clear. The critical factor is whether the agency remains locked in a reactive mode – maintaining the status quo until events force change - or whether it has developed foresight capacity that enables it to proactively respond to emerging workplace safety issues. While there are few data that enable the agency's proactive capabilities to be assessed, what evidence there is suggests that OSHA remains a reactive organization. The agency's inability to respond effectively to conventional chemical risks is indicative of an organization incapable of taking proactive steps to address emerging risks. This is borne out by a lack of movement towards the agency developing specific guidance on working safely with engineered nanomaterials, even though it has been recognized as an area of importance for some years.

Inadequate Financial Resources in the Development of the Oversight System

Experts in the Choi and Ramachandran study were skeptical about the adequacy of financial resources made available in the development of the current oversight system. However, beyond the possibility of this resulting in deficiencies in the oversight framework — an association not explicitly explored by Choi and Ramachandran — it is unlikely that this factor would be directly relevant to the oversight of nanotechnology.

Lack of Transparency as an Attribute of the System

Participants in the Choi and Ramachandran study were asked about the extent to which interested parties can obtain information on decisions that are being made within the workplace safety oversight framework. On balance, the group was of the opinion that information related to decision making is not always easily accessible, although this was not a strong opinion. Choi and Ramachandran noted that the literature is divided on the issue of transparency, but concluded that there are valid concerns in some quarters that not all decisions made by OSHA are open and transparent.

In the context of nanotechnology, lack of transparency raises two key issues: ensuring that the decision-making process is responsive and adequate, and providing assurances of adequate oversight to stakeholders — in particular to workers and their employers. While the issue of regulatory transparency and nanotechnology has not been raised previously in the context of workplace safety, it has come up in more general discussions concerning the regulation of nanomaterials.²⁷

Based on the scientific literature, it is clear that some engineered nanomaterials will present unconventional occupational risk profiles.²⁸ At some point therefore, it is likely that decisions will need to be made by regulatory authorities on specific steps to avoid harm from these materials. Confidence in these steps — and their ultimate effectiveness — will depend in part on how transparent OSHA is in the process of developing them. Choi and Ramachandran highlight discussions around the use of non-consensus standards in workplace safety and health that, it is argued, do not allow for full stakeholder input. The result is standards that are mistrusted and contested — and consequently are less effective than they could be.

Poor transparency in developing engineered nanomaterial-specific oversight could result in ineffective agency actions that do not adequately address the potential occupational risks associated with emerging materials. However, there is also a danger that overpedantic approaches to transparency could delay the development of urgently needed guidance. Ideally, solutions are needed that enable rapid yet transparent responses to challenges raised by nanomaterials in the workplace, which can draw on resources from a range of sources.

Minimal Data Requirements on Health Effects from Companies

Experts in the Choi and Ramachandran study were of the opinion that regulatory information required by OSHA from industry is, on balance, not as comprehensive as it is desirable, and that the agency's regulatory authority to address non-compliance is lacking. The experts did not comment directly on the impact of poor information provision on workplace safety. However, the paper's authors cite a number of studies indicating that increased regulation enforcement leads to increased regulatory compliance, and decreased injuries and pollution levels.²⁹

These are generic issues, and not specific to nanotechnology. Engineered nanomaterials are not unique in presenting possible workplace safety issues because of inadequate and poorly enforced information flow from industry to the regulator. However, novel risks potentially associated with some nanomaterials could exacerbate this weakness in the oversight framework. If data requirements for the safe use of specific nanomaterials are unclear, then there is an increased chance of inadequate data requirements being established by the regulator, insufficient data reporting by industry, and ineffective compliance enforcement. This is a weakness that could be reduced through clear rulemaking and guidance on working safely with engineered nanomaterials. Lack of Flexibility in Unique or Urgent Situations

Choi and Ramachandran note that it is often argued that OSHA inspectors are constrained to "go by the book," with limited flexibility to tackle safety problems not covered in regulations. This perspective was backed up by a low score from experts in the study when asked about the ability of the oversight framework to be flexible in unique or urgent situations, or when new information is obtained. When faced with a new hazard, the agency has the authority to issue Emergency Temporary Standards (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." However, as Choi and Ramachandran point out, since its inception, OSHA has only issued nine ETS, and has issued none during the past two decades.

are few nanomaterials where definitive data exist on the risks to human health, these examples suggest that treating some nanomaterials in the same manner as their non-nanoscale counterparts may lead to harmful exposures.

Even with a robust strategic research program addressing the impact of nanomaterials on human health, the rapidity with which new novel materials are being developed and used suggests that risk data will increasingly lag behind exposure in the workplace. Ensuring workplace safety with these materials will depend to a large extent on developing flexible and innovative occupational health practices and oversight approaches.

Inadequate Resources Including Expertise, Personnel, or Financial to Appropriately Handle Decisions

Poor flexibility in the face of new potential hazards does not bode well for OSHA's ability to respond to challenges associated with the use of engineered nanomaterials.

Poor flexibility in the face of new potential hazards does not bode well for OSHA's ability to respond to challenges associated with the use of engineered nanomaterials. Where new nanomaterials present a different hazard and exposure potential to nonnanoscale forms of the substance, workplace safety will depend on eschewing conventional approaches to occupational safety if they exacerbate the likelihood of harm occurring. For instance, research has suggested that nanoscale titanium dioxide is more potent if inhaled than is an equivalent mass of non-nanoscale material,30 and a draft recommendation from the National Institute for Occupational Safety and Health (NIOSH) proposes a Recommended Exposure Limit (REL) for nanoscale TiO2 of 0.1 mg/m3 - 0.067 times lower than the REL for non-nanoscale TiO2.³¹ Similarly, BSI – a British standards organization - has recommended approaches to establishing informal nanomaterial-specific exposure levels in the absence of specific hazard information.32 At the opposite end of the spectrum, there are cases of Materials Safety Data Sheets recommending carbon nanotubes be handled as graphite,³³ despite research suggesting some forms of the material could be as harmful as crystalline quartz, or amosite asbestos.³⁴ While there In assessing the current oversight system, experts gave the criterion covering capacity the lowest score amongst all criteria. As Choi and Ramachandran note, OSHA's resources have been falling as the number of workers covered by the OSH Act of 1970 have been rising. Davies notes that "OSHA traditionally has been starved for resources. In FY 1980 there were 2,950 OSHA employees. Twenty-five years later, with a greatly expanded

economy and a larger number of workplaces, there were 2,208 OSHA employees."³⁵ While it can be argued that greater efficiency has enabled the agency to be more effective with fewer resources, this was not a view generally shared by the study experts, who included OSHA employees.

Where new technologies demand new occupational safety assessments, approaches, and decisions, access to adequate expertise, personnel, and funding is essential. Engineered nanomaterials in particular present unconventional challenges that will require a new level of understanding of the potential risks, together with new approaches to managing risks. If resources are not available to develop and use this new understanding, it is hard to imagine how appropriately informed and relevant decisions on workplace oversight will be developed.

Inadequate Incentives for Compliance with System Requirements

An oversight system that provides limited incentives for compliance when addressing conventional hazards is unlikely to be more responsive to emerging hazards. This would appear to be a generic issue with the oversight system and not one that has special relevance to nanotechnology. Nevertheless, it can be argued that the emergence of a new technology (and an associated new set of occupational hazards) could be used to explore novel approaches to compliance. The Nano Risk Framework developed by DuPont and the Environmental Defense Fund³⁶ is an example of how a lifecycle-based approach to product stewardship that includes occupational safety can underpin long-term nanotechnology-based product (and market) sustainability. Although a non-government initiative, this and similar concepts may provide inspiration for nanotechnology oversight mechanisms that encourage and reward safe working practices.

Insufficient Compliance and Enforcement

Very simply, if the current oversight system is perceived as failing with conventional substances and hazards, it is unlikely to be any more responsive to emerging hazards without changes being enacted.

Little Information for Workers about Their Level of Exposure and Risk

In the Choi and Ramachandran study, this issue was associated with informed consent: stakeholders', patients', or the public's ability to know, understand, and choose their exposure and the amount of risk, as related to chemicals or trials. The question to the experts was formulated as: "To what extent does the system supply the amount and type of information so that people can make informed decisions about what they will accept?" In evaluating the responses, it is somewhat difficult to establish whether the experts felt that workers had little access to information, or whether members of the public outside the workplace had little access to information. The distinction is an important one, as it separates people who will (in principle) have some ability to influence what they are exposed to from those who have little or no influence.

While the experts felt on balance that information for informed consent was lacking, there was a large spread in the responses received. Nevertheless, the issue raises the question of whether increasing access to information could help improve workplace safety with engineered nanomaterials, and the extent to which this should be an integral part of, or complementary to, an oversight framework. Given the current paucity of information on appropriate exposure levels and work practices, it may be difficult to argue that improving workplace safety through increasing worker access to information is a high priority for OSHA. Nevertheless, this is an area in which non-regulatory organizations, including NIOSH, standards organizations, and professional bodies could well take a lead.

Lack of Post-Market Monitoring

Experts in the Choi and Ramachandran study were asked if there is a science-based and systematic process for detecting risks and benefits after commercial release of a material. On balance, the group felt that provisions for adverse effects monitoring are limited.

While it is not clear how this response relates to occupational health surveillance schemes currently in place, it does raise the issue of health surveillance related to engineered nanomaterials — for which there are no current specific requirements.

Occupational health surveillance and nanotechnology has been raised as an issue by NIOSH in "Approaches to Safe Nanotechnology: An Information Exchange with NIOSH."³⁷ In February 2009, NIOSH issued interim guidance for public review and comment on medical screenings of workers potentially exposed to nanoparticles.³⁸ The guidance states:

Insufficient scientific and medical evidence now exists to recommend the specific medical screening of workers potentially exposed to engineered nanoparticles. Nonetheless, the lack of evidence on which to recommend specific medical screening does not preclude its consideration by employers interested in taking precautions beyond standard industrial hygiene measures.

The interim document recommends that employers take prudent measures to control exposure to nanoparticles, conduct hazard surveillance as the basis for implementing controls, and consider established medical surveillance approaches to help assess whether control measures are effective and identify new or unrecognized problems and health effects.

Paul Schulte et al.³⁹ discuss the state of science and options for occupational health surveillance of workers potentially exposed to engineered nanoparticles. The authors note that, given a paucity of information on specific health effects associated with engineered nanoparticles, it is difficult to identify an appropriate evidence-based occupational health surveillance strategy for workers handling nanomaterials. As a consequence, they suggest that hazard surveillance rather than medical surveillance may be more appropriate at this time. Beyond this suggestion, Schulte et al. assess the appropriateness and applicability of health surveillance approaches along a continuum ranging from no action at one extreme to targeted medical testing at the other. While health surveillance associated with using engineered nanomaterials in the workplace may become an oversight issue in the future, it appears on balance that the current state of the science supports non-regulatory ad hoc approaches that are responsive to specific circumstances.

Summary

Choi and Ramachandran's study reveals a number of weaknesses in the current U.S. federal workplace safety oversight framework — as identified by expert opinion and MDCA, and corroborated by the peer review literature. There is little reason to suppose that these weaknesses will be less relevant to engineered nanomaterials than they are to more conventional substances. On the contrary, examination of 12 characteristics of the current oversight framework derived from the study suggests that the novel behavior of some engineered nanomaterials will further stress an already weak system.

In general, the OSHA regulatory framework addresses the potential of a substance or situation to cause harm, rather than the manner in which harm is caused, and in this respect, engineered nanomaterials come under the existing oversight umbrella. However, without better information on how the physical and chemical nature of engineered nanomaterials determine health risk, or how exposure is best monitored and controlled, compliance with conventional health and safety requirements cannot be guaranteed to protect workers in all cases. Thus, action is needed if workplace regulations are to keep pace with nanotechnology innovation.

The Choi and Ramachandran study should be interpreted with caution, given the limitations of the expert pool and the divergence in opinions provided. Nevertheless, it provides useful insight into potential stress points in the current oversight framework that may impede the safe handling of engineered nanomaterials if left unaddressed. Three areas in particular come to the fore as requiring attention when examining the current regulatory framework: resources, flexibility, and information. Without substantial increases in funding, personnel, and expertise, it is unlikely that OSHA will have either the capacity or the capability to address emerging and novel challenges such as those presented by engineered nanomaterials. As the number of new materials entering the workplace continues to increase, the agency will need to develop flexible approaches to identifying and reducing potential risks. A reliance on conventional approaches in the face of unconventional challenges will increase the probability of heath impacts that could otherwise be avoided. And finally, it is likely that the agency will need to look at new approaches to generating, sharing, and using information, if the potential for engineered nanomaterials to cause harm is to be understood and managed.

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