

Dose-Response: An International Journal

Volume 10

Issue 3 *Special Issue on Nanomaterials*

Article 11

9-2012

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Recommended Citation

Bashaw, John (2012) "HAZARDOUS SUBSTANCES, CERCLA, AND NANOPARTICLES – CAN THE THREE BE RECONCILED?," *Dose-Response: An International Journal*: Vol. 10 : Iss. 3 , Article 11.

Available at: https://scholarworks.umass.edu/dose_response/vol10/iss3/11

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HAZARDOUS SUBSTANCES, CERCLA, AND NANOPARTICLES – CAN THE THREE BE RECONCILED?

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□ Toxicology research in the nanotechnology area has focused primarily on human inhalation, ingestion or dermal exposure. Less research has been published on the impact to ecological systems resulting from a release of nanomaterials. Environmental laws such as CERCLA (“Superfund”) address the release of “hazardous substances” by obligating the party releasing the substance to (a) report the release and (b) investigate the nature and extent of the release and to then remediate it to some objective cleanup standard. Applying this regime to the release of nanomaterials, however, is complicated. First, is the nanomaterial a hazardous waste, toxic substance, or hazardous substance as defined under the environmental laws? A compound that may be defined as hazardous or toxic could have properties at the nano level that are distinctly non-hazardous. Second, what constitutes a release of a nanoparticle that would require reporting under applicable environmental laws? Typically, release reporting is based upon the weight of the hazardous substance that is released, but for nanomaterials a weight threshold might be meaningless. Third, how do you sample nanoparticles in the field and analyze them using existing instrumentation? There are few approved tests for nanomaterials. Fourth, how do you determine an objective risk-based cleanup standard for the thousands of possible nanomaterials?

Keywords: Nanoparticles, CERCLA, hazardous substances, hazardous wastes, toxic substances

INTRODUCTION

This article discusses the release of nanoparticles into soil and groundwater and the regulatory impact of such releases. There is little scientific data on the environmental impact of released nanoparticles, and, in fact, the majority of the data focuses on the release of biocidal silver nanoparticles during the washing of nano-enabled clothing (Geranio et al. 2009). Additionally, there is some research indicating that uncoated fullerenes have an effect on certain fish when exposure levels are high (Oberdörster 2004).

While most releases are accidental, there are circumstances where the release is *purposeful*. For example, nano zero-valent iron (“nZVI”) has been injected into groundwater to remediate chlorinated solvents, and

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gold and palladium nanoparticles have been used to break down pollutants in groundwater (Wong et al. 2009). The Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars has identified at least 60 sites in seven countries where nanotechnology is being used to remediate soil and groundwater contaminants. However, little data is available on the impact of such released nanoparticles to the environment, or the effect of breakdown compounds as the nanoparticles attack the contaminants.

EPA recently announced an internal working definition of nanomaterials as “an ingredient that contains particles that have been intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers” (Jordan 2010). The unique physical and chemical properties of engineered nanomaterials impart specific characteristics. These characteristics include particle size, shape, surface area, charge, chemical properties, solubility, oxidant generation potential and degree of agglomeration. Importantly, the unique physical and chemical properties of engineered nanoparticles can make them *entirely distinct* from related compounds. It is this distinction that challenges the existing paradigms for regulating hazardous substances that are released to the environment. The question is whether releases of nanoparticles can, or should, be regulated in the same way that we currently regulate releases of hazardous or toxic substances, or hazardous wastes.

ARE NANOPARTICLES HAZARDOUS SUBSTANCES UNDER CURRENT STATE AND FEDERAL ENVIRONMENTAL LAWS?

The answer to this question is important because it is the first question that must be answered in the affirmative before determining if there are release reporting obligations and site remediation requirements. Under the federal Comprehensive Environmental Response, Compensation and Liability Act, otherwise known as CERCLA or Superfund, 42 U.S.C. § 9601 *et seq.*, a hazardous substance is any substance, material, compound, element, mixture or solution that is designated or listed under a broad array of federal environmental laws. The term includes materials defined as hazardous waste under the Resource Conservation and Recovery Act (“RCRA”), 42 U.S.C. § 6901 *et seq.*, and toxic substances under the Toxic Substances Control Act (“TSCA”), 15 U.S.C. § 2601 *et seq.*, but it excludes petroleum compounds. Suffice it to say that hazardous substances include a wide universe of compounds and materials. Currently, specific nanomaterials are not listed under any of these federal laws.

Even if not listed, a compound or material can still be a hazardous substance under CERCLA through a provision in RCRA which states that any compound or material that is corrosive, reactive, toxic, or ignitable is a hazardous waste under RCRA, and thus is also a hazardous substance

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under CERCLA. Such materials are referred to as characteristic wastes and classification as such depends on whether or not a compound or material passes or fails certain analytical tests. For example, under Section 261.24 of Title 40 of the Code of Federal Regulations, a waste material that contains silver at concentrations exceeding 5 mg/l (ppm) using the TCLP or SPLP analytical tests, is a hazardous waste. Currently this is the only means, absent an explicit listing under one of the key federal environmental statutes, for a nanomaterial containing silver to be classified as a hazardous substance under CERCLA – it must fail the toxicity test under RCRA. Unless the concentration of silver is substantial, it is highly unlikely that a nanosilver compound will fail this test. Thus, for all practical purposes, most nanoparticles will not fall under the classification of a hazardous waste, hazardous substance or toxic substance under current federal regulatory programs.

This result creates a follow-up question - how should we classify nanoparticles, if at all, for purposes of release reporting and remediation? EPA has addressed this issue only within the context of TSCA and only with respect to determining if an engineered nanoparticle is a new or existing chemical substance. In January, 2008 EPA published a General Approach in which EPA decided that it would treat nanoparticles in the same manner that it historically has treated all other chemical substances (EPA 2008). In determining whether or not a nanoparticle is a new chemical substance, EPA first considers whether the macro form of the particle is already listed as one of the 83,000 chemical substances on the TSCA inventory. If it is already listed, then it is considered to be an existing chemical substance and thus does not undergo additional regulatory scrutiny. The focus is solely on the molecular identity of the nanoparticle and not the physical attributes that often make nanoparticles so unique. The problem with this approach is that a nanoparticle may have the exact same molecular identity as a listed chemical substance (i.e., it has the same spatial arrangement of atoms and the same types of chemical bonds) but it might behave completely different. Under EPA's General Approach, the nanoparticle is not subject to regulation as a new chemical substance. However, Steve Owens, head of EPA's Office of Pollution Prevention and Toxics, has recently suggested that EPA may change this General Approach but the manner of the change has not been publicized.

While not directly applicable to the classification of nanoparticles as hazardous substances, the philosophy behind EPA's General Approach would suggest that if a compound such as silver is listed as a hazardous substance under CERCLA or the Federal Water Pollution Control Act ("CWA"), 33 U.S.C. § 1251 *et seq.*, then the nanof orm of that material would also be a hazardous substance even if the nanof orm behaved completely different from its larger cousin and was completely harmless. Also, a nanoparticle that exhibits one of the characteristics of a hazardous

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waste under RCRA would still be a hazardous substance under CERCLA. But as noted above, the likelihood of that occurring for most nanoparticles appears remote.

WHAT ARE THE CHALLENGES OF REGULATING NANOPARTICLES AS HAZARDOUS SUBSTANCES?

Assume for the remainder of this paper that EPA has determined to list a specific nanoparticle as a hazardous substance under CERCLA or the CWA. Based upon the discussions herein, the following two problems (and numerous sub-problems) arise: (1) what would the Reportable Quantity, or RQ, be for the nanoparticle for purposes of release reporting under federal law; and (2) how does one investigate and remediate a release of the hazardous nanoparticle?

RELEASE REPORTING UNDER CURRENT FEDERAL ENVIRONMENTAL LAWS

There are several state and federal laws that may apply when a hazardous waste, hazardous substance or toxic substance is released into the environment. A survey of each states' reporting requirements and each of the federal environmental statutes is beyond the scope of this article. The two federal statutes of most relevance to the reporting of accidental releases of contaminants to the environment are the CWA and CERCLA. Both laws have similar language concerning the reporting of releases of hazardous substances to the environment. For example, CERCLA provides that,

“Any person in charge of a vessel or an offshore or an onshore facility shall, as soon as he or she has knowledge of any release (other than a federally permitted release or application of a pesticide) of a hazardous substance from such vessel or facility in a quantity equal to or exceeding the reportable quantity determined by this part in any 24-hour period, immediately notify the National Response Center . . .”
40 C.F.R. § 302.6(a).

The key questions concerning a reporting obligation are (1) is the released material a hazardous substance as defined in the statute, and (2) what is the quantity of the substance that was released? Both federal laws contain long lists of the chemicals that constitute hazardous substances (see 40 CFR Part 302 and 40 CFR Part 117). For each hazardous substance, CERCLA and the CWA list the threshold quantity of material that must be released in order to trigger a reporting obligation. This threshold quantity is referred to as the Reportable Quantity, or RQ. There is an additional question in considering the obligation to report a release under CERCLA, which is whether or not there has been a release to the

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environment. Generally speaking, any release of a hazardous substance outside the confines of a building is a release to the environment for purposes of CERCLA. Under the CWA, the reporting obligation arises when there is a discharge to a navigable water of the United States. (While a discussion of individual state reporting statutes is beyond the scope of this article, it is worth noting that some state reporting obligations are not based upon the quantity of material released. Instead, any quantity of hazardous waste, toxic substances or hazardous substances released into the environment may be reportable to a state environmental agency.)

There are hundreds of listed hazardous substances under both federal statutes. Some of those substances are used in engineered nanomaterials. As noted previously, silver is listed under both CERCLA and the CWA as a hazardous substance and silver has a reportable quantity of one pound under CERCLA. You can imagine, however, that it would take a lot of silver nanoparticles to exceed one pound. Also, one pound is on the low end of the reportable quantities. Many hazardous substances do not require reporting until the release threshold exceeds ten to five thousand pounds.

The RQ for reporting the release of a nanoparticle, as well as the objective remediation criteria that will be discussed below, should be based upon a scientific risk-based assessment of the particular nanoparticle. The question is where will that risk data come from? There are literally thousands of potential engineered nanoparticles. It is simply unrealistic to think that EPA will establish a separate RQ for each and every nanoparticle that is produced. A more realistic approach is to set RQs by categories of nanoparticles, but this will require a major paradigm shift in how we currently regulate hazardous substances. Currently, under TSCA the burden is on EPA to show that a chemical substance is hazardous. Until that burden is met by the agency, the chemical substance continues to be produced. EPA is considering regulatory action to obtain data from nanoparticle manufacturers under TSCA - A shift in the paradigm. It does make more sense to have that information as part of the life-cycle assessment when a nanoparticle is introduced into commerce, as opposed to making that determination late in the game at the time of disposal. What is also clear is that arbitrary RQs such as one, ten or five thousand pounds don't work for nanoparticles because rarely would they ever be released in such quantities. Under some circumstances, depending upon the nature of the nanoparticle, an extremely small release might be quite significant to human health and the environment.

SITE INVESTIGATION AND REMEDIATION OF RELEASES TO SOIL AND GROUNDWATER

The obligation to investigate and remediate a release of a hazardous substance or other defined pollutant once again varies depending upon the applicable federal or state statute at issue. However, if we treat

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nanoparticles in the same manner we treat hazardous substances, the investigation and remediation of nanoparticle releases would follow a familiar and common progression:

- Identify the location of the release
- Determine the nature and extent of the release
- Identify the cleanup standard that will apply to the compound that has been released
- Develop a remediation plan that assesses the options available to achieve compliance with the cleanup standard
- Implement the remediation plan
- Conduct post-remediation sampling and monitoring to determine the effectiveness of the remediation program

Following this progression, a typical environmental remediation program for the remediation of soil contaminated by nanoparticles would go something like this: first a Phase I Environmental Site Assessment (“ESA”) would be performed to identify Areas of Concern (“AOC”) where the particles may have been released as a result of site activities. Areas where the particles may have been stored in open, uncovered containers exposed to rainwater would be listed as an AOC as would any vents where nanoparticles might have been discharged through the air. Loading docks where the materials were transferred to and from the facility might also be listed. Second, after creating a list of AOCs, the environmental consultant performing the work would typically determine through Phase II sampling if there had been a release of nanoparticles at these AOCs. The Phase II would minimally consist of the collection of soil samples within the AOC and might even include the installation of groundwater monitor wells to assess groundwater conditions. Based upon the Phase II, some or all of the AOCs might be excluded from further investigation.

If nanoparticles are detected in an AOC, the work would progress to a Phase III ESA which would focus on the release area. Additional soil borings and monitor wells might be installed to determine the full nature and extent of the contaminated soil area and any groundwater impacted by the contaminants. Using this data, the consultant would identify applicable cleanup standards for the release area and would then formulate remediation options. The options would be narrowed down with the client and consultant (sometimes with agency and public input) settling on a single remediation plan. The plan might involve *in situ* treatment of the contaminants, or it might involve contaminated soil and/or groundwater removal. The choice depends on numerous physical site characteristics, economics, proposed future site use and regulatory obligations. After the remediation plan has been fully implemented, the final step of the remediation process is to sample the post-remediation soils and

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groundwater to determine compliance with the cleanup standards and to then monitor conditions over several years to assure that contaminant levels have not rebounded.

What is important to note is that almost all cleanup standards for environmental remediation are based on an assessment of the risks to human health and the environment for the particular contaminant at issue. In some states, objective remediation criteria have been established. For example, in Connecticut silver located in the upper four feet of soils generally must be remediated to 340 mg/kg (ppm) for residential use of the property, and to 10,000 mg/kg (ppm) for commercial and industrial uses. In other states, remediation criteria is established using formulas to calculate site specific standards based upon potential risks and exposure. The common factor is that risk assessment of some kind goes into determining the remediation criteria for a particular compound.

The challenges for investigating and remediating a release of a hazardous nanoparticle are daunting. Not only do you have the concern over establishing a risk-based cleanup standard for a particular nanoparticle, but you have the physical challenge of adequately sampling for particles measured in units of a billionth of a meter, and then finding instrumentation sensitive enough to measure such materials. Add to that the diversity and volume of different nanoparticles that will be produced over the next few years. Perhaps there should be a burden on any person who has released a nanoparticle to show through existing studies, or new studies, that the material is not toxic to human health or the environment. Failure to satisfy that burden would result in a remediation obligation. But this creates one large public policy hurdle – it looks very much like the precautionary principle that the European Union has adopted for nanoparticles under REACH (Registration, Evaluation and Authorisation of Chemicals). The general theory behind the precautionary principle is that a new chemical substance is presumed hazardous unless proven by the manufacturer to be otherwise. Many legislators in the United States have made it very clear in considering proposed revisions to TSCA that they will not support anything that looks or smells like the precautionary principle. Furthermore, this approach is too simplistic – it is one thing to say “clean it up”, but it is something quite different to say “and clean it up to x or y standard.” What is that standard? We are dealing with compounds and materials that might be here today, and gone tomorrow. The one thing that underlies this whole issue, however, is the need for better toxicology data on impacts to the environment as well as to human health.

CONCLUSION

Nanoparticles create a world of benefits and possibilities for just about every existing technology and industry sector. Nanoparticles will improve our ability to treat disease, they will allow us to better and more

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efficiently clean up our environment from historic use of toxic chemicals, they will make many of our materials, faster, lighter and stronger, and they will increase our energy efficiency. However, many of the nanoparticles that have been produced, and will be produced in the future, create their own potential hazards to the environment. Currently our legal framework is not well-adapted to identify and address nanoparticle contamination. Existing regulatory paradigms will require substantial modification to address the release of hazardous nanoparticles and our technical abilities to detect and remediate such releases must be enhanced. The very first step in this process is the continued focus on assembling the necessary life-cycle toxicity data for all engineered nanoparticles. In order to accomplish this task, manufacturers of the nanoparticles will necessarily begin to carry more of the burden in providing this data because regulatory agencies are just not equipped to assess the diversity and quantity of nanomaterials that will be produced. While adoption of the conservative precautionary principle may be excessive, continued reliance on existing paradigms that address conventional hazardous substances also do not work.

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