Nanotechnology Briefing Paper

Clean Water Act

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EXECUTIVE SUMMARY

The purpose of this briefing paper is to evaluate the existing statutory authority under the Clean Water Act (CWA or Act) to regulate nanotechnology and nanoparticles. One of the stated national goals of the CWA is the elimination of the discharge of pollutants into the navigable waters. Accordingly, the CWA generally provides the U.S. Environmental Protection Agency (EPA) with authority to regulate the discharge of “pollutants” consistent with this national goal. The term “pollutant” is defined fairly broadly so that nanoparticles discharged into a navigable water would likely be subject to regulation under the Act as a discharge of a pollutant. Thus, there appears to be adequate existing authority under the CWA that would allow EPA to regulate nanoparticles.

Although EPA likely has the authority to regulate nanoparticles, however, it would also likely be necessary for EPA to demonstrate that certain nanoparticles (e.g., specific compounds or a class or category of nanoparticles) have a potential adverse effect on human health or the environment, thus making regulation of the nanoparticle necessary and appropriate under the CWA. To this end, further research and study would likely be necessary. In addition, before any meaningful regulation could be implemented, the technology must be developed that would allow nanoparticles to be accurately monitored, measured, and controlled.

In light of the above, and by way of illustration, this paper evaluates specific sections of the CWA that have some readily apparent relevance to the regulation of nanoparticles and generally considers the following four questions:

1. Does the section have any applicability to the regulation of nanoparticles? In other words, is the section of any use to EPA if it were to find that regulation was necessary and appropriate?

2. If so, does the section provide EPA the authority to regulate nanoparticles?

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2 The American Bar Association’s Section of Environment, Energy, and Resources is neither advocating for nor against the environmental regulation of nanoparticles. This analysis only serves to inform EPA on how it could use existing legal authority, or where additional legal authority is required, to regulate nanoparticles should it choose to do so.
3. What are the technical, legal, or other problems involved in the application of this section to nanotechnology due to the unique nature of nanoparticles?

4. What are the options for dealing with such problems?


EPA may include nanoparticles as a regulated pollutant pursuant to Sections 301(g)(4) and 307(a). In doing so, EPA will have to place nanoparticles in a particular class of pollutants -- conventional, toxic, or non-conventional. CWA Section 301 requires EPA to set technology-based effluent limitations for point source discharges; CWA Section 307 requires the establishment of toxic and pretreatment effluent standards. EPA, under these sections, has the authority to establish technology-based effluent limitation guidelines and standards for nanoparticles discharged from a point source. EPA also has the authority, pursuant to CWA Section 307(b), to establish pretreatment standards for those facilities that discharge to a publicly-owned treatment works.

The main problem for addressing nanoparticles will be determining the best available technology that is economically feasible for regulated entities. Nanotechnology is still being developed and very little is known about the availability of technology to control nanoparticles in wastewater streams. EPA should consider extensive research projects, including collaborative efforts with regulated entities, and the use of technology-forcing regulations to ensure the development of appropriate control technologies.

II. WATER QUALITY RELATED EFFLUENT LIMITATIONS (CWA § 302, 33 U.S.C. § 1312)

CWA Section 502(6) defines the term “pollutant” so broadly as to include virtually any material added to a watercourse. Accordingly, for purposes of analyzing the application of the water quality provisions of the CWA to nanoparticles, it can be assumed that all the provisions of the Act dealing with the creation of and implementation of water quality standards will apply to the discharge of any form of nanoparticles to any water of the United States covered by the Act.

Section 302 of the CWA allows the EPA to create and modify water quality-related effluent limitations whenever EPA determines that the technology-based effluent limits created under CWA Section 304 are not sufficient to protect the affected waters to the degree required under the Act. The section further allows EPA to modify such water quality-based effluent limitations on economic or technical grounds, with certain special considerations in the case of toxic pollutants.

In the case of nanoparticles, it will be a necessary prerequisite for application of this section that there be a reasonably accurate scientific basis on which to make a judgment that the quality of the affected water is adversely affected by the addition of nanoparticles to the water body. While any detailed description of the process is beyond the scope of this paper, the
general outlines of the analysis can be described. First, unless there is a determination that nanoparticles are *per se* harmful, the toxicity or degree of pollution will probably be extrapolated based on the known toxicity of the same materials in non-nano quantities. So, for example, since lead is harmful as a pollutant in some quantity, EPA may assume it is harmful in smaller quantities, and act accordingly by prescribing some form of pollution abatement based on best available technology. If, on the other hand, an assumption of harm is not allowed, EPA will be required to develop data to show that the nanoparticles do in fact cause harm to the water body before it can invoke the jurisdiction of CWA Section 302.


Section 303 of the CWA provides for the adoption of state water quality standards by EPA and for the periodic revision of such standards on a three-year cycle. The burden of the section is to ensure that the state standards as approved by EPA are consistent with federal guidelines established by EPA under those provisions dealing with technology-based water quality standards, toxic effluent limitations and water quality-based effluent limitations. The section also provides for the identification of water bodies not meeting federal/state criteria, and for such water bodies, the creation of Total Maximum Daily Load (TMDL) programs.

Since there are (in all likelihood) no existing state or federal criteria for nanoparticles as such, the application of Sections 1313 and 1313a to such materials will necessarily await the development of such criteria. It is possible, however, that there may be some materials already regulated by EPA for which the applicable criteria may apply to such materials in nano form. For example, if nanoparticle X is discharged to a water body in such amounts as to be measurable at levels in excess of some existing criterion value for material X, that discharge would be subject to the provisions of CWA Section 303.

IV. INFORMATION AND GUIDELINES (CWA § 304, 33 U.S.C. § 1314)

Section 304 of the CWA provides in pertinent part that EPA shall create water quality standards for all waters of the United States for any and all pollutants, to create technology-based effluent limitations to be imposed under the National Pollutant Discharge Elimination System (NPDES) program, and to create individual control strategies for toxic pollutants. The section also provides for evaluation of and control of nonpoint source pollutants.

With respect to nanoparticles, this element of the EPA authority will in all likelihood be the most challenging. In order to create applicable water quality standards, EPA will be required to assemble a reasonable database covering all known effects of specified nanoparticles in water bodies. Such information will necessarily include toxicity studies, biological and chemical effect studies, transport/deposition data, uptake and bioaccumulation information and a host of other data to evaluate the possible adverse effects of specific nanoparticles on biological organisms, including humans. As one example, there is a recent study of “buckyballs” (carbon nanoparticles) and their effect on two aquatic species, bass and water fleas. The data showed an adverse effect on brain tissue. Such studies must be collected
and peer-reviewed before they can be used to create water quality standards that can be used to create applicable discharge criteria. Likewise, EPA will have to evaluate appropriate discharge control mechanisms to determine if they are technologically viable and economically achievable. As suggested above, it is possible that EPA can use data previously gathered on known pollutants (i.e., lead, cadmium) to extrapolate effects of such materials in nanoparticle form, although such extrapolation must be scientifically defensible in light of such principles as threshold effects.

V. STATE REPORTS ON WATER QUALITY (CWA § 305, 33 U.S.C. § 1315)

CWA Section 305 provides for the reporting of the states’ progress in implementing the provisions of the CWA to Congress. Given the state of knowledge concerning nanoparticles, it is unlikely that the states will have much to report until the scientific database expands, and EPA has created applicable water quality standards and criteria, including effluent limitations. Once the requisite data are collected, and are implemented in the form of state/federal regulations, effluent limitations, and applicable permit conditions, states will be required to include data on nanoparticles as part of their biennial reports.

VI. NATIONAL STANDARDS OF PERFORMANCE (CWA § 306, 33 U.S.C. § 1316)

CWA Section 306 pertains to national standards of performance as a means to control the discharge of pollutants. National standards of performance are based on best available demonstrated control technology, processes, or operating methods for sources within a list of categories (e.g., pulp and paper mills, organic chemicals manufacturing). The list of categories may be revised by EPA from time to time to incorporate the pertinent category of sources discharging nanoparticles, if not already within the listed categories. CWA Section 306 allows EPA to consider other factors such as the cost of achieving the reduction of nanoparticles in effluent, as well as any non-water quality, environmental impact, and energy requirements in establishing national standards. The existence of such technology or other demonstrated control alternatives for nanoparticles is a prerequisite to regulation under Section 306, and the standards are subject to change by EPA as technology and alternatives concerning nanoparticles change.

As with CWA Sections 301 and 307, advancement in science and technology are key to establishing the appropriate standards for regulating nanoparticles and achieving a reduction of nanoparticles in effluent. Additional research is required to determine whether nanoparticle performance standards should be added to existing point source categories or whether the nanotechnology industry itself will require the creation of its own category.

VII. RECORDS AND REPORTS; INSPECTIONS (CWA § 308, 33 U.S.C. § 1318)

CWA Section 308 may be EPA’s best tool presently to gather data on nanoparticles that may be discharged to waters of the United States. Congress and other regulatory agencies are currently in an “information gathering” mode with respect to nanotechnology and its effects on the environment, and the most effective way EPA can participate in that effort is to invoke Section 308 to gather data and require monitoring from nanoparticle users and manufacturers. This section grants the Administrator broad authority to require the owner or operator of a point source to maintain records, make reports, perform
monitoring and sampling, and provide information to EPA as is “reasonably” required to carry out the purposes of the Act. Section 308 also gives EPA the ability to enter and inspect facilities of an “effluent source,” along with its records.

The power to gather information does not need to be used in anticipation of an enforcement action as courts have interpreted Section 308 broadly. “The breadth of this statutory grant of authority is obvious. In our view, the statute’s sweep is sufficient to justify broad information disclosure requirements relating to the Administrator’s duties, as long as the disclosure demands which he imposes are ‘reasonable.’” In NRDC, the D.C. Circuit upheld EPA’s ability under Section 308 to require NPDES permit applicants to list all toxic pollutants currently used or manufactured as an intermediate or final product or byproduct. Thus, EPA was not limited to information related to toxic pollutants in a facility’s effluent discharge -- it could obtain information under Section 308 on all toxic pollutants at a facility, because they could be discharged from the facility. Therefore, if a facility that uses or manufactures nanoparticles is discharging to waters of the United States, EPA could utilize Section 308 to inspect the facility, obtain records, require discharge monitoring, and make reports to EPA to gain more information on the nature of nanoparticle discharges.

While EPA has abundant legal authority to collect data, technical challenges in monitoring and measuring nanoparticles in an effluent discharge may render Section 308 meaningless. EPA cannot impose unreasonable requirements under Section 308 (i.e., a high-cost experimental monitoring system), so until reasonable and effective monitoring technology is developed for nanoparticles, EPA may be limited to obtaining operational data from a nanoparticle facility. Due to the current difficulty in measuring nanoparticles in water, EPA could take first steps under Section 308 to gather data from facilities on (1) the use and manufacture of nanoparticles and (2) the frequency and volume of any discharges to waters of the U.S. from nanoparticle production facilities. EPA should also work with the scientific community to develop feasible monitoring technologies for nanoparticles, which could then be used for requiring nanoparticle users and manufacturers to install and use Section 308 monitoring and reporting programs.

VIII. ENFORCEMENT (CWA § 309, 33 U.S.C. § 1319)

CWA Section 309 governs enforcement of the CWA’s pollutant-regulation provisions. If added as a pollutant under Section 309(c)(7), EPA could use this section to enforce nanoparticle standards and limitations. Nanoparticle listings and the ability to enforce whatever standards EPA may set require an appropriate, measurable, and well-defined limit. Continued research into technologies that may effectively measure and capture nanoparticles from discharge effluent is required before EPA begins any enforcement activities.

IX. OIL AND HAZARDOUS SUBSTANCE LIABILITY (CWA § 311, 33 U.S.C. § 1321)

CWA Section 311 regulates discharges of oil and “hazardous substances,” defined under Section 311(b)(2)(A), to the waters of the United States from vessels and onshore and

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offshore facilities. EPA could conceivably designate particular nanoparticles, or specific groups of nanoparticles, as “hazardous substances” under Section 311. These materials, however, currently defy description, classification, and characterization as to what impacts they might have on human health and the environment. If future scientific and political support exists to characterize such materials as hazardous, Section 311 may serve to require cleanup of nanoparticle discharges.

X. FEDERAL FACILITIES POLLUTION CONTROL (CWA § 313, 33 U.S.C. § 1323)

CWA Section 313 simply reaffirms that federal facilities are subject to and must comply with all federal, state, interstate, and local requirements relating to the control and abatement of water pollution. While this section may not serve to add any substantive limitations, federal research, military, and production facilities may be significant sources of potential nanoparticle emissions. Should EPA regulate these discharges, enforcement initiatives involving federal facilities could set significant precedents for nanotechnology management.

XI. NONPOINT SOURCE MANAGEMENT PROGRAMS (CWA § 319, 33 U.S.C. § 1329)

Unlike with point sources, nonpoint source pollution derives from varied and often unidentifiable sources. Rainwater transports a variety of potentially harmful substances, such as sediment, fertilizer, pesticides, agricultural nutrients, motor oil, or salts, into surface and groundwater. There is no formal definition of nonpoint source pollution. CWA Section 319 is structured to accommodate the watershed-to-watershed variability of nonpoint source pollution by vesting most of the responsibility for investigation and control with the states. Among these responsibilities is (1) a state assessment report identifying waters failing to attain water quality standards and significant nonpoint source contributors; and (2) a state management program utilizing best management practices or other methods to control nonpoint source pollution for each watershed. These reports and programs are subject to approval by the Administrator. The remainder of the statute discusses funding and federal cooperation to aid the states in carrying out the listed goals.

The effect of nanoparticles on aquatic life remains largely unknown. Should evidence showing an adverse impact on surface water ecosystems appear, however, states will be obligated to evaluate the extent of water quality impairment caused by nanoparticles added through nonpoint sources. Due to their size, nanoparticles originating from industrial processes, consumer products, or an unknown number of other sources could be easily transported by rain and runoff to water bodies. Deposition of suspended, airborne nanoparticles via raindrops is also a potential source adding to nonpoint source impairment. It is possible that surface waters could become laden with nanoparticles originating from somewhere other than a point source. Should this occur, the statutory structure already in place could adequately track and potentially reduce nonpoint nanoparticle pollution provided that certain prerequisites occur. First, common to all nanoparticle pollution issues, effective measurement technologies and methods must be developed. Secondly, potential sources of nanoparticle diffusion must be identified. This may include everything from residential property to smokestacks, automobile tailpipes, and agricultural operations. Lastly, state agencies must have enough of an understanding of nanoparticles to effectively create and enforce best management practices that prevent
nanoparticles from eventually draining into surface waters, be it through runoff or aerial deposition.

Should nanoparticle impairment become a serious concern, the scientific and technical issues unique to nanoparticles may require some centralization to manage nonpoint source pollution. Best management practices might be best developed at the federal level in the form of product assembly guidelines. Examples could be the requirement of certain types of bonding to prevent nanoparticle deterioration and dispersion over time. Other requirements under the Clean Air Act to limit nanoparticle emissions could prevent suspended nanoparticle deposition in surface waters, similar to the formation of acid rain. Best management practices, however, will most likely require a reactive approach as it is unlikely that they may be designed and implemented until after EPA better understands nanotechnology uses and the fate and transport of nanoparticles in water runoff.

XII. CERTIFICATION (CWA § 401, 33 U.S.C. § 1341)

Applicants for a federal license or permit to conduct any activity that may result in a discharge into navigable waters must obtain certification from the state or an interstate water pollution control agency that the proposed discharge will comply with applicable water quality standards. Under Section 401, this would include any future water quality standards for nanoparticles.

The Section 401 certification process depends greatly on the content of the state’s water quality standards. Most state water quality rules contain provisions prohibiting the degradation of water quality and the impairment of beneficial uses. Given the uncertain state of scientific knowledge regarding the environmental and health effects of nanoparticle discharges, some states might assert that any level of nanoparticle discharge violates state water quality standards and should be prohibited or unduly restricted. EPA could begin developing guidance for states to use in establishing water quality standards for nanoparticles. This approach will be complicated by the fact that each state may decide to develop its own response to this issue pending completion of the EPA guidance.

XIII. NPDES (CWA § 402, 33 U.S.C. § 1342)

The basic features of the NPDES program are: (1) the issuance of point source discharge permits with pollutant-specific numeric effluent limitations based on either technology-forcing standards or water quality protection standards; (2) the measurement of compliance against those effluent limitations by routine and frequent monitoring of effluent quality using standardized sampling and analytical methods; and (3) the routine and frequent reporting of the effluent quality measurements through discharge monitoring reports which are readily available to and understandable by the public as well as regulators.

In the formative years of the NPDES permit program, the effluent limits tended to be technology-based rather than water quality-based. Prior to the development of industry-specific effluent limitation guidelines, NPDES permits tended to be based on the permit writer’s “best professional judgment.” As the program matured, it became more standardized. For
example, the NPDES program now includes prescribed analytical methods,\textsuperscript{4} industry-specific effluent limitation guidelines,\textsuperscript{5} specific toxic pollutant standards,\textsuperscript{6} and national recommended water quality criteria for 128 pollutants issued pursuant to CWA Section 304. Following the 1987 amendments to the CWA, renewed emphasis was placed on water quality issues (including contributions from storm water-related sources and nonpoint sources) and water quality-based effluent limitations. Where water quality-based effluent limitations are unattainable through the application of treatment technology, source-specific “best management practices” are often prescribed in addition to or in lieu of numeric effluent limitations. Best management practices are included as “special conditions” in the NPDES permit form. Other special conditions that have been employed to address unusual situations include: the collection of additional source-specific data and information above and beyond routine effluent quality monitoring; and the performance of special studies, such as ambient stream studies, toxicity reduction evaluations, sediment studies, mixing zone studies, and bioaccumulation studies, all for the purpose of acquiring data and information for future NPDES permit modifications or renewals.

Generally speaking, the discharge of any pollutant from a point source is unlawful unless the discharge is authorized by a NPDES permit.\textsuperscript{7} Presuming the nanoparticle in question is determined to be within the CWA’s broad definition of “pollutant,” the NPDES permit program is applicable to point source discharges of the nanoparticle. In order to fit neatly within the NPDES permit program, the nanoparticle in question must be detectable and measurable through reasonably reliable and feasible sampling and analytical methods. In addition, the nanoparticle must be amenable to available treatment technology.

To the extent that the nanoparticle in question is detectable and measurable, the NPDES permit application process should be able to determine anticipated concentration and mass loading values for the regulated discharge. Similarly the effluent quality of the permitted discharge will be amenable to measurement for discharge monitoring and compliance purposes. To the extent that the nanoparticle in question is treatable through available technology, there will be a basis for the establishment of technology-based effluent limitations. The establishment of water quality-based effluent limitations may lag in time pending the performance of research on effects of the nanoparticle on various surface water receptors and designated uses.

It is conceivable, perhaps likely, that the regulation of nanoparticles covered by the NPDES program will follow the same evolutionary curve described at the outset of this section. In the early years, NPDES permits will be based upon the “best professional judgment” of the permit writer. As nanotechnology sectors emerge and develop, sector-specific effluent limitation guidelines can be promulgated to standardize the regulatory outcomes of the NPDES permit application and renewal processes. In addition, water quality criteria can be derived as the field research database develops.

\begin{itemize}
\item \textsuperscript{4} 40 C.F.R. Part 136.
\item \textsuperscript{5} 40 C.F.R. Parts 400-471.
\item \textsuperscript{6} 40 C.F.R. Part 129.
\item \textsuperscript{7} CWA §§ 301(a) and 402(a), 33 U.S.C. §§ 1311(a) and 1342(a).
\end{itemize}
To the extent the nanoparticle in question is not detectable and/or reliably measurable and/or treatable, the NPDES permit program may still be able to provide some degree of regulation through the development of source-specific special conditions. The NPDES permit program enables the permit writer to employ “special conditions” to deal with atypical situations such as the emerging scientific and regulatory issues presented by nanoparticles. For example, a NPDES permit covering the discharge of nanoparticles could require the collection of “effects” data relating to ambient stream parameters, sediment, bioaccumulation in receptors, etc. It could also require the performance of toxic reduction evaluation studies or treatability studies. If the establishment of numeric effluent limitations is not technically feasible, the permit writer is authorized to specify best management practices as a means of regulating discharges through source control pending the development of a basis for specifying numeric effluent limitations.

XIV. ADMINISTRATION (CWA § 501, 33 U.S.C. § 1361)

CWA Section 501 allows the Administrator to recognize achievements in innovation related to waste treatment and pollution abatement programs. The Administrator may award a certificate or plaque to a regulated entity to recognize an outstanding “technological achievement or innovative process, method, or device in their waste treatment and pollution abatement programs.” Regional Administrators may also provide awards to eligible nominees. This recognition includes an announcement in the Federal Register and notification to the Governor of the State or Tribal leader of the jurisdiction where the recipient is located, as well as the Speaker of the House and President pro tempore of the Senate. The award does not allow for monetary awards or grants. The Administrator may use these powers to promote or recognize any regulated entity that takes substantial steps towards solving many of the problems related to nanotechnology in wastewater, including the detection and filtration of nanoparticles or, conversely, the use of nanotechnology as an innovative solution to current problems involving wastewater treatment. Few, if any, government-owned wastewater treatment plants could afford the research and development required to produce this type of novel technology. The powers of this statute and their attendant regulations could best be used to promote and recognize research and development by other entities eligible for the award, such as privately-owned corporations and universities.

XV. DEFINITIONS (CWA § 502 33 U.S.C. § 1362)

CWA Section 502 provides the definition of terms used in subchapter II of the Clean Water Act. As terms are currently defined, nanoparticles could already be considered a “pollutant,” “toxic pollutant,” or “medical waste” under the Act.

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9 40 C.F.R. § 105.1.
12 See 40 C.F.R. § 105.5.
The term “pollutant” is defined to include, *inter alia*, chemical wastes and “industrial, municipal, and agricultural waste discharged into water.”\(^{13}\) The term “toxic pollutant” is defined to include “those pollutants, or combination of pollutants . . . which after discharge and upon exposure, ingestion, inhalation or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will, on the basis of information available to the Administrator, cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction) or physical deformations, in such organisms or their offspring.”\(^{14}\) The definition is notably broad enough to include materials known to harm aquatic life, but not human beings. Provided that the Administrator is satisfied with information showing harm to human or aquatic life, EPA may issue regulations for nanoparticles under 40 C.F.R. Part 129. The term “medical waste” includes, *inter alia*, “such additional medical items as the Administrator shall prescribe by regulation.”\(^{15}\) Considering the planned use of nanotechnology in drug delivery, if adequate information exists to warrant regulation, nanoparticles could be regulated under this narrower definition.

Considering that nanoparticles conceivably fit under three separate definitions of pollutants, the Administrator may wish to consider an exclusion of nanoparticles from these sections (either through a requested congressional amendment or amendment to the Code of Federal Regulations), if they are to either be regulated in some other manner or left unregulated.

XVI. WATER POLLUTION CONTROL ADVISORY BOARD (CWA § 503, 33 U.S.C. § 13630)

CWA Section 503 creates an advisory board whose members are appointed by the President. Unlike the Effluent Standards and Water Quality Information Advisory Committee, established at CWA Section 515, the scope of its advisory role is not specifically defined. Since the Board exists to “advise, consult with, and make recommendations to the Administrator on matters of policy,”\(^{16}\) it is authorized to study and make recommendations on the issue of nanoparticle regulation.

CONCLUSION

Although EPA likely has the authority to regulate nanoparticles, however, it would also likely be necessary for EPA to demonstrate that certain nanoparticles (*e.g.*, specific compounds or a class or category of nanoparticles) have a potential adverse effect on human health or the environment, thus making regulation of the nanoparticle necessary and appropriate under the CWA. To this end, further research and study would likely be necessary. In addition,

\(^{13}\) CWA § 502(6), 33 U.S.C. § 1362(6).


\(^{15}\) CWA § 502(20), 33 U.S.C. § 1362(20).

\(^{16}\) CWA § 503(b), 33 U.S.C. § 1363(b).
before any meaningful regulation could be implemented, the technology must be developed that
would allow nanoparticles to be accurately monitored, measured, and controlled.