An Industry-Driven Approach to EHS Issues: "The NanoSafety Consortium for Carbon"

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Abstract

The NanoSafety Consortium for Carbon (NCC) is an industry-driven group formed to proactively address potential environmental, health, safety, and regulatory concerns related to the commercialization of its members' nanoscale carbon products. NCC was formed to take advantage of an offer by the EPA for a consortium of companies to providing testing regarding carbon nanotube toxicity. This article provides background on NCC's activities, purpose, and goals.

The NanoSafety Consortium for Carbon (NCC) is an industry-driven group[1] formed to proactively address potential environmental, health, safety (EHS), and regulatory concerns related to the commercialization of its members' nanoscale carbon products.[2] NCC has enlisted top scientists to help achieve its goals in an open and transparent manner and to the highest scientific standards. This article provides background on NCC's activities, purpose, and goals.

I. Background

The estimated commercial market for nanoscale carbon is predicted to exceed 5,000 tons by 2020.[3] Use is swiftly moving beyond an initial fascination with improved tennis rackets and golf club shafts, into more sophisticated uses such as video displays, aircraft wings and parts, military applications, energy storage solutions, computer chips, and drug delivery devices, just to name a few. This increasing sophistication of applications, however, has been accompanied by a cadre of vocal critics.

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[1] Current NCC members are: Angstron Materials LLC; Applied Sciences, Inc.; Cheap Tubes, Inc.; Continental Carbon Nanotechnologies, Inc.; Eikos, Inc.; Nano-C, Inc.; NanoLab; Nanoshel LLC; Pyrograf Products; SouthWest NanoTechnologies, Inc.; Unidym, Inc.; and XG Sciences, Inc. Additional information may be found at: www.nanosafetyconsortium.com.

[2] Participants' nanoscale carbon products currently include single-walled carbon nanotubes, multi-walled carbon nanotubes, double-walled carbon nanotubes, fullerenes, graphene, and specialty nanofibers.

[3] *See, e.g.*, Webinar: Lux Research, Nanomaterials: The Rise of MWNTs: Oversupply Hides Real Opportunities, *http://bit.ly/dcrrHD* (last visited July 27, 2010) (discussing market for MWCNTs); Additionally, Lux Research forecasts that the market for carbon nanotubes will reach $155 million in 2011, $203 million in 2012, $269 million in 2013, $365 million in 2014, and $502 million in 2015. *Source*: Lux research. Inc., *www.luxresearch.com*.

As with many emerging technologies, uncontrolled exposure to certain nanoscale materials during the manufacturing process may present unknown EHS risks. Simply put, because they are so small, many researchers theorize that if inhaled in a workplace setting, carbon nanoparticles may have the ability to reach places in the body that larger particles are unable to reach. It is also uncertain how the body will react to such small substances if inhaled. Potential exposure to dispersed nanoparticles drops once they are embedded in a matrix or incorporated into a final product. Thus, a primary concern at the moment is possible inhalation exposure during the manufacturing process. There are also concerns regarding possible dermal exposure and inadvertent environmental releases during the manufacturing process.

While these concerns are real, they are uncertain. This uncertainty has generated negative attention. As an example, a single scientific study published in May 2008[4] generated a global deluge of negative media headlines.[5] Unfortunately, a lot of this tumult was the result of a distortion of what the study actually said about the potential risks of the nanomaterials which it evaluated. Further, the headlines could not explain that the authors themselves admitted that their work was only a first step down an exceedingly long path and that much more research was necessary.[6] However, the use of terms like "danger," "fear," "threat," "scare," "cancer," "mesothelioma," and "asbestos" in media headlines coupled with carbon nanotubes obviously caused concern.

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[4] C. Poland, et al., *Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathology in a pilot study*, 3 NATURE NANOTECHNOLOGY 423 (July 2008), (published online May 20, 2008). Along with their paper, the authors also published a document entitled "Supplementary Information" which describes in detail how they conducted the research.

[5]Exemplar headlines include: "Are Nanotubes the Next Asbestos?," *Chemical Week*, June 2, 2008; "Carbon Nanotubes That Look Like Asbestos, Behave Like Asbestos," *Law & Health Weekly*, June 7, 2008; "Cancer risk seen in nanotechnology," *Los Angeles Times*, May 21, 2008; "Carbon nanotubes as bad as asbestos, says study," *Indo-Asian News Service*, May 21, 2008; "Carbon nanotubes, key ingredient in nanotechnology work, mimic asbestos in mouse tests," *AP Worldstream*, May 20, 2008; "Comparison of Nanotubes to Asbestos Spurs Call for EPA, Hill Action," *Inside EPA*, May 23, 2008; "Danger of Nanotube," *Mirror*, May 21, 2008; "Effects of Nanotubes May Lead to Cancer, Study Says," *Washington Post*, May 21, 2008; "Fears over wonder nanotubes," *West Australian*, May 22, 2008; "Hi-Tech Fibres Scare," *Herald Sun*, May 22, 2008; "How safe are nanoparticles?," *Christian Science Monitor*, May 21, 2008; "In Study, Researchers Find Nanotubes May Pose Health Risks," New York Times, May 21, 2008; "Nanotech could cause mesothelioma," ABC Premium News, May 21, 2008; "Nanotubes, Like Asbestos, Could Threaten Health," *NPR*, May 21, 2008; "Nanotubes may pose risk that asbestos does, study reports," *Virginia-Pilot*, May 21, 2008; "New cancer alert," *Birmingham Mail*, May 21, 2008; "Study links nanotubes to possible lung illness," *International Herald Tribune*, May 22, 2008; "Study: Nanotubes Pose Same Danger as Asbestos," *Post Tribune*, May 21, 2008; and "Study Waves Cautionary Flag About Nanotubes," *NPR*, May 23, 2008; a still more exhaustive list is available at http://www.nanolawreport.com/2008/06/articles/media-rips-carbon-nanotubes/.

Contrary to the headlines of many newspaper articles, the Poland Study is insufficient to establish that inhalation of MWCNTs causes mesothelioma or any disease. In reality, the study's actual findings, as opposed to its suggested implications, are quite limited. When carefully reviewed, the authors claim—at most—to have established their hypothesis that long rigid MWCNTs, when injected into the abdominal (not lung) mesothelium-lined cavity of mice, cause a reaction similar to that experienced when long asbestos fibers are injected into the same type of mouse mesothelium, i.e., inflammation and the formation of granulomas. The Poland Study does not purport to show that the granulomas progress to mesothelioma. Nor do the authors claim to have proven that inhalation of nanotubes would cause the same inflammation and granulomas in lung mesothelium, mouse or human. Certainly the Poland Study cannot be understood to show that inhalation of nanotubes by humans will cause mesothelioma of the lung. *See* J. Monica, et al., *A Nano-Mesothelioma False Alarm*, 5 NANOTECHNOLOGY LAW & BUSINESS, No. 3, 319-33 (Fall 2008).

[6] Poland, *supra*, note 4.

While these headlines were filled with hype, the responsible commercialization of nanoscale carbon—like any new chemical substance—requires vigilant consideration of EHS issues in order to minimize any reasonably foreseeable risks to health or the environment. Civil law and ethics demand as much.

To this end, the National Institute for Occupational Safety and Health (NIOSH) has done an excellent job studying potential workplace exposure to nanomaterials and has issued comprehensive best practice guidelines on how to use those materials in the workplace.[7] While there are still information gaps, businesses can rest assured that they are adequately protecting their workers if they follow NIOSH's lead—at the very least they are following state-of-the-art scientific recommendations by the top experts in the field.

NIOSH's extensive workplace guidelines highlight what the author believes is most notable about the state of EHS risk and hazard research related to nanomaterials. Information gaps are not surprising—they are inevitable with any new technology. More significant is the amount of research being undertaken in the area. Simply put, the amount of time, money, and effort is unprecedented for the development of a new technology.

For example, over the past decade, leading scientists and regulators have conducted a tremendous amount of research trying to understand these potential risks. As evidence, the federal government will spend over $116 million in 2011 investigating the potential EHS risks of nanoscale materials.[8] Additionally, the leading database of research articles on the subject logs in an astounding 4,229 articles dating back over the past decade.[9] One would be hard pressed to find other examples of such proactive efforts for other incipient chemical substances.

And government is not the only group actively working on EHS issues related to nanoscale materials. Researchers from top universities, standards organizations, and advocacy groups from around the world are examining the same issues. Many businesses involved in nanotechnology have also devoted much time and effort to this issue—both individually and through trade groups, associations, and joint ventures. The Environmental Defense/DuPont Nano Risk Framework released in 2008 is a good example of these efforts.[10] Additionally, the American Chemistry Council[11] and the Society Chemical Manufacturers and Affiliates[12] both have active nano-EHS committees,

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[7] *See, e.g.*, NAT'L INST. FOR OCCUPATIONAL SAFETY AND HEALTH, CTRS. FOR DISEASE CONTROL AND PREVENTION, DEP'T OF HEALTH AND HUMAN SERVICES, APPROACHES TO SAFE NANOTECHNOLOGY: AN INFORMATION EXCHANGE WITH NIOSH v (2006), *available at* http://www.cdc.gov/niosh/topics/nanotech/pdfs/Approaches_to_Safe_Nanotechnology.pdf; NAT'L INST. FOR OCCUPATIONAL SAFETY AND HEALTH, CTRS. FOR DISEASE CONTROL AND PREVENTION, DEP'T OF HEALTH AND HUMAN SERVICES, PROGRESS TOWARD SAFE NANOTECHNOLOGY IN THE WORKPLACE: A REPORT FROM THE NIOSH NANOTECHNOLOGY RESEARCH CENTER. 3 (2007), *available at* http://www.cdc.gov/niosh/docs/2007-123/pdfs/2007-123.pdf; NAT'L INST. FOR OCCUPATIONAL SAFETY AND HEALTH, CTRS. FOR DISEASE CONTROL AND PREVENTION, DEP'T OF HEALTH AND HUMAN SERVICES, STRATEGIC PLAN FOR NIOSH NANOTECHNOLOGY RESEARCH AND GUIDANCE, FILLING THE KNOWLEDGE GAPS (2009), *available at* http://www.cdc.gov/niosh/docs/2010-105/pdfs/2010-105.pdf.

[8] NANOSCALE SCIENCE, ENGINEERING, AND TECHNOLOGY SUBCOMM. ON TECHNOLOGY, NAT'L SCIENCE AND TECHNOLOGY COUNCIL, THE NATIONAL NANOTECHNOLOGY INITIATIVE: RESEARCH AND DEVELOPMENT LEADING TO A REVOLUTION IN TECHNOLOGY AND INDUSTRY, Supplement to the President's 2011 Budget 10 (2010), *available at* www.nano.gov/NNI_2011_budget_supplement.pdf.

[9] Int'l Council on Nanotechnology, *nanoEHS Virtual Journal, http://icon.rice.edu/virtualjournal.cfm* (last visited July 27, 2010).

[10] Nano Risk Framework, *http://www.nanoriskframework.com* (last visited July 27, 2010).

[11] American Chemistry Nanotechnology Panel, *http://tinyurl.com/3xq3kp5* (last visited July 27, 2010).

[12] Soc'y of Chemical Manufacturers & Affiliates, http://www.socma.com/ChemSortia/?subSec=9&articleID=47#top (last visited July 27, 2010).

and industry associations such as the Nanotechnologies Industry Association[13] and the NanoBusiness Alliance[14] broadly address these issues with and through their constituents.

Despite all of this activity, what has been lacking thus far is an industry group specifically focused on the immediate EHS needs surrounding the commercialization of their products. Simply put, while several groups have focused on larger policy issues, until now no group of companies has banded together to focus on how to best address EHS and regulatory issues presenting hurdles to the successful commercialization of their specific products. NCC was formed to provide just such an industry-driven approach to addressing these issues.

II. Developing Bottlenecks

The reader can probably imagine how difficult it is for a small or midsized company to conduct business amid the existing EHS uncertainty surrounding certain nanomaterials. The economy is slow. Capital, resources, and personnel are at a premium. The knowledge necessary to ensure the safe development of nanoscale materials is relatively new and quickly changing. The mass of existing EHS studies is daunting to assimilate, with an avalanche of additional publications on the way. In short, companies find an ever-mounting task to master with scarce resources. Many of NCC's members are faced with innovating new products and applications in this environment. Several have found that a commercialization bottleneck has developed around EHS uncertainty related to certain types of nanoscale carbon. Customers (rightly) want to know if the materials they are purchasing and using pose undue EHS risks and whether they face downstream liability. Additionally, entrepreneurs are concerned about investing in an industry allegedly poised to become "the next asbestos," no matter how exciting these new materials and applications. Thus, while commercialization is still occurring, potential EHS risks have caused some to pause.[15]

As this commercial bottleneck developed, a parallel regulatory bottleneck grew out of the same EHS concerns. In early 2008, EPA introduced its Nanoscale Material Stewardship Program which sought to gather existing EHS data from companies working with nanomaterials, as well as create a future EHS-related research plan—all on a voluntary basis.[16] While a noble effort, the program received insufficient voluntary industry participation.[17] A new approach became necessary. Thus, despite having been manufactured and sold in the US for several years and being regulated as an existing chemical, a policy shift occurred in late 2008 under which most engineered carbon nanomaterials became regulated by EPA as "new chemical substances" under Section 5 of the Toxic Sub-

[13] Nanotechnology Industries Association, *http://www.nanotechia.org* (last visited July 27, 2010).

[14] nanoBUSINESSalliance, *http://www.nanobusiness.org* (last visited July 27, 2010).

[15] Anecdotally, one international company ceased manufacturing multi-walled carbon nanotubes after the May 2008 Poland Study. Another California chemical distributor stopped carrying nanoscale carbon and has no plans to resume sales. Additionally, a major U.S. insurance company refused to insure companies manufacturing carbon nanotubes. The state of California followed with a carbon nanotube data call-in January 2009 which targeted 26 university, research, and business organizations.

[16] ENVTL. PROT. AGENCY, CONCEPT PAPER FOR THE NANOSCALE MATERIALS STEWARDSHIP PROGRAM UNDER TSCA, 1-2 (2007), *available at* http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&d=EPA-HQ-OPPT-2004-0122-0058.

[17] OFFICE OF POLLUTION PREVENTION AND TOXICS, ENVTL. PROT. AGENCY, NANOSCALE MATERIALS STEWARDSHIP PROGRAM, INTERIM REPORT 11 (2009), *available at* http://www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf.

stances Control Act (TSCA).[18] The time for voluntary efforts in place of regulation was drawing to a close.

III. EPA Case-by-Case Regulation of Nanoscale Carbon

While certainly not a "death knell," being regulated as a "new chemical substance" under TSCA can trigger very expensive and time consuming regulatory requirements and restrictions. For example, under Section 5 of TSCA, a company must provide EPA with 90 days written pre-manufacturing notice (PMN) before manufacturing or importing a new chemical substance or engaging in a new use of an existing chemical substance.[19] Despite its name, a PMN is much more than a simple "notice" document. It is quite detailed and requires a significant amount of technical data.[20] Further, when deciding whether or not to approve a PMN, EPA may choose to issue a protective rule or order if it finds that (i) the available information "is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance" which "the manufacture, processing, distribution in commerce, use, or disposal of such substance ... may present an unreasonable risk of injury to health or the environment," or (ii) "there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment."[21] For many new chemical substances, the issuance of a protective rule or order is now the EPA norm, not the exception.

Along these lines, although it still analyzes and processes PMNs for nanoscale materials on a case-by-case basis, EPA has essentially determined that most carbon nanomaterials are new chemical substances under TSCA because they have different molecular identities from bulk versions of carbon and graphite.[22] EPA has thus placed specific limitations and conditions upon their manufacturer, import, or sale in commercial quantities.

For example, in the fall of 2008, EPA treated two types of carbon nanotubes as "new chemical substances" and entered into two consent orders[23] with their manufacturer which specifically conditioned the manufacturing, sale, marketing, and/or import of the company's multi-walled and single-walled nanotubes in the U.S. on, among other things:

1. Delivering 1 gram of the carbon nanotubes to EPA with a copy of Material Safety Data Sheet for the product;
2. Conducting a "90 day inhalation toxicity study in rats with a post exposure" observation period of up to 3 months, including bronchoalveolar lavage fluid analysis (under OPPTS 870.3465 or OECD 413 guidelines);

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[18] Envtl. Prot. Agency, *TSCA Inventory Status of Nanoscale Substances—General Approach*, http://www.epa.gov/oppt/nano/nmsp-inventorypaper.pdf (last visited Mar. 30, 2009).

[19] Toxic Substances Control Act (TSCA), 15 U.S.C. § 2604 (2007), *available at* http://epw.senate.gov/tsca.pdf, *also http://uscode.house.gov/search/criteria.shtml*, search by title and section (2010 version).

[20] *See, e.g.*, E. Brown, et al., TSCA DESKBOOK, ENVIRONMENTAL LAW INSTITUTE, 16-25 (1999).

[21] TSCA, *supra* note 19.

[22] Envtl. Prot. Agency, *TSCA Inventory, supra* note 18.

[23] OFFICE OF POLLUTION PREVENTION AND TOXICS, ENVTL. PROT. AGENCY, REGULATION OF A NEW CHEMICAL SUBSTANCE PENDING DEVELOPMENT OF INFORMATION, RE: PREMANUFACTURE NOTICE NUMBER P-08-0177, CONSENT ORDER AND DETERMINATIONS SUPPORTING CONSENT ORDER, *available at http://www.nanolawreport.com/EPA%20Premanufacture%20Notice%20Number%20P-08-0177.pdf, see also* 40 C.F.R. 721.10155-56, *available at* http://edocket.access.gpo.gov/2009/pdf/E9-14843.pdf.

3. Submitting specific material characterization data within six months;
4. Ensuring employees "use gloves impervious to nanoscale particles and chemical protective clothing;" and
5. Ensuring employees "use a NIOSH-approved full-face respirator with an N-100 cartridge while exposed by inhalation in the work area."[24]

While some of these conditions are easily met—like providing a material sample to EPA and ensuring that workers wear impermeable gloves and respirators—others present tangible difficulties. In particular, the second requirement—the 90 day rat inhalation toxicity study—is a very complicated and expensive test. Depending upon which laboratory is undertaking the study and what preliminary testing is included in the scope of the work, the cost of such a test can range from $350,000 to $500,000 per nanoscale material tested. Such costs could cripple a small or midsized company—especially if it has several materials to test for TSCA approval purposes. Also, these costs can be daunting to even the largest of companies seeking approval of a large number of substances.

Additionally, a certain level of unique scientific expertise is necessary to even begin such a testing project. Nanotoxicology specialists are required. Even generating a nano-aerosol to use in a 90 day rat inhalation test in the first instance presents novel problems, as does properly characterizing the materials going into the test.[25] Modifying existing testing protocols to adequately account for the extremely small size and unique properties of certain nanoscale materials is also necessary.[26] Thus, beyond simple cost barriers, a 90 day rat inhalation test for carbon nanomaterials is not something that just any toxicology lab, toxicologist, or manufacturer can easily undertake.

IV. A Unique Opportunity

Perhaps realizing the potential obstacles presented by a 90 day inhalation toxicity testing requirement, EPA has provided a unique opportunity in its consent orders allowing manufacturers to pool together to submit joint representative toxicity testing data in certain circumstances:

> If, for example, a consortium of companies commit to testing a representative set of MWCNT for subchronic mammalian toxicity, EPA may consider waiving the triggered testing requirement. EPA would be willing to facilitate the process in coordination with other ongoing health effects testing for MWCNT nationally and internationally. EPA would consider accepting the results of such testing in lieu of triggered testing in this order.[27]

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[24] More recent consent orders for nanoscale carbon products have also required companies to certify that there are no releases to water during manufacturing processes at their facilities.

[25] *See, e.g.*, A. Gupta, et al., Generation of C_{60} nanoparticle aerosol in high mass concentrations, JOURNAL OF AEROSOL SCIENCE (May 2007), *available online at* www.sciencedirect.com.

[26] *See, e.g.*, Org. for Econ. Cooperation and Dev., Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials, Env/Jm/Mono (2009) 21 (July 21, 2009), *available at* http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=ENV/JM/MONO(2009)21&doclanguage=en.

[27] OFFICE OF POLLUTION PREVENTION AND TOXICS, ENVTL. PROT. AGENCY, REGULATION OF A NEW CHEMICAL SUBSTANCE PENDING DEVELOPMENT OF INFORMATION, RE: PREMANUFACTURE NOTICE NUMBER P-08-0177, CONSENT ORDER AND DETERMINATIONS SUPPORTING CONSENT ORDER, *available at* http://www.nanolawreport.com/EPA%20Premanufacture%20Notice%20Number%20P-08-0177.pdf, page vii.

NCC was formed to take advantage of this offer in an attempt to ameliorate the above-referenced commercialization and regulatory bottlenecks. The offer is unique in that—under EPA's current thinking—any individual company seeking a TSCA Section 5 consent order covering nanoscale carbon that EPA has determined to be a new chemical substance is typically required to individually conduct a 90 day inhalation test on its product within a certain number of years allotted by EPA. Thus, if 40 companies go into EPA individually with 40 products, 40 separate tests are likely to be required, even if the materials are substantially similar. However, if the same companies go into EPA as a consortium and are able to negotiate an agreed testing protocol, there is an opportunity to conduct joint testing of a representative set of materials. Of course, whether a representative set of materials can even be fashioned for any joint testing is one of the key scientific challenges to such a proposal. But the theory is that rather than requiring multiple tests by multiple companies, perhaps the companies can join together in a handful of representative tests. This not only allows the companies to pool resources, expertise, and skill, it also allows EPA to avoid being inundated with duplicative test results and aids it in obtaining testing data that it does not already possess and believes is needed to continue its regulatory analysis. Both sides benefit from a consortium approach.

V. NCC's Structure

NCC is structured so that it can make relatively quick decisions on important issues without unnecessary delay.[28] Decisions that sometimes take years to make can be made by NCC in months, those that take months made in weeks, and those that sometimes take weeks made in days. This is not to say that NCC does not deliberately consider each step it takes in a thorough and thoughtful manner. However, NCC's commercial approach and experience operating in the business world allows it a flexibility not often found in some other groups focusing on nano-related EHS issues.

NCC is governed by a management committee consisting of one representative from each company. The committee makes all significant policy and financial decisions, and meets monthly to conduct business and to move along NCC's programs. Full consortium meetings occur quarterly and may be held in person, by telephone, by internet, or a combination thereof. Full consortium meetings are open to all consortium participants and are used to update attendees on NCC's activities and provide an open forum to discuss any issue pertaining to NCC's stated purpose and objectives. Membership in NCC is open to any business entity actively involved in the manufacturing, distribution, or use of nanoscale carbon. We hope to recruit over the next year several additional members beyond our twelve founding companies.

1. NCC's Advisory Board and External Liaisons

One of NCC's top goals is to work with the best independent scientific minds. Of course, having the best minds agree to assist has immediate benefits, and presumably leads to the best approach and the best results. Having input from a variety of scientists will also provide any testing regime with what is hoped to be "gold standard" credibility. To further this objective, NCC's advisory board charter and bylaws provide that its advisory board and external liaisons are completely independent and free to voice whatever opinions they have on the issues tackled by NCC. Any dissent will be preserved in writing upon request of any advisory board member or liaison.

2. Transparency and Independence

Another of NCC's top goals is public transparency and credibility. Participants are determined to avoid accusations that they are out conducting behind the scenes tests in some dark lab, manipulating the true results, and then attempting to "dupe" regulatory authorities. Data from any final

[28] NCC's bylaws and advisory board charter may be found at www.nanosafetyconsortium.com.

toxicity testing will be made public and published in a leading peer-reviewed journal—good, bad, or indifferent. Additionally, where some past studies by others have been treated as confidential business information, NCC's studies will be made publicly available. Finally, as should be evident from NCC's structure and reliance on an external advisory board and liaisons, NCC is most concerned with conducting and sponsoring all projects to the highest level of scientific accuracy and precision.

3. NCC's Initial Objectives

NCC has several initial objectives. First, as explained above, NCC plans to develop and implement a mutually agreeable testing regime for a suite of representative carbon nanomaterials in order to fulfill the testing requirements contained in any TSCA Consent Order entered into by EPA and any NCC member regarding its existing carbon nanomaterials. This project will enlist the services of top independent scientists. Two of the primary obstacles to accomplishing this objective are (i) can a set of representative materials be developed for testing purposes which are acceptable to EPA, and (ii) what testing regimes will generate new data that EPA finds valuable enough to allow a consortium approach? Obviously, much collaboration will be needed between NCC's advisory board, external liaisons, and EPA.

Second, as part of any overall representative testing regime, NCC plans to develop and implement a mutually agreeable approach allowing a reasonable range of modification to NCC's members' products without requiring renewed comprehensive toxicity testing. Consortium members believe this is an important feature in order to provide them with some assurance that as they modify existing products within reasonable ranges they will not be required to "start over" the entire TSCA testing/consent order process. Of course, the key issue here is determining the "reasonable range" of any such modifications allowed by EPA. A process must be developed which assures EPA that they have reasonably accounted for any potential new risks from modified materials, while at the same time providing the manufacturers some latitude to pursue commercialization and innovation. Again, close cooperation will be needed between NCC's advisory board, external liaisons, and EPA.

Third, NCC plans to provide EPA with industry input and perspective concerning the parameters of any data call-in covering nanoscale carbon which may be issued by EPA under Section 8 of TSCA.[29] EPA has indicated that it intends to issue data-call in covering certain nanomaterials sometime in 2010.[30] Best estimates are that this will occur in December 2010. While it is unknown exactly what data EPA will request under any rule, a good bet is that it will cover the information requested in EPA's prior Nanoscale Materials Stewardship Program and existing PMN requirements. NCC's members hope to be ahead of the curve on this issue, as most (if not all) this information will have already been compiled as part of the proposed toxicity testing program. To the extent additional data is necessary, NCC can provide the EPA with its own insights regarding any difficulties presented by such a request. Finally, NCC will be able to provide EPA with valuable information regarding the actual time and costs incurred in collecting this data in the first instance, which could be used by EPA in formulating any final rule.

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[29] Section 8(d) of TSCA allows EPA to issue rules requiring a manufacturer to submit "lists of health and safety studies . . . conducted or initiated [by the manufacturer] with respect to such substance or mixture at any time, . . . known to such [manufacturer], or . . . reasonably ascertainably by such [manufacturer]." 15 U.S.C. § 2607. This is sometimes referred to as a "data call-in."

[30] GOVERNMENT ACCOUNTABILITY OFFICE, NANOTECHNOLOGY: NANOMATERIALS ARE WIDELY USED IN COMMERCE, BUT EPA FACES CHALLENGES IN REGULATING RISK, GAO-10-549 (June 2010), *available at* http://www.gao.gov/new.items/d10549.pdf.

Fourth, NCC plans to provide EPA with industry input and perspective regarding the parameters of any testing rule concerning nanoscale carbon which may be issued by EPA under Section 4 of TSCA.[31] Again, such a rule is predicted for December 2010, although its contours remain speculative. Given EPA's propensity for 90 day inhalation tests thus far, no one should be surprised if that test or a similar test is a component of any final testing rule. NCC's experience gearing up for such a test should provide some valuable information to EPA.

Finally, NCC hopes to coordinate with NIOSH to conduct workplace exposure assessments of its members' facilities. As of July 2010, NIOSH's field study team has already conducted workplace assessments for over a dozen companies working with nanoscale materials. Under this program, NIOSH goes into a facility and takes baselines measurements to determine whether any manufactured nanoparticles are being released into the workplace. If any such releases are discovered, the company then takes any corrective action suggested by NIOSH and the facility is reevaluated. NCC hopes to partner with NIOSH to conduct these evaluations for its members' facilities.

4. NCC Benefits

Beyond the obvious benefit of sharing costs to conduct otherwise expensive inhalation toxicity testing, NCC also provides its members with several less obvious benefits.

First, NCC's members have the comfort of being part of a group of leading manufacturers using the best science to address EPA's potential EHS concerns regarding nanoscale carbon in a transparent manner. This is especially important given that EPA's voluntary Nanoscale Materials Stewardship Program is no longer the cornerstone of nano-specific regulatory efforts. Being part of NCC also prevents the entrenchment of a "you first" mentality which often accompanies companies seeking innovative solutions to tough regulatory uncertainties.

Second, NCC's members benefit through the use of the highest quality and best representative group of nanoscale carbon test materials to reduce the likelihood of rogue test findings which are potentially applicable to the entire industry. A criticism of some past EHS testing has been that the materials going into the test were not fully characterized and the testing regimes themselves were not adequately described. Some other test results which would be most beneficial to the consortium remain confidential and unavailable. By working with the top independent scientists, NCC hopes to minimize these difficulties and make sure that whatever testing data is generated is reliable and readily available.

Third, NCC is ensuring the use of the best and most highly qualified neutral expert scientists. While NCC's members are prepared to live with the results of any testing conducted under this program, a criticism of past studies has been the perception that some may have been written by researchers dependent upon attracting future funding for their projects. There was an accompanying fear that benign test results may be under reported because they do not generate much interest for funding future studies. NCC hopes to reduce these concerns by using top independent research scientists for its projects.

Fourth, NCC members benefit through the coordination of its efforts with the American National Standards Institute (ANSI), the International Organization for Standardization (ISO), and the Organization for Economic Cooperation and Development (OECD). Simply put, NCC's work will not be done in a vacuum and will fully consider the approaches being used across the world to address the very same EHS concerns regarding nanoscale carbon.

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[31] OFFICE OF POLLUTION PREVENTION AND TOXICS, ENVTL. PROT. AGENCY, REGULATION OF A NEW CHEMICAL SUBSTANCE PENDING DEVELOPMENT OF INFORMATION, RE: PREMANUFACTURE NOTICE NUMBER P-08-0177, CONSENT ORDER AND DETERMINATIONS SUPPORTING CONSENT ORDER, *available at* http://www.nanolawreport.com/EPA%20Premanufacture%20Notice%20Number%20P-08-0177.pdf.

Fifth, NCC members benefit through accurate write-up and submission of test results to EPA in a timely, fair, and articulate manner. Additionally, all of the scientists working on the project will have the opportunity to co-author the final report from the study, which NCC hopes to have published in a leading peer-reviewed journal. Thus, not only will the process be open and transparent, but NCC will make sure that its results are adequately publicized and disseminated so that others will be able to take advantage of this state-of-the-art project.

Sixth, NCC benefits its members by ensuring compliance with all existing federal and state laws regarding joint research projects, and by ensuring that test results are legally admissible and accepted for consideration in any future administrative and/or legal proceedings. Obviously, it is important to make sure that legal precautions are undertaken with any joint research project. Additionally, while many prior tests would not be admissible in court due to their speculative nature,[32] NCC intends to conduct its projects with an eye towards ensuring the admissibility of any results and data should it be necessary in any future EHS-related litigation.

VI. Next Steps

NCC's management committee recently asked its advisory board and external liaisons to consider the possible development of a multi-tiered testing regime to present to EPA consisting of the following components:

- **Tier One**: Comprehensive materials characterization using OECD and ISO criteria to be coordinated with the National Institute for Standards and Technology and the U.S. Army Corps of Engineers. These parameters may include: agglomeration/aggregation, composition, particle size and distribution, purity, shape, specific surface area, surface chemistry, surface charge, catalytic properties, concentration, crystalline phase, dustiness, fat solubility, grain size, length, water solubility, and zeta potential.

- **Tier Two**: Comprehensive workplace assessments to be coordinated with NIOSH based on their good nanomanufacturing guidelines and other documents.

- **Tier Three**: Select life cycle analysis for each NCC member accounting for any potential EHS risks and hazards during its manufacturing process.

- **Tier Four**: Creation and implementation of a monitoring program to ensure that there are no releases to water of nanoscale carbon above predetermined levels in NCC's members' facilities.

- **Tier Five**: 90 day in vivo inhalation toxicity testing of purified representative samples of multi-walled carbon nanotubes, single-walled carbon nanotubes, fullerenes, graphene, and carbon nanofibers based on modified OECD and/or EPA OPPT testing guidelines.

- **Tier Six**: Provision of all resulting data and information to EPA. Open publication and dissemination of final test results (with appropriate protection of members' proprietary property, such as that dealing with the development, formulation, and methods of production pertaining to their

[32] *See, e.g.*, J. Monica, et al., *A Nano-Mesothelioma False Alarm*, 5 NANOTECHNOLOGY LAW & BUSINESS, 319-33 (Fall 2008).

products).

Once NCC's advisory board has had an opportunity to review and modify (or reject) the testing proposal and reduce its recommendations to writing, NCC will then present the proposal to EPA for its consideration and (hopefully) approval. NCC plans to submit its proposal to EPA in September 2010.