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Nanotechnology Law Report

Legal Issues Surrounding Nanotechnology & General Nanotechnology News & Events

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porterwright

INSIDE THIS ISSUE

ISO Publishes Nanotechnology Definition

The International Standards Organization (ISO) recently completed its first step in developing standards for nanotechnology. The definitions are revealed in ISO/TS 27687:2008, Nanotechnologies – Terminology.

The three main materials covered by this first set of definitions and terminology are:

- Nanoparticle;
- Nanofibre; and
- Nanoplate.

ISO expects this release to be the first of a series of standards for definitions and terms related to the nanotechnology sector.

It is encouraging to see the first results of ISO's multi-year effort to establish standards for the sector. As we have opined before, meaningful regulation cannot occur without a standardized set of definitions and language. However, the release of additional definitions now begins to raise the next question/problem: resolving potential competing standards in an effort to have standardization in the sector to provide greater certainty.

Confusion at the FDA

FDA Week reported in August that a meeting at the Food and Drug Administration in late July failed to result in any agreement about a possible policy on nanomaterials. The FDA Nanotechnology task force met on July 22, 2008 to consider the creation of a policy for nanomaterials but failed to come to any consensus on whether one should be drafted, let alone what the contents should be.

The primary disagreement appears to be whether to issue a policy at all or simply rely on existing statutory and regulatory controls. The panel was split on this issue, resulting in no action in the short term. The split was right down the middle with five panel members voting in favor of a policy, five voting against, and one abstaining.

The panel agreed, however, that FDA should collaborate with OSHA and EPA should either agency begin drafting a policy concerning nanoparticles. FDA also held a public meeting in September to discuss particle size in drugs and how to obtain such information from its current database.

FDA's reaction is not wholly surprising given the state of nanotechnology regulation. However, the even split was somewhat unexpected. The debate seems to center around data submissions by companies seeking FDA approval on new nano-related products versus what is already required.

First Commercial Insurance Exclusion for Nanotechnology

In late September, Continental Western Insurance Group issued what appears to be one of the first nano-specific commercial insurance exclusions in the United States. Although Continental originally posted the exclusion and two supporting documents on its website, the materials were removed after BNA published an article about the exclusion. Visit our website to view the operative documents.

A summary of each of Continental's three documents follows.

Background on Nanotubes

Continental's "Background on Nanotubes" document explains the policy behind its exclusion:

> "The intent of this exclusion is to remove coverage for the, as of yet, unknown and unknowable risks created by products and processes that involve nanotubes. The exclusion is being added to make you and your customers explicitly aware of our intent not to cover injury and/or damage arising from nanotubes, as used in products and processes…"

The primary reason for the exclusion appears to be recent reports comparing carbon nanotubes to asbestos. You can find information about the press coverage of the May 2008 articles comparing multi-walled carbon nanotubes to asbestos at <http://www.nanolawreport.com/2008/06/articles/media-rips-carbon-nanotubes>. Another factor in Continental's decision appears to be the often-cited nano consumer product inventory published by the Project on Emerging Nanotechnologies.

Based on the asbestos analogy and PEN's product database, Continental concludes that it "would not be prudent for us to knowingly provide coverage for risks that are, as of yet, unknown and unquantifiable. We are all too aware of what happened to companies involved with asbestos-related exposure in the past, and see this as a very similar issue."

Notice to Policyholders

Continental's draft Notice to Policyholders makes it clear that it covers most of Continental's insurance groups, including: Acadia Insurance Company; Continental Western Insurance Company; Fireman's Insurance Company of Washington, D.C.; and Union Insurance Company. The notice references the actual exclusion, which is attached the notice and explains that this "endorsement excludes bodily injury, property damage, and personal and advertising injury related to the exposure of nanotubes and nanotechnology in any form. This include the use of, contact with, existence of, presence of, proliferation of, discharge of, dispersal of, seepage of, migration of, release of, escape of, or exposure to nanotubes or nanotechnology."

Nanotubes and Nanotechnology Exclusion

The exclusion itself reiterates same language contained in the notice. It further contains specific exclusions for "existence, storage, handling, or transportation of 'nanotubes' or 'nanotechnology'…any manufacturing processes or products including same, and any losses arising from lawsuits related to 'nanotubes' and/or 'nanotechnology.'"

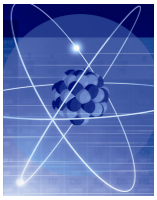
The exclusion defines "nanotubes" as "hollow cylinders of carbon atoms or carbon fibers or any type or form of (nanotechnology) which contains remarkable strength and electrical properties used in any products, goods, or materials." "Nanotechnology" is defined as "engineering at a molecular or atomic level."

Both definitions are vague. For example, a hollow carbon fiber fishing rod that makes no claim to contain nanoscale materials would still technically be included in the definition of 'nanotubes" because it is a hollow cylinder made of carbon atoms. Similarly, attempting to entirely exclude "nanotechnology" is unworkable because it is really just science on an extremely small scale.

Rather than excluding all "nanotechnology," Continental more likely meant to exclude all nanoscale materials. Even then, such a blanket exclusion would be extremely broad because many nanoscale materials have not been shown to pose any environmental, health, or safety risks. Further, even within the category of carbon nanotubes, recent researchers' warnings about potential EHS risks have been largely confined to long, thin, needle-like carbon nanotubes, while excluding other varieties.

Talking the Talk: Standardizing the Language of Nanotechnology

This third article in a series on standards for the nanotechnology community explains how agreements for terminology and nomenclature are creating the common baseline that is needed for global collaboration and understanding.



As an ever increasing array of industry sectors embraces the rapid development of materials at the nano scale, stakeholders around the planet have attempted to weave a new "nano" vocabulary into their communications.

Consistent and globally-accepted nomenclature and terminology – the fundamental building blocks for any burgeoning industry – tops the list of stakeholder needs. Until there is consensus, even terms that are frequently cited in relevant scientific literature, e.g., nanotechnology, nanoparticle, nanostructure, nanoscale and nanomaterial are at risk of being interpreted differently between nations and industries.

In a June 2004 letter to the American National Standards Institute (ANSI), Dr. John H. Marburger, III, director of the Office of Science and Technology Policy to the Executive Office of the President, wrote:

> "As new materials, structures, devices, and systems are developed that derive their properties and function due to their nanoscale dimensions, it will become increasingly important to the researchers, manufacturers, regulators, and other stakeholders to have an agreed upon nomenclature with which to communicate."

Dr. Marburger asked ANSI to step forward to facilitate the development of standards in the area of nanotechnology, starting with nomenclature and terminology.

The Institute responded by forming in August 2004 a cross-sector coordinating body known as the ANSI-Nanotechnology Standards Panel (www.ansi.org/nsp). The Panel does not itself develop standards; rather, it works with other national, regional, and international standards bodies, as well as industry, academic, and government stakeholders, to establish work plans, harmonize efforts, and mitigate duplication or overlap.

Terminology is the body of specialized terms used in a subject of study – in other words, the vocabulary for a particular topic. It is technology-driven, promoting transparency and facilitating communication and understanding.

Nomenclature is defined as the selection of names for things in a particular field, or as the system used for developing unambiguous names. It includes a description of the system concept and a structure through which new names can be developed.

As the Panel became more and more engaged in coordination activities within the United States, the International Organization for Standardization (ISO) and, then later, the International Electrotechnical Commission (IEC) each formed Technical Committees (TCs) to create and promote the implementation of nanotechnology standards. The Panel quickly took on a new global perspective.

Experts understood that the road to consensus would be bumpy. Many of the participating nations had already made clear their perspectives about the characterization of nano-objects and what constituted "work at the nanoscale." There were distinct differences of opinion about whether the definitions for nanotechnology terminology should consider the size of the object, the unique properties that materials exhibit at the nanoscale, or both. [Ultimately, consensus was reached that it should be both.]

Work in Progress for Terminology and Nomenclature

Upon its formation in 2005, the founding members of ISO Technical Committee (TC) 229, Nanotechnologies, including the United States, agreed that a standardized naming system and standardized terms were needed to facilitate communication among the many sectors that deal with nanotechnologies.

U.S. participation in ISO/TC 229 and its Working Groups begins in the U.S. Technical Advisory Group (TAG) to ISO/TC 229, chaired by Clayton Teague, director of the National Nanotechnology Coordination Office. The TAG, which is administered by ANSI, is organized into Working Groups that mirror their efforts on the scope of each TC 229 WG.

Under the leadership of convenor Dr. Clive Willis (Canada), a working group on *Terminology and nomenclature* (ISO/TC 229/WG 1) was created and charged with defining and developing unambiguous and uniform terminology and nomenclature that can be used by any stakeholder, from manufacturing and research to government agencies and regulatory bodies.

The mirror U.S. activity for nanotechnology terminology and nomenclature is chaired by Martha Marrapese of Kel-

ler and Heckman. Experts from academia, government, standards developing organizations, and the legal arena comprise the group's membership

One of the WG's first actions was to agree that industries should resist the temptation to simply add the prefix "nano" to already existing, well-defined terms. WG 1 members also agreed to try to avoid redefining technical terms that are already in common usage and not nano-specific.

The WG's first published work, *Nanotechnologies – Terminology and definitions for nano-objects – nanoparticle, nanofibre, and nanoplate* (ISO/TS 27687), defines the basic terms frequently used in nanotechnology literature. Included in this technical specification are definitions for terms such as "nanoscale" (the size range from approximately 1nm to 100nm) and "nano-object" (a material with one, two, or three external dimensions at the nanoscale). The document also establishes a hierarchy of terms that describe some of the more specific forms of nano-objects based on their dimensions.

Three additional WG 1 work items are still under development:

- ISO/NP TS 12144, *Nanotechnologies – Core terms – Terminology and definitions* and ISO/NP TR 12802, *Nanotechnologies – Terminology and nomenclature* – Framework provide a prioritized and systematic approach for developing further definitions as needed.
- ISO/NP TS 12921, *Nanotechnologies – Terminology and definitions for nanostructured materials* will help foster a common understanding among worldwide industrial, academic, and public sectors related to nanomaterials.

The audiences for WG 1's work are expansive. In addition to its collaborative work with IEC's nanotechnology committee (IEC TC 113), requests have also been received for additional definitions that will apply to terms commonly used in nanomanufacturing sectors, including: IT and telecommunications; aerospace and automotive industries; energy and utilities; materials and chemical industries; forest and paper products industries; food industries; pharmaceuticals, biomedical, and biotechnology; environment and national security; and clothing and personal care.

"Terminology and nomenclature are important underpinnings of nanotechnologies standards activities," said Ms. Marrapese. "They inform the other areas of standards development, including measurement and characterization, health, safety and environment issues, and product quality specifications. They also serve as the basis for how vocabulary is used and specific materials are identified for the purposes of international research, commercial activities, intellectual property protection, and government oversight and support."

Getting Involved in ISO/TC 229 WG 1

Participation in the U.S. TAG ISO/TC 229 Working Group is open to all nationally interested stakeholders. The TAG actively seeks participants who have expert knowledge in all aspects of nanotechnology terminology and nomenclature. To join the ANSI-accredited U.S. TAG for ISO/TC 229 or any of its WGs, contact Heather Benko (hbenko@ansi.org; 212.642.4912).

For more information on the U.S. TAG for ISO/TC 229, visit http://www.ansi.org/isotc229tag.

Stay Tuned: The next article in this series will introduce ISO/TC 229/WG 2, *Measurement and characterization*.

Nanotechnology and the Consumer Product Safety Commission

Late last month, the Woodrow Wilson International Center for Scholar's Project on Emerging Nanotechnologies (PEN) published a paper on the ability of the U.S. Consumer Product Safety Commission (CPSC) to deal with possible environmental, health, and safety risks potentially posed by the use of some nanoscale materials in certain consumer products.

E. Marla Felcher, "The Consumer Product Safety Commission and Nanotechnology," Project on Emerging Nanotechnologies, PEN 14, August 2008.

The article begins with an analysis of PEN's online consumer nanoproduct inventory, which is used to support the author's claim that "nanotechnology-enabled products" have made their way into every category of product under the CPSC's jurisdiction. Of the 60 products on PEN's website, the author claims that "all of them are available for purchase by consumers," and approximately "half of nanotechnology consumer products currently on the market would fall under CPSC's jurisdiction." She notes that "[e]very day, new nanoengineered products make their

way into stores' shelves, among them kids' pants, teddy bears, baby bottles, pacifiers, teething rings, plastic food storage containers, socks, chopsticks, humidifiers, mobile phones, computer processors and tennis rackets."

In a loaded rhetorical follow-up question the author asks: "Is it safe for an infant to spend hours each day sucking on a nano-enhanced pacifier?" The question does more to cement the author's predilection against the use of nano-scale materials in consumer products than it does to present readers with a true quandary. Moreover, while PEN's online inventory is a great tool, the author fails to take into account that many of the products on the site have never been commercialized or have long been taken off the market. Such an analysis would provide a helpful balance to the article's "pending emergency" tone.

Getting beyond initial issues, the author's key concerns appear to have less to do with potential nano-specific product risks than with CPSC foundational issues. The author's primary complaint appears to be that the CPSC has no premarket testing authority. She also believes that there is "[a]mple evidence" that companies do not do premarket testing or self-report hazards and defects – a conclusion many dispute.

In keeping with her general approach, the author lists "Five Generic Weaknesses in CPSC's Product Oversight Capacity:" 1. "CPSC's Data Collection System is Not Nano Ready;" 2. "CPSC has Limited Ability to Tell the Public About Health Hazards Associated with Nanoproducts;" 3. "CPSC Has Limited Ability to Get Recalled Nanoproducts Out of Use;" 4. "CPSC Lacks Sufficient Enforcement Staff to Identify Manufacturers That Fail to Report Nanoproduct Hazards;" and 5. "CPSC Does Not Have Sufficient Authority to Promulgate Mandatory Safety Standards for Nanoproducts."

While some of these points are valid, they are not nano-specific. In fact, this section of the article would suffer little if the prefix "nano" and the term "nanotechnology" were eliminated from the text. The same could be said for several of the prior papers published by PEN in which the authors' complaints and cautions appear more related to broader environmental, health, and safety governance issues than to nano-specific difficulties.

To get to the heart of the paper, most readers will want to flip to the last section where the author lists several recommendations to correct the problems she perceives with the CPSC.

The author recommends that the CPSC should: 1. "Build the agency's nanotechnology base and expertise;" 2. Identify companies making "nanoproducts and request that they submit research studies, risk assessment data and any information they hold that will enable CPSC scientists to assess the safety of nanoproducts;" (She notes that the Consumer Product Safety Act provides sufficient authority to accomplish this recommendation); 3. "Coordinate with other health and safety agencies, and combine efforts to evaluate the risks associated with nanoproducts;" and 4. "Convene a CHAP to evaluate the health and safety risks associated with nanoproducts currently on the market that are intended for use by children."

The author's second CPSC recommendation is the most interesting and could benefit from further development. If the Consumer Product Safety Act provides sufficient authority to allow the CPSC to ask companies making nanoproducts to submit safety and risk assessment data (as the author suggests), that should go a long way to satisfying the author's nano-information gathering concerns. The potential civil liability facing companies marketing nanoproducts without first collecting such data after it has been specifically requested by the CPSC would act as a hefty deterrent to the potential misconduct she fears.

The author also recommends two Congressional remedies: 1. "Amend the Consumer Product Safety Act to give CPSC the authority to require manufacturers to identify the presence of nanomaterials in their products;" and 2. "Adopt Section II of the Consumer Products Safety Act Bill recommended to Congress by the NCPS in its 1970 Field Report." This would give the CPSC the ability to promulgate "safety standards for any 'new' consumer products". . . where there exists a lack of information adequate to determine the safety of such product in use by consumers."

It is hard to argue against the author's first Congressional recommendation. Collecting more information is a good thing as long as the requirements are not onerous and the CPSC actually has the ability to process and use the data productively. Although mentioned in the "Foreword," more CPSC funding specifically dedicated to nanotechnology safety issues is left out of the author's Congressional "should do" list. Arguably, many of the author's issues with the CPSC could be diminished with additional funding, staff, and resources to more fully address nanotechnology issues.

All in all, the paper is well worth reading as long as PEN's and the author's predispositions are kept in mind.

Environmental Defense and NMSP

The advocacy group Environmental Defense Fund recently issued a press release declaring that all the data submitted to the EPA under the voluntary Nanoscale Materials Stewardship Program is entering a "black hole." However, this conclusion is premature at best, and sector damaging at worst.

In its press release, Environmental Defense Fund cites to limited participation and the fact that after six months of the program's existence, "EPA has made virtually no information public about the limited number of submissions it has received. As a result, the public can have little confidence that the program is providing the information the Agency will need to protect citizens, consumers, workers and the environment from the potential risks of nanotechnology, according to Environmental Defense Fund (EDF)." In addition, EDF is comparing the participation in the NMSP to the weak response received by the United Kingdom on its voluntary program, DEFRA. EDF also points to EPA's original prediction of 240 submissions from 150 companies for the basic program and 15 participants in the in-depth program. Although these numbers may not have been fully realized, let's look closely at the facts now that the basic program submission deadline has passed.

First, while the NMSP has been running for six months, the entirety of that time was spent collecting submissions from voluntary participants. There was no indication from EPA that they would release information collected on a rolling basis or somehow provide their evaluation as submissions were received. EPA has stated that it will take time to evaluate all of the submissions and release its thoughts after a period of review. In fact, EPA stated on its NMSP website: "EPA will **publish an interim report on the program in approximately a year from its launching on January 28, 2008.** A more detailed report and program evaluation will be published after approximately two years. At the time of the two-year report, EPA intends to determine the future direction of both the basic reporting and in-depth data development phases, although adjustments or decisions on future steps may be made at an earlier point if sufficient experience is gained. This would also include consideration of use of regulatory authorities under TSCA." (emphasis added). Consequently, EPA is taking time to consider all of the information and publish two overall reports, including an interim evaluation.

Second, let's look at the numbers. EPA received submissions from 20 organizations (including some household names) covering approximately 90 nanoscale materials. Further, another 10 organizations committed to the basic program but have not yet submitted any information. Beyond the fact that this is potentially a significant amount of technical data to sift through, this is not analogous to DEFRA's program where, to date, 11 submissions (including two in the last quarter, the report for which was just released) have been received since September 2006. Comparing EPA's response to DEFRA's is simply unfair. Additionally, three companies have committed to the in-depth program and more can still be added. Although it is clear that EPA did not receive the level of participation it hoped for, there potentially (depending on what was submitted) is very significant information in the hands of EPA, and that should not be discounted.

Declaring failure minutes after the deadline for submission passes is irresponsible and does nothing more than contribute to rumor and hearsay. EPA received a significant response from the nanotechnology sector, and it will take time for the agency to fully understand the information it now possesses. With perhaps over 100 materials to evaluate, EPA's response cannot be instantaneous, and for it to be so would conflict with its reasoned position of wanting to understand the questions surrounding nanomaterials before making statements. Good regulation does not come from snap judgments and unconsidered public statements. EDF should give the agency time to understand what it has. EDF has two choices: Wait for the release of the report or file a public records request for all of the publicly available information that was submitted. But declaring failure through a press release does not help the agency or sector get closer to the answers being sought.

Tired of Waiting ... for EPA to Act [with apologies to Ray Davies]

The following article is contributed by Richard Denison, Senior Scientist with the Environmental Defense Fund. It is in response to the preceding nanolawreport article regarding EPA's NMSP program.

EDF's recent news release that gave a less-than-glowing review to the performance of EPA's Nanoscale Materials Stewardship Program (NMSP) engendered a critique from Michael Heintz of Porter & Wright, accusing us of being

"irresponsible" and potentially "sector damaging." Our release had lamented the mediocre level of participation and lack of transparency surrounding the NMSP.

Michael's basic argument is that we should have more patience and let the NMSP play out over the next two years before saying anything. Those of us following the issue over the past several years know that we've all been waiting a long time already, even as hundreds of nano products have hit the shelves.

EPA dallied nearly 2.5 years after accepting, in November 2005, its own federal advisory committee's recommendation to launch a voluntary program. Also going against that advice, EPA made the program open-ended, while the committee had recommended a limited duration on the order of six months. And — despite being urged to do so by us and other commenters on the draft program plan circulated last year — EPA failed to provide any meaningful metrics by which to measure whether the NMSP is yielding sufficient information or not.

Finally, while EPA is still paying lip service to the possibility of some day developing mandatory reporting rules if enough companies don't volunteer, its advisory committee recommended in 2005 that such rules be developed in parallel with the NMSP — a step EPA appears not even to have begun.

Since our news release, participation in the NMSP has bumped up a bit. As of August 5, EPA had received basic program submissions from 20 companies, with an additional 10 pledging to make such submissions and three indicating interest in the in-depth program.

Moreover, almost certainly in direct response to our criticism, EPA has now actually posted the submissions it received from seven of the 20 companies — while indicating it can't post those from the 13 other companies because the submitters claimed their documents to be confidential business information (CBI). That's a welcome if small step toward the greater transparency we've called for. Why should we have to wait, as Michael argues, until EPA issues its interim evaluation to get access to non-CBI submissions EPA has already received?

I've had a look at those submissions EPA has posted, by the way, and urge Michael and all of you to do so. Despite EPA's statement that they are the "non-confidential submissions," in fact a very large fraction of the information they contain is marked as CBI.

And while EPA notes that the submissions "cover more than 90 nanoscale materials," information on 63 of those materials came from one company, and 81 materials are covered by the seven companies with posted submissions. Hence, as we suspected, most companies have submitted information on only a single nanomaterial.

Finally, with few exceptions, the extent of information provided is exceedingly limited even where it is not claimed CBI: For most materials, only cursory information on the material identity and physical-chemical properties is all that is provided. Health and environmental effects information has been provided for at most half a dozen of the materials, and some companies have claimed even that information to be CBI, despite the fact that TSCA prohibits health and environmental studies from being eligible for CBI status.

Call me impatient, but I don't think that launching, after years of delay, a years-long process to collect whatever selective information a selective group of companies already possesses and chooses to provide to EPA is a sufficiently vigorous response to the legitimate public expectation that EPA (and other federal agencies) should be taking effective action to identify, understand and address the possible risks of nanotechnology.

Collecting existing information was only supposed to be step one in EPA's determination of an appropriate regulatory response. How long would Michael have us wait for that?

EPA Consent Order

In mid-September, EPA and Thomas Swan & Co. Ltd. released the agency's first manufacturing consent order with regard to nanotubes. The consent order was entered into between the two parties through the pre-manufacture notice (PMN) portion of the Toxic Substances Control Act (TSCA).

The consent order addresses the manufacture of a multi-walled nanotube product at the Swan Chemical, Inc. plant in New Jersey. Additionally, the consent order is the result of several months of collaboration between the company and the agency. The consent order addresses the Elicarb (r) MW product.

The Order itself has not been released to the Federal Register, or another source, for first-hand review. While it is being touted by Thomas Swan & Co. as setting "the standard for future control of" nanotube products, we are unable to determine the extent of the agreement. Once the Order is released for public consumption, there will be a follow-up article relating our thoughts on the contents.

porterwright

1919 Pennsylvania Ave., N.W.
Suite 500
Washington, DC 20006-3434

1919 Pennsylvania Ave., N.W.
Suite 500
Washington, DC 20006-3434

925 Euclid Ave.
Suite 1700
Cleveland, OH 44115-1483

41 South High St.
Columbus, OH 43215-6194

One South Main St.
Suite 1600
Dayton, OH 45402-2028

250 East Fifth St.
Suite 2200
Cincinnati, OH 45202-5118

5801 Pelican Bay Blvd.
Suite 300
Naples, FL 34108-2709

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www.nanolawreport.com
John C. Monica, Jr.; (202) 778-3050; jmonica@porterwright.com

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