ENVIRONMENTAL DEFENSE
finding the ways that work

May 22, 2006

Ms. Ann R. Klee
General Counsel
US Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N. W.
Mail Code: 2310A
Washington, DC 20460

Dear Ms. Klee:

It has come to Environmental Defense's attention that the American Chemistry Council's Nanotechnology Panel (henceforth, the "Panel") is circulating a document[1] arguing that an engineered nanomaterial having a chemical structure that is already included on the TSCA Inventory is not a "new" chemical substance within the meaning of TSCA and, accordingly is not subject to TSCA's PMN provisions. Environmental Defense strongly disagrees with the Panel's assertions, and believes that, under both the letter and the spirit of TSCA, engineered nanomaterials *are* "new" substances under TSCA (and thus subject to PMN review), even where a material has a chemical structure that is identical to a substance already included on the Inventory, unless the nanomaterial's chemical and physical properties are demonstrably identical to an existing conventional substance with the same chemical structure.

The remainder of this letter sets forth the basis for our views.[2]

1. Designating engineered nanomaterials as "new" is sound environmental policy.

Engineered nanomaterials are expected to be immensely useful in many applications. But as illustrated by asbestos, CFCs, DDT, leaded gasoline, PCBs, and numerous other substances, the fact that a product is useful does not ensure it is benign to health or the environment. And if it proves harmful after widely entering commerce, the consequences can include lengthy regulatory battles, costly clean-up efforts, expensive litigation quagmires, and painful public-relations debacles.

[1] This letter is offered as a response to Part I of a document dated March 2006 titled "Views of the American Chemistry Council Nanotechnology Panel on the broad scope of EPA's authority under TSCA to address any potential risks from engineered nanoscale materials."

[2] Environmental Defense previously sent EPA a letter, dated September 2, 2004, addressing this and related issues; a copy of that earlier letter is attached.

To try to avoid such consequences, Congress in 1976 enacted the Toxic Substances Control Act (TSCA). Among other provisions, TSCA requires that the producer of a new chemical file a Premanufacture Notice (PMN) with the Environmental Protection Agency (EPA) at least 90 days before commencement of manufacturing. Though the PMN process has some serious limitations, it provides at least some opportunity for a common-sense "look before we leap" – allowing EPA to review and assess the potential risks of a new material before it reaches the market and, if necessary, to require further information or to limit its use.

As noted in the Conference Report accompanying TSCA's enactment:

> "[T]he most desirable time to determine the health and environmental effects of a substance, and to take action to protect against any potential adverse effects, occurs before commercial production begins. Not only is human and environmental harm avoided or alleviated, but the cost of any regulatory action in terms of loss of jobs and capital investments is minimized. For these reasons the conferees have given the Administrator broad authority to act during the notification period."[3]

It is inconceivable that Congress would have intended to accompany that broad grant of authority with a narrow interpretation of which chemicals qualify as "new" under TSCA.

2. Engineered nanomaterials are of interest precisely because they are "new," that is, they possess significantly enhanced or novel properties as a direct result of their "nano-ness."

The National Nanotechnology Initiative (NNI) defines nanotechnology as involving all of the following:

> "1. Research and technology development at the atomic, molecular or macromolecular levels, in the length scale of approximately 1-100 nanometer range. 2. Creating and using structures, devices and systems that have **novel properties and functions because of their small and/or intermediate size**. 3. Ability to control or manipulate on the atomic scale." (emphasis added)

Hence, by definition, an engineered nanomaterial comprised of substances already on the Inventory is being developed *because* it has "novel properties" that differ significantly from those of the conventional material.

[3] Conference report No. 1679, 94th Congress, Second Session (1976), page 65. Reprinted in *Legislative History of the Toxic Substances Control Act*. Committee Print: House Committee on Interstate and Foreign Commerce. Washington, DC: U.S. Government Printing Office.

Another clear indication of the "newness" of nanomaterials is the fact that they are being widely patented. In its latest (2006) *Nanotech Report*, Lux Research reports that nearly 4,000 U.S. nanotechnology patents have been issued since 1985.[4]

3. TSCA's definition of "chemical substance" encompasses more than the substance's molecular structure.

TSCA defines a "chemical substance" as a substance of a "particular molecular identity." Section 3(2)(A). The Panel argues that "molecular identity" is synonymous with "molecular structure." This argument ignores both basic canons of statutory construction and common sense, as demonstrated below.

The term "molecular structure"[5] appears twice in TSCA:

In Section 8(a)(2)(A):

> (2) The Administrator may require under paragraph (1) maintenance of records and reporting with respect to the following insofar as known to the person making the report or insofar as reasonably ascertainable:
> (A) The common or trade name, the chemical identity, and **molecular structure** of each chemical substance or mixture for which such a report is required.

In Section 26(c)(2)(A):

> (2) For purposes of paragraph (1):
> (A) The term "category of chemical substances" means a group of chemical substances the members of which are similar in **molecular structure**, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some
> other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.

Examination of these provisions makes clear the following:

a. The fact that Congress separately used both "molecular identity" and "molecular structure" demonstrates that it did not consider them to be synonymous. This is a basic canon of statutory construction.

The term "identity" appears only twice in TSCA, once as part of the term "molecular identity" in Section 3(2)(A)'s definition of "chemical substance" and the other time as part of the term

[4] See www.nanotechwire.com/news.asp?nid=3283.

[5] Similar terms in common usage that could arguably be equated with molecular structure include molecular formula, chemical formula, or chemical structure. None of these terms appear in TSCA, however.

"chemical identity" in Section 8(a)(2)(A) (both quoted above). In this second appearance, it is clearly distinguished *within the same phrase* from "molecular structure," with each term *separately* listed as something that need to be reported. If Congress believed, as the Panel argues, that "molecular (or chemical) identity" was wholly synonymous with "molecular (or chemical) structure (or formula)," why would it have separately listed both of these terms in the same phrase? Simply put, it wouldn't, demonstrating that the two terms are not synonymous.

b. Nothing in TSCA precludes the definition of "chemical substance" from including physical and chemical properties.

The Panel argues that the definition of a chemical substance never mentions physical or chemical properties, which is true. The Panel then leaps to the conclusion that the definition thus somehow *excludes* such properties. This conclusion is wholly unsupported.

Moreover, Section 26(c)(2)(A)'s definition of chemical identity, quoted above, does refer to physical and chemical (as well as biological) properties. By noting that such properties can be similar, thereby supporting the grouping of chemical substances into a category, Congress implicitly recognizes the converse: that physical and chemical properties can also be used to distinguish chemical substances.

4. EPA's longstanding application of TSCA's definition of "chemical substance" routinely encompasses more than the substance's molecular structure where molecular structure alone is insufficient to define the substance.

a. EPA's definition and its routine listing on the Inventory of "UVCB" substances demonstrates that EPA can and does consider physical properties in defining a chemical substance.

The Panel claims that EPA *cannot* consider physical or chemical properties when defining a chemical substance: "EPA does not have the discretion under Section 3(2) to interpret the phrase "particular molecular identity" so that it encompasses a substance's physical and chemical properties...." This assertion is directly contradicted by EPA's own longstanding practice in defining chemical substances.

The TSCA Inventory includes tens of thousands of so-called Class 2 substances. EPA defines Class 2 substances as "those having chemical compositions not completely definite or known; therefore, a Class 2 substance cannot be characterized by one definite, complete chemical structure diagram." 60 Fed. Reg. at 16299. The subset of Class 2 substances most relevant here are those termed UVCB substances, formally known as Chemical Substances of **U**nknown or **V**ariable Composition, **C**omplex Reaction Products and **B**iological Materials. UVCBs are defined by EPA as that subset of Class 2 substances "that have no definite molecular formula representation and either partial structural diagrams or no structural diagrams." *UVCB Guidance* at 2, available online at www.epa.gov/opptintr/newchems/pubs/uvcb.txt. The guidance further states that "[e]ach name for a UVCB substance includes more than one molecular entity: as

such, each UVCB can be considered to be a category of molecules, often closely related."[6] *Id.* at 2.

EPA lists many UVCBs on the Inventory using "supplemental definitions" that extend beyond their Chemical Abstracts (CA) names but are integral parts of their names for TSCA purposes. According to EPA's *UVCB Guidance*:

> "**Chemical substance definitions often include** such information as the typical or allowed carbon number ranges or **physical property ranges**, the types of atoms or substances that may be included, and the raw material sources or processes of manufacture. Many definitions use a standard format. Typically, the first sentence states that the substance is a combination of substances of a certain class and indicates the nature or the process by which it was derived. The next sentence (or sentences) usually identifies the predominant components and perhaps an **approximate boiling range or other characteristic physical data**." (*Id.* pp. 3-4, emphases added)

That is, EPA can – and routinely does – define chemical substances for TSCA purposes, including for listing of specific chemicals on the TSCA Inventory, with *explicit* consideration of and reference to their physical properties, as well as their chemical structure. It does so because chemical structure is an insufficient descriptor of the relevant characteristics of the chemical substance.[7]

b. EPA's definition of UVCB substances[8] also demonstrates that EPA can and does consider other factors such as the manufacturing process in defining a chemical substance.

The Panel also implies (pp. 8, 11, 20) that EPA does not and cannot consider other factors beyond chemical structure in defining a chemical substance, such as the method by which it is produced or whether different production methods result, for example, in materials with different particle sizes. Again, this assertion is inconsistent with EPA's practice in defining chemical substances.

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[6] As EPA considers a UVCB to be a category of chemicals, it is worth noting that Section 26(c)(2)(A) defines a "category of chemical substances" as "a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties ... ." This definition would suggest that physical, chemical and biological properties could be considered as among the defining characteristics for UVCBs. As we discuss below, this is in fact the case.

[7] EPA and many other experts in the field of nanotechnology have argued that there is a critical need for a nomenclature system that accounts for physical structure and other physical and chemical properties as well as chemical structure and composition, in defining individual engineered nanomaterials. The development of such systems is being pursued by national (e.g., ASTM, ANSI) and international (e.g., the International Standards Organization) standard-setting organizations.

[8] Formally known as "Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials).

In describing its "Inventory Review," an explicit step in EPA's PMN review procedure, EPA makes clear that it considers factors beyond chemical structure, including process-related factors, in establishing a chemical substance's name for purposes of listing it on the Inventory:

> "The Inventory review is an extremely important component of the PMN review process, from both legal and technical standpoints. The Inventory review, performed by chemists within ICB [the Industrial Chemicals Branch], has two major functions. The first is to **establish a complete and accurate chemical name for the new substance**. The chemist compares the chemical structure, molecular formula, **the reactants, and the reaction scheme** for consistency with the CAS name submitted in the PMN."[9] (emphases added)

Hence, factors such as the reaction process are considered by EPA in the fundamental practice of naming a chemical substance for TSCA purposes. This fact is made even more explicit in the excerpt from EPA's *UVCB Guidance* already quoted above (repeated below with the relevant phrases emphasized):

> "**Chemical substance definitions often include** such information as the typical or allowed carbon number ranges or physical property ranges, the types of atoms or substances that may be included, and the raw material sources or **processes of manufacture**. Many definitions use a standard format. Typically, the first sentence states that the substance is a combination of substances of a certain class and indicates the nature or **the process by which it was derived**. The next sentence (or sentences) usually identifies the predominant components and perhaps an approximate boiling range or other characteristic physical data." (*Id.* at 3-4, emphases added)

In short, EPA can and routinely does consider factors beyond chemical structure in order to define a chemical substance, and it does so in particular when chemical structure alone is insufficient. Engineered nanomaterials are perfect examples of such chemical substances: Their enhanced or novel properties, which in many cases are a direct function of the means by which they are produced, are what make them new, giving them their own molecular identity and distinguishing them from existing chemical substances possessing the same molecular structure. To ignore such factors would be to ignore the very nano-ness of engineered nanomaterials.

In conclusion, we believe that it is entirely consistent with both the language of TSCA and EPA's own longstanding regulations and practice to designate engineered nanomaterials as "new" substances under TSCA (and thus subject to PMN review), even where a material has a chemical structure that is identical to a substance already included on the Inventory, unless the nanomaterial's chemical and physical properties are demonstrably identical to an existing conventional substance with the same chemical structure.

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[9] Chemistry Assistance Manual for Premanufacture Notification Submitters, EPA 744-R-97-003, March 1997, Chapter 1, p. 15, available online at www.epa.gov/opptintr/newchems/pubs/chem-pmn/.

Ms. Ann R. Klee
May 22, 2006

We appreciate your consideration of our views on this important matter, and would be pleased to discuss the issue further with you at your convenience.

Sincerely,

Richard A. Denison, PhD
Senior Scientist

Karen Florini
Senior Attorney

Cc:

Susan Hazen, OPPTS
Charles Auer, OPPT
Jim Alwood, OPPT
Jim Willis, OPPT
Don Sadowsky, OGC

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ATTACHMENT

September 2, 2004

The Honorable Susan B. Hazen
Acting Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Ms. Hazen:

Nanotechnology, the design and manipulation of materials at the molecular and atomic scale, is one of the most exciting fields in high technology – one that could revolutionize the way our society manufactures products, produces energy, and treats diseases. Innovative nanotechnology products are already reaching the market in a wide variety of consumer products; they also appear to hold great promise for environmentally beneficial applications in solar power production, groundwater cleanup, and many other areas.

However, just as nanomaterials' novel chemical and physical properties can make these substances extraordinarily useful, their novel properties may lead to new risks to workers, consumers, and the environment. As recently noted by the Royal Society and Royal Academy of Engineering of the United Kingdom:

> The properties of materials can be different at the nanoscale. ... Nanomaterials have a relatively larger surface area [that] can make materials more chemically reactive. ... [Q]uantum effects can begin to dominate the behaviour of matter at the nanoscale ... affecting the optical, electrical and magnetic behaviour of materials. ... The very properties of nanoscale particles being exploited in certain applications (such as high surface reactivity and the ability to cross cell membranes) might also have negative health and environmental impacts.[1]

Similarly, insurance giant Swiss Re has observed "Never before have the risks and opportunities of a new technology been as closely linked as they are in nanotechnology.

[1] The Royal Society & The Royal Academy of Engineering, 2004. *Nanoscience and nanotechnologies: opportunities and uncertainties*. London: The Royal Society & The Royal Academy of Engineering. Available at www.royalsoc.ac.uk/policy (accessed August 18, 2004).

It is precisely those characteristics which make nanoparticles so valuable that give rise to concern regarding hazards to human beings and the environment alike."[2] As a result, nanomaterials may present novel health and environmental risks that would not be predicted from the behavior of their larger-scale counterparts.

Nanomaterials are expected to be immensely useful in many applications. But as illustrated by asbestos, CFCs, DDT, leaded gasoline, PCBs, and numerous other substances, the fact that a product is useful does not ensure it is benign to health or the environment. And if it proves harmful after widely entering commerce, the consequences can include lengthy regulatory battles, costly clean-up efforts, expensive litigation quagmires, and painful public-relations debacles.

To try to avoid such consequences, Congress in 1976 enacted the Toxic Substances Control Act (TSCA). Among other provisions, TSCA requires that the producer of a new chemical file a Premanufacture Notice (PMN) with the Environmental Protection Agency (EPA) at least 90 days before commencement of manufacturing. Though the PMN process has some serious limitations, it provides at least some opportunity for a common-sense "look before we leap" – allowing EPA to review and assess the potential risks of a new material before it reaches the market and, if necessary, to require further information or to limit its use.

To date, however, it appears that not a single PMN has been filed for a nanomaterial, even though growing numbers of products containing nanomaterials are already on the market. Nor does it appear that any exemption notices for such materials, or even inquiries from prospective manufacturers as to whether a nanomaterial appears on the TSCA Inventory (termed "*bona fide* inquiries"), have been filed. While some applications of nanomaterials appear to be in products that are exempt from TSCA because they are subject to the Food, Drug, and Cosmetic Act, many of them appear to be squarely within TSCA's scope.[3]

One illustration of the current confusion over nanomaterials can be found in the fact that some Material Safety Data Sheets for carbon nanotubes carry the CAS number – and often display the health and environmental data – for graphite. From a scientific standpoint, this makes no more sense than listing graphite with the CAS number for diamond. While graphite, diamonds, and carbon nanotubes are all composed of carbon, the physical and chemical properties of the three substances are quite distinct, reflecting their radically different molecular structures.

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[2] Swiss Re (2004). Nanotechnology - Small matter, many unknowns. Available at http://www.swissre.com/INTERNET/pwswpspr.nsf/fmBookMarkFrameSet?ReadForm&BM=../vwAllbyIDKeyLu/YHAN-5YUCVT?OpenDocument (accessed August 18, 2004).

[3] Of these, some uses may not have triggered PMN requirements because the nanomaterials were imported as part of finished "articles." However, it is not clear whether this is true of all current applications.

Moreover, we understand that some observers have suggested that at least some nanomaterials may qualify for exemptions from PMN requirements. Such suggestions, coupled with the absence of filings of PMNs or exemption notices, imply that, at the least, there is considerable confusion as to the applicability of TSCA's requirements to nanomaterials. Even if all U.S. production of nanomaterials to date has been within the scope of the PMN exemption for R&D materials, it is clear that commercial-scale production will soon begin.

Accordingly, we write to ask that the Environmental Protection Agency (EPA) promptly take the following actions with regard to chemical substances produced via nanotechnology:[4]

1. For nanomaterials that have a molecular structure that is not already included on the TSCA Inventory, highlight the fact that they are "new" chemical substances within the meaning of TSCA and that accordingly they are subject to TSCA's PMN provisions. Though this point should come as no surprise to nanomaterial producers, articulating it will provide a useful reminder to industry, as well as important information for the public.

2. For nanomaterials that have a molecular structure identical to a substance already on the Inventory, clarify (through issuance of a public statement or Guidance) that they nonetheless constitute "new" substances for TSCA purposes and thus are subject to TSCA's PMN provisions unless the nanomaterial's chemical and physical properties are demonstrably identical to the conventional substance. By definition,[5] an engineered nanoparticle or nanofilm comprised of substances already on the Inventory is being developed precisely *because* it has "novel properties" that differ significantly from those of the conventional material. Hence its molecular identity can and should be considered "new," regardless of whether its molecular formula or structure is "new." Significantly, TSCA defines a chemical substance as one that has "a particular molecular identity" (TSCA section 3, 15 USC section 2602(2)). EPA thus has discretion to interpret the term "molecular identity" to have a meaning encompassing more than just molecular formula or structure, in order to ensure that novel substances are in fact identified as "new" and hence receive the careful review they warrant by being subject to PMN requirements.

As noted in the Conference Report accompanying TSCA's enactment, "the most desirable time to determine the health and environmental effects of a substance, and to

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[4] The National Nanotechnology Initiative (NNI) defines nanotechnology as involving all of the following: "1. Research and technology development at the atomic, molecular or macromolecular levels, in the length scale of approximately 1-100 nanometer range. 2. Creating and using structures, devices and systems that have novel properties and functions because of their small and/or intermediate size. 3. Ability to control or manipulate on the atomic scale." For purposes of this letter, use the term "nanomaterials" is intended to exclude nano-sized materials that are naturally occurring or unintentionally produced, in contrast to engineered nanomaterials.

[5] See point 2 in the NNI definition quoted in footnote 4 above.

take action to protect against any potential adverse effects, occurs before commercial production begins. Not only is human and environmental harm avoided or alleviated, but the cost of any regulatory action in terms of loss of jobs and capital investments is minimized. For these reasons the conferees have given the Administrator broad authority to act during the notification period."[6] It is inconceivable that Congress would have intended to accompany that broad grant of authority with a narrow interpretation of which chemicals qualify as "new" under TSCA.

It is also worth noting that this approach mirrors the recommendation of the United Kingdom's Royal Society and Royal Academy of Engineering that nanomaterials (specifically including chemicals in the form of nanoparticles or nanotubes) be treated as new substances for regulatory purposes (Recommendation 10).[7]

3. Clarify, through issuance of a public statement or Guidance, that the types of nanomaterials now being produced for commercial use do not qualify for the polymer exemption from PMN requirements under 40 CFR section 723.50(e). In addition, EPA should affirmatively determine whether the existing criteria that define those polymers that are eligible for the exemption can be appropriately applied to polymeric nanomaterials that may be developed in the future, or whether additional or different criteria are needed.

4. Use the discretion provided under section 723.50(d) to determine that, until a sufficient basis is established for setting thresholds appropriate for nanomaterials, such materials are not eligible for the existing exemptions from PMN requirements available for substances produced annually in quantities of 10,000 kilograms (approximately 22,000 pounds) or less, and for "low release/low exposure" substances. Given that a defining characteristic of most if not all nanomaterials is that they exhibit dramatically higher levels of activity per unit mass than conventional materials, the existing thresholds defining de minimis production volume, release and exposure should not be applied to nanomaterials. While at some point it may be appropriate for EPA to provide such exemptions from PMN requirements for certain types of nanomaterials, too little is now known to establish such criteria in advance of PMN review.

This recommendation is also consistent with that of the Royal Society, which urged reconsideration of the production thresholds that trigger testing for new chemicals (Recommendation 10) in light of the novel properties of nanomaterials.[8] Moreover, it should be noted that EPA has previously set more rigorous (i.e., lower) exemption thresholds for certain classes of chemicals of particular concern, specifically persistent,

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[6] Conference report No. 1679, 94th Congress, Second Session (1976), page 65. Reprinted in *Legislative History of the Toxic Substances Control Act*. Committee Print: House Committee on Interstate and Foreign Commerce. Washington, DC: U.S. Government Printing Office.

[7] See footnote 1.

[8] See footnote 1.

bioaccumulative and toxic (PBT) chemicals in the context of the Toxics Release Inventory.

5. State publicly that EPA is unlikely to approve a PMN for a nanomaterial in the absence of hazard and exposure data sufficient to characterize its potential risks, and that where such data are not submitted, EPA will likely require its generation and submission. Unlike conventionally produced materials, for which a substantial body of information already exists that EPA can and does use to assess the potential risks of a new chemical based on its structure and function, the novel character of nanomaterials and the dearth of information and experience relevant to assessing their potential risks argues for an information-driven approach at this time. Making such a statement would both assist industry in planning to meet such data-generation needs, and provide assurance to the public.

In sum, we ask that you issue guidance, and where necessary initiate rulemaking, to clarify that nanomaterials are subject to the PMN process and to ensure that there are no "nano-loopholes" in TSCA. This request is given urgency by recent studies suggesting that some nanomaterials possess properties that may present risks to human health or the environment, as summarized in the Royal Society's recent report. While such data are too limited at present to draw definitive conclusions, they clearly indicate that there is no basis for assuming that nanomaterials are intrinsically non-hazardous. Accordingly, nanomaterials should be subject to PMN requirements and undergo a robust PMN review.

Thank you for attention to this matter. We would appreciate a response indicating how the Agency intends to address the issues raised above.

Sincerely,

Richard A. Denison, Ph.D., Senior Scientist

Karen Florini, Senior Attorney

cc: Charles M. Auer, Director, Office of Pollution Prevention and Toxics