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ENVIRONMENTAL DEFENSE

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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. 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.

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[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).

[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).

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.

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]

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[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.

[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.

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 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

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

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, 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

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[8] See footnote 1.