



ENVIRONMENTAL DEFENSE

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USEPA's Public Meeting on the Development of a
Voluntary Nanoscale Materials Stewardship Program
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I appreciate the opportunity to provide the following comments on EPA's "Concept Paper for the Nanoscale Materials Stewardship Program under TSCA" and "TSCA Inventory Status of Nanoscale Substances – General Approach," which were noticed in the *Federal Register* on July 12, 2007. (Docket# EPA-HQ-OPPT-2004-0122-0058)

A. Comments on EPA's "Concept Paper for the Nanoscale Materials Stewardship Program under TSCA"

EPA held its first public meeting on engineered nanoscale materials on June 23, 2005. Shortly thereafter, EPA called upon its federal advisory committee, NPPTAC, to form a multi-sector work group to advise EPA on an overall approach to address the potential risks of such materials.¹ I represented Environmental Defense on that work group. EPA requested that we act quickly to complete our work on an extremely demanding schedule over the hot summer months. With all of us believing that EPA was eager to act on what we came up with – and sharing that strong sense of urgency – we worked hard to reach agreement on a proposal. We solicited and incorporated public comments on it, which were received in writing and at yet another public meeting (held on September 29), and finalized and delivered our proposal on time. After consideration by the full NPPTAC, the proposal was forwarded to the EPA Administrator in November, and promptly embraced by EPA.²

A core element of the work group's proposal was a framework for a voluntary program. The work group viewed the main purpose of such a program as quickly informing EPA and the public as to which nanoscale materials were in or soon to enter commerce and the extent of risk-relevant information that was available about them. It was a shared expectation that EPA would in turn expeditiously determine what additional information it should call for and what actions it should take to ensure protection of human health and the environment. The proposal called for volunteers to sign up during a period limited to 6-12 months,³ and, for the "basic" program track, to submit requested available information and apply basic risk management practices within three months of sign-up.

As a member of the work group, Environmental Defense supported the proposal for a voluntary program because:

- It was one part of the overall proposed approach, which also encompassed a number of concurrent regulatory steps intended to provide a "backstop" to the voluntary program.
- It was to be limited in duration and completed expeditiously.

- We recognized that developing and finalizing regulatory vehicles – even if immediately initiated – would require considerable time, and that a voluntary program could – as an interim measure – both supplement and inform such vehicles.

We are now gathered nearly two years later. During this time, the urgency for action has only grown: Hundreds of nanoscale material-containing consumer products have entered the market, and long lists of unmet research needs have been drawn up by EPA and other national and international bodies. Yet we still lack more than a cursory understanding of what nanoscale materials are or are soon to be in commerce, for what applications and in what quantities, and what information is available about them. Had the NPPTAC proposal been acted upon by EPA as intended, the basic program would have been completed well before now.

Instead, EPA has issued a new “concept paper” describing a framework for a voluntary program and is holding yet another public meeting. Why EPA felt the need to effectively start over by issuing a new proposed framework, and why it took so long to do so, is difficult to understand given that the framework EPA is now proposing is quite similar to that proposed by NPPTAC two years ago.

But of equal concern is the fact that EPA has jettisoned key elements of the NPPTAC proposal:

- No deadlines: EPA’s proposal is for an open-ended program, with no deadlines for companies to sign up, deliver information or apply basic risk management practices. The only timelines identified in the concept paper are loose and apply only to EPA: it “may publish” an interim report after one year, “will develop” a report and evaluation after two years, and then will make a decision on whether to continue the program. Elsewhere, EPA indicates that an information collection schedule for the program “does not apply.”⁴ Nor has EPA indicated even an approximate time by which it intends to launch the program.
- No regulatory backstop: EPA’s proposal does not include any mention of co-development of reporting rules under TSCA Sections 8(a) and 8(d), which the NPPTAC proposal called for and identified as a “near-term need” to provide a backstop to the voluntary program:⁵ “EPA should proceed with developing appropriate TSCA Section 8(a) and 8(d) rules, coordinated with the NVP [nanoscale materials voluntary program] in a timely manner to create incentives for participation in the NVP, and obtain the needed information for EPA to carry out their responsibilities under TSCA.”⁶ Indeed, EPA indicated to NPPTAC in 2005 that it had *already* initiated development of such rules.⁷ Yet, other than a perfunctory reference to its authority under TSCA to issue such rules,⁸ EPA’s documents provide no indication of any activity or intent to develop such rules.

The Basic Program Track

Given the absence of the essential features just described and the enormous delay, Environmental Defense is unable to support EPA’s proposal for a voluntary “basic” program. At this point, we instead urge EPA to rapidly develop and implement mandatory reporting rules – a step it claimed to have initiated more than two years ago but for which there is no evidence of any actual progress. The need for these rules has only grown more apparent over the last two years in view of the extremely poor rate of participation in the United Kingdom’s Voluntary

Reporting Scheme (VRS), which was launched in September 2006. Nine months into that two-year program, a total of nine submissions have been made, only seven of which are from companies.⁹ (Indeed, given the poor response, the UK government is itself anticipating the need for “compulsory measures.”¹⁰) Similarly, a voluntary survey recently conducted in Denmark yielded so little response and so little information that it did not warrant publishing.

This tepid response has led to urgent discussions at the OECD (which include USEPA representatives) as to how governments can make it easier for companies to participate in voluntary programs. Even during the NPPTAC discussions, it was a widely-held view and concern that incentives for companies to volunteer were likely very limited. Disturbingly, measures now being discussed at the OECD to increase participation include: providing even greater allowances for claiming information to be confidential and hence not to be disclosed, limiting the ways in which governments would use any information they receive, and allowing data to be submitted in any form and format – making it harder to compile, compare and share. In our view, the US and other OECD members are losing sight of a key original objective of such programs – to build public trust and confidence by making robust information available – an aim that would be severely compromised if these kinds of measures to boost participation are taken.

We are also increasingly concerned about the significant potential for participation in a voluntary program to be both limited and selective. The result could well be a highly skewed picture regarding the range of nanoscale materials in or soon to be in commerce. If, for example, only those companies that are more visible or more responsible choose to participate, then information received will be far from representative and could mislead more than it could assist.

Mandatory reporting rules, in our view, are the only viable means to ensure a level playing field and submission of a comprehensive and representative set of information. Should EPA choose to proceed with a voluntary program, it should not supplant or delay development of such reporting rules. Moreover, the “basic” program track¹¹ should be conducted over a period of at most a few months: A month for companies to decide whether to sign up, and two months to gather and submit the request information, should be more than enough time, given that extensive public discussion of such a program has been underway for more than two years and the information to be reported is limited to that already “known or reasonably attainable.”¹² As evidenced by the poor participation rate in the UK voluntary program, an open-ended program with no clear deadline for signing up only invites delay: Companies have every incentive to hang back and wait to see who will go first.

The In-Depth Program Track

With respect to the proposed “in-depth” program track, here again other events have overtaken EPA to a significant degree. As EPA briefly notes in Annex D to its concept paper, the OECD has established a Working Party of Manufactured Nanomaterials (WPMN).¹³ An explicit task now underway in the WPMN is to undertake in-depth hazard data development for representative nanoscale materials. EPA’s paper does not describe how its proposal relates to this international effort. From our perspective, it makes little sense for the US to pursue its own independent hazard testing program, and EPA’s resources and efforts would be better spent in ensuring that the WPMN initiative is as robust and expeditiously executed as possible.

However, EPA's list of elements that could be contained in the "plans of action" it envisions as the product of the in-depth program track include a number of components beyond hazard testing:

- Monitoring or estimating exposures and releases;
- Evaluating the effectiveness of protective equipment or engineering controls;
- Developing a model worker education program; and

These elements, in our view, should be vigorously pursued and would not be duplicative of other efforts. We urge EPA to focus its stewardship program efforts on these components and to work closely with NIOSH in doing so. These efforts should be initiated immediately, as they do not depend on the outcomes of reporting or testing initiatives, whether voluntary or regulatory.

B. Comments on EPA's "TSCA Inventory Status of Nanoscale Substances – General Approach"

New vs. existing inventory status: Environmental Defense strongly disagrees with EPA's proposed approach to determining the TSCA Inventory status of a nanoscale material the bulk form of which (with the same chemical structure) is already listed. EPA's proposed approach would effectively ignore the very nano-ness of such nanoscale materials. We have expounded at length elsewhere on this topic,¹⁴ so we will only briefly amplify on our views here. EPA's proposed approach is not required by precedent, as EPA claims, and it reflects bad policy, plain and simple.

- **Not required by precedent:** EPA effectively says it cannot consider particle size (and by implication, any other nano-specific characteristics) to distinguish among substances on the Inventory because it has not done so in the past. The first and simplest response to this argument is that EPA may well not have needed – or recognized that it needed – to make such distinctions before nanoscale materials came along and rendered such distinctions critically important. The real question is whether it can if it needs to. As we have documented extensively elsewhere, EPA has ample authority under TSCA to distinguish among chemical substances based on factors such as physical properties and production processes. Moreover, we have shown that it has actually done so where such factors are necessary to clearly and unambiguously identify and name a substance or distinguish among substances.¹⁵

In its paper, EPA maintains that "since EPA generally has not considered *units of matter beyond molecules*, such as physical aggregates, to be reportable under the TSCA Inventory, EPA has not used particle size to distinguish for Inventory purposes two substances that are known to have the same molecular identity" (page 4, emphasis added). Putting aside EPA's erroneous equating of "molecular identity" with chemical structure,"¹⁶ EPA's statement is contradicted by one of its own examples cited in the paper one page earlier (page 3): EPA indicates that it has identified as having distinct molecular identities different crystal lattice forms, each of which is comprised of the same molecule (the example cited is the molecule titanium dioxide). It is very hard to understand why EPA was able and willing to make the distinction in this example between two super-molecular, aggregate forms of the same molecule, yet says it cannot do so in the case of nanoscale vs. larger super-molecular aggregates.

- **Bad policy:** EPA’s approach is bad policy for the following reasons:
 1. It pretends that nanoscale materials are nothing new: Nanoscale materials are of commercial interest precisely because they have new and enhanced properties that differentiate them from their bulk counterparts (where such counterparts exist). It is widely acknowledged, and there is mounting corroborating evidence, that such different properties also mean they can differ with respect to their biological activity. Policy that treats them as if they aren’t different is illogical and flies in the face of common sense.
 2. It eliminates any possibility of pre-market review: There is widespread agreement, including from many in industry, that the potential risks of nanoscale materials should be examined upfront, rather than waiting until a problem develops.¹⁷ While there is considerable debate over how best to accomplish this objective, it is incumbent on EPA to demonstrate how anything like that will take place under its proposed policy for nano forms of existing materials. Under TSCA, a decision that a chemical substance is “existing” rather than “new” has profound policy consequences: EPA’s proposed approach would remove the *only* means by which any government review of the affected nanoscale materials can be assured prior to commencement of their manufacture. (This policy defect is even further exacerbated by the fact that EPA has not included any mention of using so-called “existing chemical SNURs” (Significant New Use Rules) as part of its approach. While we question the adequacy of using such SNURs (see below), some have argued that EPA can and should use them to provide an alternative means of achieving the goal of ensuring upfront review of nanoscale materials.)
 3. It is very short-sighted: EPA justifies its approach by saying it will continue adhering to “the approach EPA has historically taken under TSCA” (page 2). This stance is short-sighted and hardly reassuring when we are dealing with only the first wave of a whole new class of materials for which particle size and other physical-chemical characteristics are paramount in identifying and addressing their potential risks. Most of today’s nanoscale materials are variants on existing materials,¹⁸ and so it is tempting to minimize the differences and try to get away with just tweaking the current system. Such an incremental approach to these new and rapidly evolving materials is bound to break down, and likely sooner rather than later.

EPA is clearly having difficulty acknowledging from a policy perspective that the “identity” and properties of even the current generation of nanoscale materials are dictated not only by chemical structure, but also by their physical attributes. Consider the more complex and dynamic elements expected to emerge in next-generation nanoscale materials, and mixed biological-chemical materials, and so forth. Now is the time for EPA to start thinking through how to identify and evaluate materials based on more than just chemical structure, regardless of whether they are variants of existing chemicals. Postponing the inevitable won’t work when it comes to managing nanoscale materials and other anticipated advances in materials technologies.

Significant New Use Rules (SNURs): Conspicuously absent from EPA’s documents is any discussion of the option of using “existing chemical SNURs” as an alternative to designating nanoscale forms of existing chemicals to be new chemical substances under TSCA. But because EPA staff have discussed this option frequently in the past, and others have promoted it,¹⁹ we will summarize our serious concerns about the feasibility of this approach.²⁰

- *Rarely used:* EPA has frequently issued SNURs in conjunction with its review of premanufacture notifications (PMNs) for new chemicals: more than 1,300 such “new chemical SNURs” had been issued as of the end of 2005.²¹ In contrast, “existing chemical SNURs” are far rarer: EPA had issued only about 40 “existing chemical SNURs” as of May, 2006.²² “New chemical SNURs” can be and usually are issued as direct final rules,²³ whereas “existing chemical SNURs” must proceed through full notice-and-comment rulemaking. Hence, both EPA’s SNUR authorities and its history of issuing them argue, if anything, for – not against – the designation of nanoscale versions of existing chemicals as “new” chemicals, bolstered by issuance of “new chemical SNURs” where needed.
- *No precedent for basing “existing chemical SNURs” on physical properties:* Proponents of “existing chemical SNURs” argue that they could: (a) invoke physical characteristics and properties to distinguish nanoscale from bulk forms of the same chemicals; and (b) be issued for broad categories of nanoscale materials that share such physical attributes but do not share the same or similar chemical structures. None of the existing chemical SNURs ever issued by EPA have incorporated either of these features, however.²⁴ As discussed earlier, EPA has invoked a lack of precedent as a rationale for not using physical properties like particle size to designate nano forms of existing substances to be new chemicals; yet a lack of precedent applies to SNURs as well.
- *Evidentiary burden to issue SNURs:* By definition, a SNUR cannot be used to regulate any existing use. Hence, not only are existing uses of nanoscale materials off limits to a SNUR approach, but EPA needs to have or develop sufficient information to know which uses of a material are and are not “new.” To issue a SNUR, EPA must develop information on and consider several factors, including the projected production and processing volume of the chemical substance; the anticipated extent to which the new use changes the type or form, and increases the magnitude and duration, of exposure to humans or the environment associated with the new use; and the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.²⁵ This evidentiary burden will be a greater challenge to meet in the relatively information-poor environment surrounding nanoscale materials, posing a classic *Catch-22*.

These and other serious challenges would need to be overcome were EPA to propose the use of “existing chemical SNURs” as a means to ensure that engineered nanoscale materials are effectively assessed prior to commercial introduction.

Failure to address exemptions from new chemical notification requirements: EPA’s approach fails to address another widely acknowledged concern about the applicability of TSCA Section 5’s provisions to nanoscale materials deemed to be new chemicals: the need to re-examine currently available exemptions from notification requirements and revise them to reflect the characteristics of nanoscale materials.²⁶ These exemptions include the Low Volume Exemption (LVE), the Low Release and Exposure Exemption (LOREX), and the Polymer Exemption (PE). The first two exemptions are based in whole or in part on mass measures that were developed for conventional substances. Experts are virtually unanimous in stating that the potential for nanoscale materials to have much greater activity per unit mass, due to increased surface area or other related factors, means that mass-based thresholds need to be developed with specific consideration of nanoscale materials and not simply carried over from those used for conventional substances. The polymer exemption is based on consideration of the bioavailability of conventional polymers. Yet evidence indicates polymer nanoparticles can enter and behave

within biological systems in very different ways, so there is a pressing need to revisit the existing criteria that define exempt polymers and determine the extent to which they can be appropriately applied to polymeric nanoscale materials.

Conclusion

While a voluntary program made sense as a starting point two years ago when first proposed, we have concluded that it no longer does. Given the major delays in moving toward launch of such a program, and the various events that have occurred and the experience gained at home and abroad in the intervening two years, we urge EPA to move expeditiously to develop and implement mandatory reporting rules applicable to all companies producing, importing and handling engineered nanoscale materials. Such rules are necessary if EPA is to gain a comprehensive, accurate picture of the extent and nature of nanoscale materials in commerce and information available about them. And only such rules will yield a level playing field for companies and build a sense of confidence among the public that EPA is proceeding on the basis of sound information.

If EPA nonetheless chooses to pursue a voluntary reporting program, it should not supplant or delay development of mandatory reporting rules. Any such program should be of very limited duration, so as to quickly collect whatever information is to be provided by volunteers, and the selective and likely unrepresentative nature of such information should be recognized.

With respect to the “in-depth” program track, EPA should focus any testing-related efforts on ensuring that the OECD testing program is as robust and expeditiously executed as possible. EPA can and should, however, vigorously engage and assist companies in developing “plans of action” that implement protective risk management practices.

We also urge EPA to rethink its approach to determining the Inventory status of engineered nanoscale materials. In our view, EPA has ample authority and discretion to implement a sound, forward-looking policy, and should not squander an opportunity to do the right thing by an overly rigid reliance on a very narrow view of its own past practice. The most glaring defects of EPA’s documents are their failure to acknowledge and consider the implications of EPA’s proposed approach with respect to EPA’s ability both to carry out its responsibility to ensure that engineered nanoscale materials do not pose undue risks to human health or the environment, and to keep up with the ever-accelerating pace of technology and new materials development.

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Endnotes

¹ This group was the Interim Ad Hoc Work Group on Nanoscale Materials formed under the auspices of the National Pollution Prevention & Toxics Advisory Committee (NPPTAC).

² NPPTAC, “Overview Document on Nanoscale Materials,” November 22, 2005, available online at www.epa.gov/oppt/npptac/pubs/nanowgoverviewdocument20051125.pdf

³ *Ibid*, pp. 10-11. A second sign-up period was to be provided for new companies or materials that emerged after the first period, or under other exceptional circumstances, but was to be implemented so as not to allow entities eligible from the outset to delay or defer signing up.

⁴ See EPA’s “Supporting Statement for an Information Collection Request (ICR),” Section 5(d), page 9. See also Section 6(a)(2), page 15, where EPA refers to a “three-year ICR period.”

⁵ NPPTAC Overview Document, *op. cit.*, p. 8.

⁶ *Ibid*, p. 11.

⁷ *Ibid*, pp. 2, 7 and 8.

⁸ EPA, “Concept Paper for the Nanoscale Materials Stewardship Program under TSCA,” Annex C, pp. 16 and 18.

⁹ See Department for Environment, Food & Rural Affairs, “Third quarterly update on the Voluntary Reporting Scheme for engineered nanoscale materials,” July 2007, at www.defra.gov.uk/environment/nanotech/policy/pdf/vrs-report3.pdf.

¹⁰ *Ibid*, Conclusions section.

¹¹ We recognize that an in-depth program that entails new testing would obviously need a longer period, but urge that EPA also specify short deadlines to sign up for it and deadlines for data submission.

¹² “Concept Paper for the Nanoscale Materials Stewardship Program under TSCA,” p. 3.

¹³ See the Organization for Economic Cooperation and Development’s (OECD’s) nanotechnology public website at webdomino1.oecd.org/comnet/env/wp-nano.nsf.

¹⁴ See articles and letters posted at www.environmentaldefense.org/article.cfm?ContentID=5132.

¹⁵ See letter from Environmental Defense to EPA General Counsel Ann R. Klee, May 22, 2006, pp. 3-6. available at www.environmentaldefense.org/documents/5265_StatusofNMsUnderTSCA.pdf; and Environmental Defense, “A response to ABA’s ‘Regulating Nanomaterials Under TSCA Section 5,’” August 31, 2006, available at www.environmentaldefense.org/documents/5421_EnDefNanoBriefing.pdf.

¹⁶ See letter from Environmental Defense to EPA General Counsel Ann R. Klee, *op. cit.*, pp. 3-6.

¹⁷ See, for example, the Joint Statement of Principles of Environmental Defense and American Chemistry Council Nanotechnology Panel, submitted at EPA’s June 23, 2005 public meeting, available at www.environmentaldefense.org/documents/4857_ACC-ED_nanotech.pdf.

¹⁸ Overwhelmingly if measured by production volume, and possibly even by material count, nanoscale versions of existing chemical substances constitute the majority of nanoscale materials in commerce. This is why EPA’s approach to the “new” vs. “existing” issue is of paramount importance.

¹⁹ See, for example, “Regulation of Nanoscale Materials under the Toxic Substances Control Act,” prepared by the Section of Environment, Energy and Resources, American Bar Association, dated June 2006, available at www.abanet.org/environ/nanotech/pdf/TSCA.pdf.

²⁰ For more detail, see Environmental Defense, “A response to ABA’s ‘Regulating Nanomaterials Under TSCA Section 5,’” *op. cit.*

²¹ Personal communication from Anna Coutlakis, New Chemicals Program, OPPT, August 20, 2006.

²² List provided by OPPT on August 22, 2006.

²³ In 1989, EPA issued regulations specifying an “expedited process” for issuing new chemical SNURs, whether in conjunction with a Section 5(e) consent order (CFR 721.160) or not following such an order (CFR 721.170). The expedited process provides for such SNURs to be issued as direct final rules in most cases. According to EPA, all but 17 of the new chemical SNURs it has issued used the expedited process, though not all of those were done through direct final rules.

²⁴ Our examination of the existing chemical SNURs issued to date found that none have used particle size or other such physical properties to define what constitutes a “significant new use.” And all such SNURs issued for categories of chemicals apply only to substances with very similar chemical structures.

²⁵ See Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)).

²⁶ This need was identified by NPPTAC in 2005; see NPPTAC Overview Document, p. 9.