

**Alaska Community Action on Toxics \* The Alliance of Nurses for Healthy  
Environments \* Breast Cancer Fund \* Center for Environmental Health  
Clean and Healthy New York \* Clean Production Action \* Clean Water Action  
Commonweal \* Connecticut Coalition for Environmental Justice \* Ecology Center  
Environment America \* Environmental Defense Fund \* Environmental Health  
Strategy Center \* Learning Disabilities Association of America \* Natural Resources  
Defense Council \* Science & Environmental Health Network**

**Comments on  
Certain High Production Volume Chemicals; Test Rule and Significant New Use  
Rule; Fourth Group of Chemicals: Proposed Rule**

**EPA-HQ-OPPT-2010-0520**

**76 Federal Register 65580-65608 (Friday, October 21, 2011)**

**Submitted January 18<sup>th</sup>, 2012**

**Summary**

The undersigned organizations hereby submit the following comments on EPA's proposed rule addressing a batch of 45 "orphan" chemicals from the High Production Volume (HPV) Challenge Program. In general, we applaud EPA's proposal to couple its issuance of a test rule for the 23 of these HPV chemicals for which it can make the requisite exposure findings, with a Significant New Use Rule (SNUR) for the other 22 HPV chemicals for which it cannot make such findings.

Previous final test rules for earlier batches of HPV orphan chemicals were issued without an accompanying SNUR, and hence did not address those orphan HPV chemicals initially included in the proposed rule for which EPA was unable to make the exposure findings needed to justify issuance of a test rule under the Toxic Substances Control Act (TSCA). That approach leaves open the possibility that production or use of such chemicals could expand in the future in a manner that would present significant exposure potential, without EPA learning of such expansion in a timely manner and having the ability to require development of basic information sufficient to screen such chemicals to determine if they may be hazardous to human health or the environment.

Given that HPV chemicals are, by definition, produced in aggregate volumes greater than or equal to one million pounds per year, we strongly support the proposal that EPA – when unable at present to require testing – at least be able to review the risks associated with a significant new use of such a chemical before that new use is initiated. Using the combination of a test rule and a SNUR is a more thorough approach to identifying the potential risks posed by these 45 chemicals and will better allow EPA to fulfill its responsibility to protect human and environmental health from hazardous chemicals.

However, while we strongly support the current proposed rules, we believe this same approach needs to be expanded to other groups of chemicals originally included in the HPV Challenge

Program. EPA should issue SNURs or test rules for the following additional groups of HPV chemicals that either were removed from, or have yet to be adequately tested under, the program:

- chemicals included in previous proposed rules on HPV orphan chemicals, but not in the corresponding final rule, due to lack of sufficient evidence of substantial human exposure or environmental release;
- chemicals that were initially identified as being HPV, but were designated no longer HPV based on production volume data that emerged later through Inventory Update Rule (IUR) reporting, despite the infrequent nature of the reporting that compromises its ability to reflect true production volume;<sup>1</sup> and,
- chemicals that were sponsored through the HPV Challenge Program (or a sister OECD program), but for which a base set of hazard information is still lacking.

We have provided in our comments below the approach we suggest EPA take to address each of these groups of chemicals.

### **Responses to the Request for Public Comment**

Below are our comments on each relevant question for which EPA is soliciting comment. They are numbered in accordance with EPA's numbering in the proposed rule.

#### **1. EPA requests comments on its proposal to combine a test rule and a SNUR for the fourth batch of HPV chemicals. EPA also intends to apply this approach to actions on HPV chemicals identified in future cycles of the Chemical Data Reporting (CDR) rule.**

*The current proposal:* Issuing a SNUR along with a test rule for the fourth batch of HPV chemicals will better ensure that EPA has access to the information it needs to achieve safe management of these chemicals. Finalizing this proposed rule will allow EPA to work within its existing authority both to require testing for chemicals for which it can currently justify a test rule and to ensure that it is notified of changes in the production or use of other HPV chemicals that may increase their release or exposure potential. We support this action and believe that it is both appropriate and wholly justified to combine test rules and SNURs for HPV chemicals identified in future cycles of CDR reporting.

We support the proposed combined issuance of a test rule and SNUR for the 45 orphan HPV chemicals because it will increase the hazard and release/exposure information that is available to EPA and to the public. The hazard data that will be developed for chemicals subject to the test rule will be valuable for regulatory decisions and will better support the ability of the public and the market to make better-informed decisions about

---

<sup>1</sup> As described below, this group includes chemicals removed from the program by EPA whether or not the removal occurred in the course of finalizing a test rule and hence extends beyond orphan chemicals.

chemicals. The requirements of the SNUR will ensure EPA is promptly made aware of changes in the uses of the subject HPV chemicals. We strongly support the requirement in the SNUR that companies notify EPA about any use of a chemical in a consumer product or any use that would expose more than a certain number of workers at a single corporate entity (see our later comments on the appropriate threshold).

The information that becomes available under each of the components of the proposed rule will contribute to EPA's efforts to improve transparency and access to information. As EPA states in the Federal Register notice for this proposed rule: "Open access to information allows individuals, communities, businesses, and governments to make informed decisions and policies that incorporate environmental and health considerations and minimize external and/or unintended harmful impacts" (76 FR 65583). Enhancing EPA's, the market's, and the public's ability to make "informed decisions" is fundamental to improving the chemicals management system in the U.S.

In addition, we applaud EPA's efforts through this combined rule approach to enhance efficiency to the benefit of all stakeholders. Pairing the test rule with a SNUR facilitates EPA's administration of the rule by making industry responsible for providing data that will allow EPA to determine whether an HPV chemical may be subject to a test rule. Otherwise, EPA would have to continually reassess exposure potential, including by developing multiple reporting or notification rules, wasting time and resources. At the same time, the combination of the rules will likely facilitate the industry's management of its regulatory obligations by streamlining the requirements into a single rule.

*Future HPV chemicals:* Applying the combination of a test rule and a SNUR to HPV chemicals identified in the future will also help EPA to better protect human health and the environment for chemicals with elevated potential for release and exposure. In reference to the chemicals subject to the SNUR, EPA states that "simply removing such a chemical substance from the test rule in such circumstances, without including it in the SNUR, would not provide a regulatory mechanism for timely notification to EPA in the event of changed circumstances that would likely justify the issuance of a test rule for the chemical substance" (76 FR 65582). EPA cannot properly do its job without prompt notification through a SNUR that a HPV chemical is being used in a new way.

*Other chemicals currently or previously identified as HPV:* In considering the benefits of coupling a test rule with a SNUR, we came to the conclusion that this approach would not only improve EPA's management of HPV chemicals identified in the *future*, but would also help the Agency address chemicals it has previously identified as HPV. EPA has withdrawn many chemicals it initially identified as HPV for a variety of reasons throughout the history of the HPV Challenge Program. Many other chemicals sponsored years ago under the program (or its OECD counterpart) have yet to have a complete base set of hazard information developed and made public. We advise EPA to address these chemicals using a strategy analogous to that laid out in the present proposed rule, as follows.

1. First, EPA should go back and issue a SNUR to address those HPV chemicals included in the proposed but removed from the final test rules for earlier batches of HPV orphan chemicals, due to lack of sufficient evidence of substantial human exposure or environmental release.<sup>2</sup> As with the current proposal, the SNUR would require notification to EPA of changes in the production or use of those chemicals that would lead to a significant increase in exposure or release.

2. Moreover, this same rationale and the need for an analogous solution extend to three other groups of HPV chemicals that were included in the original HPV Challenge Program:

- The 405 chemicals that were removed from the program because they were purportedly “no longer HPV” – based on the spotty production data EPA gathered for only one year out of every four years under the Inventory Update Rule. For these chemicals, a SNUR should be issued, under which an increase in their production to the HPV level would be among the significant-new-use triggers requiring notification to EPA.
- The 13 chemicals included in the earlier proposed HPV orphan chemical test rules that were removed because they were purportedly no longer HPV. Here again, a SNUR should be issued for these chemicals, under which an increase in their production to the HPV level would be among the significant-new-use triggers requiring notification to EPA.
- HPV chemicals that are sponsored (and hence not orphans), but for which a base set of hazard information is still not available. Many chemicals sponsored under the Challenge or its sister HPV program managed by the Organization for Economic Cooperation and Development (OECD) have languished for long periods of time without execution of the data development called for by sponsorship, or never had complete base sets of hazard information submitted. For these chemicals, for which basic hazard information is still denied to the public many years after initiation of these programs that were supposed to deliver it, EPA should either:
  - issue a SNUR, where – if consistent with the regulations for issuing SNURs – a notification-triggering event would be the absence of a complete base set of hazard information; the SNUR would provide EPA with the opportunity to review the chemical and determine if it can justify a test rule for the chemical or set conditions under which a testing requirement would be triggered; or
  - determine for each such chemical (as it has done in the current proposal):
    - that the requirements for issuance of a test rule are met, in which case EPA would issue such a rule, or

---

<sup>2</sup> By our count, there are six such chemicals: CAS# 65996-79-4, Solvent naphtha (coal); 65996-82-9, Tar oils, coal; 65996-92-1, Distillates (coal tar); 68187-57-5, Pitch, coal tar-petroleum; 68988-22-7, 1,4-Benzenedicarboxylic acid, 1,4-dimethyl ester, manuf. of, by-products from; and 73665-18-6, Extract residues (coal), tar oil alk., naphthalene distn. residues.

- that the requirements for issuance of a test rule are not met, in which case EPA would issue a SNUR instead that specifies among the triggers for notification those changes in production or use of the chemical that would lead to exposure or release sufficient to meet the requirements for issuance of a test rule.

**2. “EPA is proposing to incorporate the ‘B Policy’ worker exposure threshold into the proposed SNU designations because it is a clear, numeric criterion that has been used to determine substantial human exposure since 1993. EPA is interested in receiving comment concerning use of the ‘B Policy’ in this context.”**

Although we have concerns about EPA’s reliance on the B Policy (see our comments under #5), we generally agree that it is reasonable to use the same definition of “substantial human exposure” for the SNUR as for the test rule. As discussed further below, EPA must ensure that the definition is accurate and protects vulnerable populations.

**4. “EPA solicits comment on whether any of the chemical substances proposed for the test rule or the SNUR should be subject to neither a test rule nor a SNUR.”**

We share EPA’s expectation that either a test rule or a SNUR will be the appropriate action for each of the 45 chemicals. The comment opportunity for this and other analogous future rules provides ample means for the manufacturer or processor of a subject chemical to present evidence to counter such an expectation and properly substantiate why neither action is appropriate for a specific chemical.

In the case of a test rule, it is possible that a submitter could justify the removal of a chemical by proving that there is a long-term decline in production volume such that it is and will reliably remain below one million pounds per year, but this would not justify removal from the SNUR since “substantial production is not a required finding for SNURs” (76 FR 65597). We support EPA’s expectation that a chemical that does not meet the exposure criteria for the test rule should be automatically added to the corresponding SNUR.

**5. EPA requests comment on its intent to use the thresholds from its B Policy to define “substantial human exposure” with respect to worker exposure to trigger the SNUR notification, but to apply the 1,000-worker threshold to each corporate entity rather than at a national scale as it does for test rules. The Agency asks whether there is a better alternative.**

We recognize that for a SNUR the trigger threshold needs to be based on a value that an individual corporate entity can determine on its own, and that such an entity may well not have knowledge of national-scale thresholds. However, EPA’s proposed approach

could result in a much higher effective threshold triggering SNUR notifications; for example, if five corporate entities would be subject to the SNUR, then as many as 5,000 workers might be exposed to a substance without notification being triggered. To avoid this possibility, we believe EPA can and should set a lower entity-specific threshold for worker exposure to trigger a SNUR than the national-scale threshold specified in its B policy. Section 5(a)(2) of TSCA does not require the use of a specific or constant number to define “substantial human exposure.” In regard to the process of issuing a SNUR, TSCA mandates only that EPA consider:

“(A) the projected volume of manufacturing and processing of a chemical substance,

“(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

“(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

“(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.”

We suggest the following as a basis for setting a lower, entity-specific threshold for worker exposure. Our analysis of the publicly reported data from the 2006 IUR shows that an average of 5.2 companies reported manufacturing a given HPV chemical (with more than a dozen HPV chemicals reported by more than 100 companies!). On this basis, we suggest EPA set a worker exposure threshold of no greater than 200 workers per corporate entity.

Because the consequence of triggering a SNUR is merely EPA review and not a requirement to test, EPA would have ample time to consider national-scale exposure in the course of determining whether to impose a testing requirement on a chemical that triggered a SNUR.

Although we understand the desire to quantify a particular threshold so that the trigger for a SNUR is clear, EPA should ensure that its specification of such pre-determined, quantitative thresholds does not constrain its ability to impose a SNUR on chemicals that may pose a significant risk to human health and the environment but don't necessarily meet such rigid numeric thresholds. A chemical may well merit being subject to a SNUR even though it falls below EPA's specific, worker-based threshold.

An overly rigid approach to using thresholds is *especially* likely to restrict EPA's ability to act in the event that the chemical is actually or potentially problematic for vulnerable populations. Using exposure of 1,000 workers (or even 200 workers) per corporate entity and broad consumer use (with the presumption that at least 10,000 consumers are exposed) as the only allowable triggers for substantial human exposure for a SNUR does *not* adequately address either:

- (1) human exposures that occur through means or pathways other than workplaces or consumer use, i.e., indirect human exposures resulting from environmental releases, food or water contamination, etc., or
- (2) exposures to subpopulations that may be especially susceptible to the chemical in question or disproportionately exposed to it through multiple sources (e.g., waste sites, brownfields), but do not necessarily meet the pre-set triggers.

EPA needs both to retain authority and explicitly consider exposures of vulnerable populations and additional means and routes of exposure in deciding whether human exposure is “substantial” when considering the need to issue SNURs applicable to specific chemicals. This is of particular concern to the environmental justice community, in part because their experience has shown that such pre-set thresholds are rarely set low enough to address the real-world, on-the-ground exposures faced by their communities.

We recognize the necessity for criteria to define “substantial human exposure”, but we do not endorse exclusive use of the B policy worker and consumer exposure criteria for a test rule OR a SNUR. EPA should consider that disproportionate exposure to a particular group is also a valid trigger for taking action on an HPV chemical.

**6. EPA notes that only a long-term decline in the production volume of a chemical would likely justify the removal of that chemical from the HPV chemical test rule or SNUR, and requests that stakeholders supply relevant trend information – if available – in their comments.**

In requesting trend information on the production volume of the 45 HPV orphan chemicals, EPA notes that the fluctuations in production volume from one year to the next mean that providing information from the most recent IUR reporting cycle (which entailed reporting of data for a single year) will not suffice to establish that a chemical is no longer HPV. EPA also notes that evidence of below-HPV levels of production is also not a basis for concluding that a SNUR is not justified, given that “substantial production is not a requirement for a SNUR” (76 FR 65597).

We agree with this conclusion. EDF conducted its own analysis of fluctuations in production volume using data collected by EPA over recent IUR cycles, which can be found in the comments EDF submitted along with approximately 30 signatories on the proposed amendments to the IUR (see Appendix A of the comments<sup>3</sup>). The analysis confirms that there are drastic fluctuations in production volume. For example, 307 HPV chemicals “disappeared” between the 2002 and 2006 IUR reporting cycles. However, as the analysis indicates, it is highly unlikely that all of these chemicals actually dropped below the reporting threshold of 25,000 pounds per year per site. Instead, the

---

<sup>3</sup> “Comments submitted by Richard A. Denison, Senior Scientist, and Allison Tracy, Chemicals Policy Fellow, Environmental Defense Fund, on behalf of Matthew S. Tejada, Executive Director, Air Alliance Houston, et al.” on EPA’s Proposed Rule for TSCA Inventory Update Reporting Modifications. Docket ID: EPA-HQ-OPPT-2009-0187. [www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0187-0069](http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0187-0069).

analysis supports the conclusion that a one-year snapshot of production volume is not an accurate measure of true production volume.

The upcoming CDR submission period in February to June of this year can be expected to provide additional and more up-to-date information on these 45 chemicals and other chemicals previously identified as HPV. Hence, even if a company submits comments suggesting a chemical EPA has included in the current proposed rule should be removed because it is “no longer HPV,” at the very least EPA should await the impending round of CDR reporting to make such a determination. (Of course, a single company will not necessarily even know whether its chemical is or is not HPV, because that determination is based on aggregate national production plus import levels.)

Given that CDR reporting this year will reflect two years of production volume information (for 2011 and 2010), such reporting indicating production at levels below HPV should not in itself suffice to remove a chemical from the current rule, in the absence of compelling evidence of a longer-term decline in production volume.

**8. EPA asks for input on how it might pursue its goal to integrate predictive molecular and computational methods in accordance with the National Research Council’s Report, “Toxicity Testing in the 21<sup>st</sup> Century: A Vision and a Strategy.” In particular, it seeks “to enhance efficiency and reduce reliance on animal testing.” It seeks to do so in its efforts “to prioritize chemical substances and support hazard findings for testing in the future” (76 FR 65597).**

We are optimistic about the potential capabilities of computational toxicology in understanding the effects of chemicals. High Throughput Screening (HTS) offers a number of benefits: It is efficient; is geared toward understanding the biological activities of chemicals at a mechanistic level; allows for the testing of chemicals in different cell types and over a wide range of doses; offers an innovative potential approach for evaluating the effect of a chemical at early stages of development, and has particular relevance to humans because of the ability to use human cell cultures and human enzymes in the assays. Additionally, HTS assays may aid in understanding and evaluating the effects of chemical mixtures.

However, we have reservations about the accuracy of computational toxicology methods at this early stage. First, the current battery of tests only targets a subset of biological pathways, and hence will not detect adverse effects on pathways beyond those that are targeted. Second, most HTS assays lack the ability to generate – and therefore assess the activity of – potential metabolites of chemical substances. Third, these assays typically use immortalized cell lines and consequently may give results that are not truly reflective of cellular behaviors in living organisms. Fourth, the potential for false positives and false negatives is worrisome and raises concerns for all stakeholders. Fifth, there are challenges in extrapolation between outcomes observed *in vitro* and *in vivo*.



If the HTS methods are not fully validated prior to reliance on them as substitutes for conventional tests, EPA may improperly exonerate hazardous chemicals or penalize low-risk chemicals. These are only a few of the many issues that must be addressed before EPA relies exclusively on computational methods for decisions with potential regulatory consequences.

Therefore, we suggest that EPA allow for the integration of such test methods in its evaluation of the HPV orphan chemicals, but as a supplement, not a replacement for, conventional testing methods. This will have the added benefit of yielding data that will aid in the validation of the newer testing methods.

**10. EPA also indicates that stakeholders may submit data from a “category or SAR approach” to fill an endpoint, provided that the results are substantiated in an accompanying document.**

Although we support that there can be a scientifically sound basis for using data from quantitative structure activity relationships (QSARs) or analog or category read-across approaches to provide information on a chemical, we urge EPA to carefully review the validity of such data submitted in place of testing. Over-reliance on such methods was a feature of both the HPV Challenge Program<sup>4</sup> and EPA’s ChAMP Initiative.<sup>5</sup> Our concern that such methods might be improperly applied by industry in order to avoid testing has been raised by the European Chemicals Agency’s (ECHA) experiences with the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation. A recent Chemical Watch interview with Jochan Flosbarth, president of the German Federal Environment Agency, includes his perspective on the quality of registration dossiers under REACH. He notes that in the majority of dossiers that ECHA has reviewed, “(QSAR) models had been used without fulfilling the conditions for the application of them.”<sup>6</sup> The German Agency’s assessment further notes that “in almost all cases only the best favourable value from the point of view of the registrant (e.g., the lowest prediction value for bioaccumulation) was used, without any scientific explanations.” The assessment also notes that modeling studies were not documented well enough for ECHA to ascertain reproducibility.

**12. EPA requests comment on whether it should continue to use OECD SIDS as the foundation of the testing endpoints. Should future test rules on HPV chemicals incorporate or rely on other data sets? What tests should be**

---

<sup>4</sup> See pages 4 and 25 of Environmental Defense Fund’s report “High Hopes High Hopes, Low Marks: A final report card on the High Production Volume Chemical Challenge.”

[http://www.edf.org/sites/default/files/6653\\_HighHopesLowMarks.pdf](http://www.edf.org/sites/default/files/6653_HighHopesLowMarks.pdf)

<sup>5</sup> See, for example, Environmental Defense Fund’s blog post entitled “Questionable Risk Decisions under ChAMP: The Fatty Nitrogen Derived Cationics Category.”

<http://blogs.edf.org/nanotechnology/2009/05/01/questionable-risk-decisions-under-champ-the-fatty-nitrogen-derived-cationics-category/>

<sup>6</sup> Ahrens, Ralph Heinrich. “UBA chief: strengthen burden of proof on firms under REACH.” *Chemical Watch European Business Briefing* 40 September 2011: 5-6. *Chemical Watch*. Web. December 23, 2011.

## **added? Should EPA develop different sets of testing endpoints depending on the exposure (e.g., to children vs. workers vs. environment)?**

EPA has characterized the OECD SIDS as “the minimum data set needed to make an informed, preliminary judgment about the hazards of a given HPV chemical.”<sup>7</sup> The OECD’s webpage on SIDS confirms the minimum nature of the SIDS: “(SIDS) - the minimum amount of data that is required for making an initial hazard assessment of chemicals”.<sup>8</sup>

Hence, outside of the very limited derogations (e.g., for closed-system intermediates) from certain endpoints allowed under SIDS, full SIDS data sets should always be provided – wholly independent of exposure considerations. For chemicals used in consumer applications, additional endpoints may be necessary to ensure that exposure is not posing a risk to human health. EPA should also consider requiring additional tests when there are potential exposure concerns for vulnerable populations (e.g., pregnant women, children, workers, or disproportionately exposed communities) or particular environmental settings (e.g., sediment or soil).

While the OECD SIDS continues to be an appropriate *minimum* data set, EPA should also ensure that its testing requirements address the potential for other critical endpoints, in particular developmental effects on the neurological and immunological systems. To that end, it should consider requiring testing for developmental neurotoxicity and developmental immunotoxicity. Options for doing so include the following OECD tests:<sup>9</sup>

- Extended One Generation Reproductive Toxicity Study (OECD test guideline 443), as long as EPA makes the developmental neurotoxicity and developmental immunotoxicity modules mandatory;
- Developmental Neurotoxicity Study (OECD test guideline 426); and
- Neurotoxicity Study in Rodents (OECD test guideline 424).

### **Additional Comments**

**Economic burden:** Issuing a test rule in combination with a SNUR is an efficient approach to gaining needed information on HPV chemicals. In addition, the simultaneous development and issuance of combined rules increases the predictability of regulatory requirements for the industry and thereby enhances economic stability with respect to any costs associated with the regulations.

---

<sup>7</sup> See page 15 of EPA’s November 2004 report, “Status and Future Directions of the HPV Challenge Program.” <http://www.epa.gov/hpv/pubs/general/hpvstatr.htm>

<sup>8</sup> “Data Gathering and Testing: SIDS, the SIDS Plan and the SIDS Dossier.”

[http://www.oecd.org/document/21/0,3746,en\\_2649\\_34379\\_49204757\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/21/0,3746,en_2649_34379_49204757_1_1_1_1,00.html)

<sup>9</sup> These OECD test guidelines are available at [http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects\\_20745788](http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788).

EPA's use of tiering (distinct requirements for Tier 1 and Tier 2 entities) to determine which companies must conduct testing under the test rule will place the majority of the burden on large manufacturers who have the capacity and the experience to comply with the rule. EPA notes that it designed the tiers for this proposed rule to reduce the potential for a negative impact of regulations on small enterprises. Still, the proposed rule ensures that, where they face testing requirements, Tier 2 companies participate in cost-sharing measures.

Companies are not required to comply with this test rule if they do not know and cannot reasonably ascertain whether they manufacture or process a chemical subject to the test rule. Although we do not oppose this approach, we believe EPA needs to articulate clearer criteria by which such a determination is to be made. There is an obvious financial incentive companies have to seek to take advantage of this provision to evade regulation and the associated costs, so it is essential that only those companies that truly warrant such an exception benefit from it.

The test rule and the SNUR are part of a larger objective to improve the safety of chemicals and restore confidence in the chemicals industry, making this rule beneficial to all stakeholders. Companies may derive economic benefits from their compliance, including by facilitating EPA's ability to assess the safety of their chemicals and to appropriately apply regulatory requirements where needed. EPA encourages companies to submit as much information as possible to assist in EPA's review of the chemicals, but increasing the public availability of information on these chemicals will also help to restore trust in the industry. The information that companies supply is crucial to mitigate human and environmental exposures to hazardous chemicals, assess the benefits as well as risks of chemicals, and consider the benefits and risks of using alternatives.

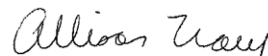
We note that EPA does not provide a quantitative estimate of the benefits of the proposed rule. Although there is a qualitative discussion, we believe that EPA could infer monetary values from those benefits and thus confirm that the proposed rule is a net benefit to society. For example, the proposed rule would help to prevent increases in healthcare costs that result from uncontrolled chemical exposures.

We appreciate your consideration of these comments.

Sincerely,



Richard A. Denison, Ph.D.  
Senior Scientist  
Environmental Defense Fund



Allison Tracy  
Chemicals Policy Fellow  
Environmental Defense Fund

On behalf of:

Pamela K. Miller  
Executive Director  
Alaska Community Action on Toxics

Barbara Sattler, RN, DrPH, FAAN  
Chair, Board of Directors  
The Alliance of Nurses for Healthy  
Environments (ANHE)

Jeanne Rizzo, R.N.  
President and CEO  
Breast Cancer Fund

Ansje Miller  
Eastern States Director  
Center for Environmental Health

Kathleen A. Curtis, LPN  
Executive Director  
Clean and Healthy New York

Mark Rossi, Ph.D.  
Co-Director  
Clean Production Action

Lynn Thorp  
National Campaigns Director  
Clean Water Action

Sharyle Patton  
Director, Health and Environment Program  
Commonweal

Mark A. Mitchell M.D., MPH  
Senior Policy Advisor, Connecticut Coalition  
for Environmental Justice

Tracey Easthope, MPH  
Director, Environmental Health Project  
Ecology Center

Shelley Vinyard  
Clean Water Advocate  
Environment America

Michael Belliveau  
President and CEO  
Environmental Health Strategy Center

Patricia A. Lillie  
President  
Learning Disabilities Association of America

Daniel Rosenberg  
Director, Toxic Chemicals Reform Project  
Natural Resources Defense Council (NRDC)

Joseph H. Guth, J.D., Ph.D.  
Legal Director  
Science & Environmental Health Network