

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-8463-7; Docket ID No. EPA-HQ-ORD-2006-0812]

### Child-Specific Exposure Factors Handbook

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of peer-review panel workshop.

**SUMMARY:** The Environmental Protection Agency (EPA) is announcing that Eastern Research Group, Inc. (ERG), an EPA contractor for external scientific review, will convene an independent panel of experts and organize and conduct a peer-review workshop, to review the external review draft document titled, "Child-Specific Exposure Factors Handbook" (EPA/600/R-06/096A). EPA provided an opportunity for public comment on the draft document from October 2006 to January 2007. The draft document was prepared by the National Center for Environmental Assessment (NCEA) within EPA's Office of Research and Development. The "Child-Specific Exposure Factors Handbook" provides a summary of statistical data on various exposure factors used in assessing children's exposures, including: Drinking water consumption; soil ingestion and mouthing behavior; inhalation rates; dermal factors including skin surface area and soil adherence factors; consumption of retail and home-grown foods; breast milk intake; and human activity pattern data. Once completed, this report will serve as a resource for exposure assessors for estimating children's exposures. An interim final version of this handbook was published in 2002. This updated version provides analysis of exposure factors data using the age groups for children recommended in the EPA document entitled, "Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants" (EPA/630/P-03/003F) (Available on line at <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=146583>).

EPA released this draft document in October 2006, solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. This document has not been formally disseminated by EPA. It does not represent and should not be construed to represent any Agency policy or determination.

In preparing a final report, EPA will consider the public comments submitted to EPA's docket during the

public comment period, and the contractor's report of the external peer-review workshop, including any oral public comments received at the workshop.

**DATES:** The peer-review panel workshop will begin on September 19, 2007, at approximately 8 a.m. and end at 4 p.m. on September 20, 2007. Members of the public may attend the peer-review panel workshop. Time will be set aside on the morning of September 19, 2007, for registered attendees who wish to make brief oral comments (for more information refer to the instructions for registration below).

**ADDRESSES:** Eastern Research Group, Inc. (ERG), an EPA contractor for external scientific review, will convene an independent panel of experts and organize and conduct a peer-review panel workshop to review this draft document. The peer-review panel workshop will be held at The Navy League Building, located at 2300 Wilson Boulevard, Arlington, VA. Observers may attend the peer-review panel workshop through a registration process by calling ERG's conference line between the hours of 9 a.m. and 5:30 p.m. EDT at (781) 674-7374 or toll free at (800) 803-2833, or by faxing a registration request to (781) 674-2906 (please reference the CSEFH Peer-Review Panel Workshop and include full address and contact information), or by sending an e-mail to [meetings@erg.com](mailto:meetings@erg.com) (subject line: CSEFH Peer-Review Panel Workshop; body: Include full address and contact information). Pre-registration is strongly recommended as space is limited, and registrations will be accepted on a first-come, first-served basis. The deadline for pre-registration is September 12, 2007. If space allows, registrations will continue to be accepted after this date, including on-site registration. Time will be set aside during the morning of the first day of the meeting to hear comments from observers, and individuals will be limited to a maximum of five minutes. Please inform ERG when registering if you wish to make a comment at the workshop.

The draft document, "Child-Specific Exposure Factors Handbook," is available primarily via the Internet on the National Center for Environmental Assessment's home page under the Recent Additions and the Data and Publications menus at <http://www.epa.gov/ncea>. A limited number of paper copies are available from the Technical Information Staff, NCEA-W; telephone: (202) 564-3261; facsimile: (202) 565-0050. If you are requesting a paper copy, please provide your name,

mailing address, and the document title, "Child-Specific Exposure Factors Handbook". Copies are not available from ERG and copies will not be available onsite.

#### FOR FURTHER INFORMATION CONTACT:

Questions regarding registration and logistics for the external peer-review panel workshop should be directed to ERG, 110 Hartwell Avenue, Lexington, MA 02421-3136; telephone: (781) 674-7374 or toll free at (800) 803-2833; facsimile: (781) 674-2906; e-mail: [meetings@erg.com](mailto:meetings@erg.com).

If you need technical information about the draft document, please contact Jacqueline Moya, National Center for Environmental Assessment (NCEA); telephone: (202) 564-3245; facsimile: (202) 565-0079; e-mail [moya.jacqueline@epa.gov](mailto:moya.jacqueline@epa.gov).

Dated: August 29, 2007.

**Rebecca Clark,**

*Acting Director, National Center for Environmental Assessment.*

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## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2007-0490; FRL-8146-2]

### TSCA Section 21 Petition on Nonylphenol and Nonylphenol Ethoxylates; Response to Citizens' Petition

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** On June 6, 2007, the Sierra Club, the Environmental Law and Policy Center, the Pacific Coast Federation of Fishermen's Associations, the Washington Toxics Coalition, Physicians for Social Responsibility, and UNITE HERE petitioned EPA under section 21 of the Toxic Substances Control Act (TSCA) to initiate rulemaking proceedings under sections 4 and 6 of TSCA. Specifically, petitioners requested that EPA require manufacturers and importers to conduct certain health and safety studies under TSCA section 4; and also require, under TSCA section 6(a), labeling on all products containing nonylphenol (NP) and nonylphenol ethoxylates (NPEs), and limit the use of NP and NPEs where the use of these substances presents an unreasonable risk to public health and the environment. For the reasons set forth in this notice, EPA is granting the petitioners' request to initiate a proceeding for chronic aquatic toxicity testing under TSCA section 4 and will

also request comment on potential additional testing related to certain of the petitioners' requests, but is denying the petition in regard to TSCA section 6 and to the remaining specific TSCA section 4 requests.

**FOR FURTHER INFORMATION CONTACT:** For general information contact: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

For technical information contact: Mary Dominiak or John Schaeffer, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8104 or (202) 564-8173; e-mail address: [dominiak.mary@epa.gov](mailto:dominiak.mary@epa.gov) or [schaeffer.john@epa.gov](mailto:schaeffer.john@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, import, or distribute in commerce NP or NPEs. Potentially affected entities may include, but are not limited to:

- Chemical manufacturers (including importers) (NAICS codes 325, 32411, e.g., chemical manufacturing and petroleum refineries) of one or more of the subject chemicals.
- Surface active agent manufacturers (NAICS code 325613).
- Industrial launderers (NAICS code 81233).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

###### B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPPT-2007-0490. All documents in the

docket are listed in the docket's index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>.

##### II. Background

###### A. What is a TSCA Section 21 Petition?

Section 21 of TSCA allows citizens to petition EPA to initiate a rulemaking proceeding for the issuance, amendment, or repeal of a rule under TSCA section 4, 6, or 8 or an order under TSCA section 5(e) or 6(b)(2). A TSCA section 21 petition must set forth facts that the petitioner believes establish the need for the action requested. EPA is required to grant or deny the petition within 90 days of its filing. If EPA grants the petition, the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the **Federal Register**. The petitioners may commence a civil action in a U.S. district court to compel initiation of the requested rulemaking proceeding within 60 days of either a denial or the expiration of the 90-day period.

###### B. What Criteria Apply to a Decision on a TSCA Section 21 Petition?

1. *TSCA section 21.* TSCA section 21, itself, does not expressly identify the basis under which EPA should decide whether to grant or deny a citizens' petition. Rather, TSCA section 21(b)(1) requires that the petition set forth the facts that it is claimed establish it is "necessary" to issue a rule or order that is the subject of the petition. In addition, TSCA section 21 establishes standards the court must use to decide whether to order EPA to initiate rulemaking in the event of a lawsuit filed by the petitioner after denial of a TSCA section 21 petition. (15 U.S.C. 2620(b)(4)(B)). Further, TSCA section 21 implicitly incorporates the statutory standards under TSCA sections 4 and 6 for issuing regulations, requiring petitioners to "set forth the facts which it is claimed establish that it is necessary to issue...a rule under section [4 or 6]." (15 U.S.C. 2620(b)(1) (emphasis added)). Accordingly, EPA has relied on the standards in TSCA section 21 and in TSCA sections 4 and 6 as the basis for evaluating and deciding on the NP/NPE petition.

2. *Legal standards regarding TSCA section 4 test rules.* Under TSCA section 4, EPA must make a number of findings in order to issue a rule to require testing. In all cases, EPA must find that data on a chemical are insufficient to evaluate its effects and that testing of the chemical is necessary to develop the missing data. (15 U.S.C. 2603(a)(1)(A) and (B)). In addition, EPA must either find that:

- i. The chemical may present an unreasonable risk of injury or
- ii. The chemical is:
  - a. Produced in substantial quantities, and
  - b. May either:
    - A. Result in significant or substantial human exposure, or
    - B. Result in substantial environmental release.

TSCA section 21 allows a court to order EPA to initiate rulemaking if the court makes essentially the same determination after a *de novo* review of the petition. However, TSCA section 21 omits the third finding required under TSCA section 4 from the findings that a court must make in order to require EPA to initiate TSCA section 4 rulemaking—i.e., the finding that "testing is necessary to develop the data." (15 U.S.C. 2620(b)(4)(B)(i)). Nonetheless, EPA believes TSCA section 21(b)(4) is best interpreted as incorporating all of the TSCA section 4 findings. The alternative would be to read the statute as empowering a court

to require EPA to initiate a rule even where the Agency could not make proposed findings consistent with TSCA section 4 or take final action on the rule. EPA's interpretation is supported by legislative history. (House conference report (H. Conf. Rept.) 94-1679 at 97-99 (1976)).

3. *Legal standards regarding TSCA section 6 control rules.* In evaluating the request for rules under TSCA section 6 to control chemicals, EPA assessed whether such rules are necessary to protect against unreasonable risk. This is the same test the court would apply under TSCA section 21.

The finding of unreasonable risk is a judgment under which the decisionmaker determines that the risk of health or environmental injury from a chemical outweighs the burden to society of potential regulations. An unreasonable risk decision cannot be made considering risk alone. Rather, the probability of harm must be considered against the impacts of regulation. In promulgating any rule under TSCA section 6, the statute requires that the Administrator consider:

- The effects of the substance or mixture on health and the environment and the magnitude of the exposure of human beings and the environment to the substance or mixture.
- The benefits of the substance or mixture for various uses and the availability of substitutes for such uses.
- The reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health. (15 U.S.C. 2605 (c)).

#### *C. What Action is Requested Under this TSCA Section 21 Petition?*

On June 6, 2007, the Sierra Club, the Environmental Law and Policy Center, the Pacific Coast Federation of Fishermen's Associations, the Washington Toxics Coalition, Physicians for Social Responsibility, and UNITE HERE petitioned EPA to take action under TSCA section 4 for seven categories of tests and under TSCA section 6 for four categories of restrictions. The requested actions under TSCA section 4 are:

1. Require testing to "fill the gaps" for chronic toxicity of NPE oligomers (oligomers are the 1-2 mole ethoxylate of NP, also known as "short-chain" NPEs) to aquatic organisms.
2. Require the testing of mixtures to "fill the gaps" regarding the additive toxicity of NP and NPE oligomers to aquatic organisms.

3. Require testing on the estrogenic disruption impact, including multi-generational and population level impact, of NP and NPEs to aquatic organisms.

4. Require testing of NP and NPEs for vitellogenin gene expression.

5. Require testing to ascertain certain aspects of NP and NPE toxicity to humans, including general population exposure, metabolism, dermal absorption, and placental development.

6. Require epidemiology testing for industrial laundry workers exposed to NPEs.

7. Require testing to determine exposure to NPEs in residential indoor air.

The requested actions under TSCA section 6 are:

1. Require labeling on all products containing NP and NPEs.
2. Restrict the use of NPEs where the user cannot verify that the chemicals will receive proper wastewater treatment.
3. Ban the use of NP and NPEs in industrial and consumer detergents.
4. Require pollution prevention planning by facilities that use 2,000 kilograms (kg) or more of NP or NPEs.

#### **III. Disposition of Petition**

Using the criteria in Unit II.B. to assess the NP/NPE petition, EPA has concluded that, with respect to petitioners' first request for chronic toxicity testing of "short-chain" NPEs, the petitioners have provided facts demonstrating that existing data may be insufficient to permit a reasoned evaluation of the effects of the chemicals, and that the chemicals are produced in substantial quantities and either may result in significant or substantial human exposure, or may result in substantial environmental release. Accordingly, EPA grants the petitioners' request that EPA initiate a proceeding for the issuance of a rule under TSCA section 4 regarding chronic aquatic toxicity testing on certain NPEs. However, EPA has determined that petitioners have not provided facts to support the conclusion that the other tests they requested are necessary to permit a reasoned evaluation of the chemicals and EPA is, accordingly, denying the petitioners' remaining specific TSCA section 4 testing requests. Further, EPA has determined that petitioners failed to provide sufficient justification for any of the requested control actions under TSCA section 6 and, therefore, EPA is denying these requests. Each of the petitioners' requests is addressed specifically in the following discussion.

#### *A. Grant of Request to Initiate a Section 4 Test Rule*

Petitioners' first request was that EPA initiate testing to determine the chronic toxicity of NPEs, especially "short-chain" NPEs, "for development of protective water quality criteria and standards that account for the full range of negative impacts from NP and NPEs." EPA agrees that data concerning the chronic effects of "short-chain" NPEs appear to be limited (Refs. 1 and 2) and may be insufficient to adequately evaluate the risk of chronic exposures to aquatic organisms from "short-chain" NPEs. However, to develop a properly tailored test requirement that would provide EPA with sufficient data, EPA believes it would be most productive to examine a number of additional considerations prior to the issuance of a proposed rule. These considerations include determining which NPEs might be studied to adequately characterize the potential risk presented by chronic exposures to these chemicals, based on such factors as the potential for aquatic organisms to be exposed to them. For example, NP1EO and NP2EO have been detected in the environment and may be the candidates for further testing, but other NPEs, including various derivatives and degradation products, may not need to be considered. EPA further notes that, if adequate acute aquatic toxicity testing data are not already available on specific NPEs in the same species appropriate for chronic testing, those acute data may need to be developed in order to set appropriate concentration levels for chronic testing and for calculating acute-to-chronic ratios. Additional considerations may include determining how many taxa are needed, and which species in those taxa would be most appropriate in order to properly characterize the potential aquatic toxicity of the chemicals present in freshwater and saltwater systems. EPA may also consider whether chronic aquatic toxicity testing for NP in saltwater fish species may be warranted, and whether testing to assess the toxicity and fate of sediment-bound NP in both freshwater and marine/estuarine habitats should be considered, since these data are limited (Refs. 2, 3, and 4). Finally, EPA notes that the apparent focus of the petition is the development of water quality criteria (WQC). Although petitioners have referenced testing designed to satisfy the requirements imposed by States and EPA for data sufficient for setting WQC values, EPA notes that the standards for setting WQC are different than the standard for requiring testing under TSCA section 4, and a reasoned

evaluation of the chemicals under TSCA may require different tests than the full battery of studies necessary to issue such criteria. Accordingly, rather than initially proposing a rule pursuant to TSCA section 4, where the Agency would present its preliminary conclusions on these points, EPA will publish an Advanced Notice of Proposed Rulemaking (ANPRM) initiating proceedings under TSCA section 4. The ANPRM will identify these issues for public comment. The information received from this process would guide EPA in developing a proposed testing program under TSCA section 4.

#### *B. Denials of Requests to Initiate TSCA Section 4 Test Rules*

Petitioners' second request was that EPA "fill the data gaps regarding the additive toxicity of NP and NPE oligomers to species." Petitioners requested testing of unspecified mixtures of NP and NPEs in acute and chronic assays to address this perceived gap. The petitioners noted that, given their similar structure and mode of action, the toxicity of NP and NPEs may be additive. EPA currently believes that the question of additive toxicity of various NPEs would not be addressed effectively by requiring the testing of unspecified mixtures of them. Additive toxicity is often more pragmatically addressed by using methods to combine the results of testing the individual components of mixtures. Petitioners provided no rationale to explain why this more pragmatic approach of testing individual chemicals would be inadequate in this instance. Therefore, EPA does not believe it has the basis at this time to support the finding required under TSCA section 4(a)(2) for ordering the testing of mixtures: That the effects of the mixture "may not be reasonably and more efficiently determined...by testing the chemical substances which comprise the mixture." EPA considers that obtaining certain acute and chronic aquatic toxicity data on the appropriate individual NPE, as described in this unit in the response to petitioners' first request, could provide useful information addressing the additive toxicity question raised by petitioners. EPA thus denies the specific request that EPA order the testing of mixtures, but EPA may consider multiple approaches to addressing the questions concerning possible additive toxicity in the ANPRM.

Petitioners' third request was that EPA conduct research on individual endocrine disruption impacts and on the relationship between individual endocrine disruption impacts and

population-level impacts, including multi-generation effects. In general, EPA questions whether such mechanism-specific testing is needed to permit a reasoned evaluation of these chemicals given other data that exist and the additional data that EPA would consider in the ANPRM. Available studies already evaluate effects on the test organisms' mortality, growth, and reproduction, which are apical to any endocrine disruption that may occur. As summarized in EPA's Office of Water Ambient Water Quality Criteria (WQC) Document for NP, the ability of nonylphenol to induce estrogenic effects has seldom been reported at concentrations below the freshwater final chronic value of 6.6 micrograms/Liter ( $\mu\text{g/L}$ ) (Ref. 3). EPA considers at this time that the existing data, particularly combined with the acute and chronic aquatic toxicity data that EPA proposes to discuss in its ANPRM, would be sufficient to evaluate effects on individuals and populations (Refs. 3, 5, and 6). In addition, test methods to assess multi-generational impacts are not currently available, and it is not yet certain that such methods would provide data that would significantly advance understanding beyond existing chronic study data with regard to NP, given that NP demonstrates estrogenic effects at concentrations at or above which chronic effects are also seen. The Office of Prevention, Pesticides, and Toxic Substances (OPPTS) Endocrine Disruptor Screening Program (EDSP) is currently developing and validating freshwater and saltwater fish 2-generation test methods and also a crustacean (mysid) 2-generation test method. However, those methods are not expected to be fully validated before 2010, and additional work with the test method will be required to demonstrate the benefit of performing these studies. As noted in the WQC document, when the appropriate EDSP testing protocols have been developed and validated, EPA may consider whether additional testing of NP and NPE might be warranted (Ref. 3). For these reasons, EPA cannot conclude that the available information relevant to this requested testing is insufficient to permit a reasoned evaluation of the health or environmental effects of these chemicals or that the requested testing is necessary, and EPA, therefore, denies this request.

Petitioners' fourth request was that EPA apply a specific vitellogenin gene expression assay to NP and each individual NPE. In general, EPA questions whether such mechanism-specific testing is needed to permit a

reasoned evaluation of these chemicals given other data that exist. Several different vitellogenin gene expression tests exist (Refs. 7, 8, and 9), but each serves the same purpose of demonstrating the potential of a chemical for estrogenic expression. The Agency considers that available information on NP and various NPEs is sufficient to adequately demonstrate and evaluate the estrogenic expression of NP and also to provide enough of a basis on which to project the lesser contribution of various NPEs, making further vitellogenin assays unnecessary (Refs. 5, 6, 10, and 11). Accordingly, EPA cannot conclude that the available information relevant to this requested testing is insufficient to permit a reasoned evaluation of the health or environmental effects of these chemicals or that the requested testing is necessary, and EPA, therefore, denies the request for a TSCA section 4 test rule requiring the vitellogenin gene expression assay.

Petitioners' fifth request encompasses a diverse cluster of testing, including dermal absorption, oxidative metabolism, the effects of NP on human placental development, and NP and NPE exposure to the general population of the United States. Data to evaluate these effects either already exist or are being generated under other programs and need not be duplicated. For example, a combination of existing human and animal studies provides a reasonable understanding of the metabolism of NP in humans. The data available indicate a metabolic profile common to phenols (Refs. 12, 13, and 14). In addition, studies on dermal absorption of NP and NPEs have already been conducted and have concluded that dermal absorption of NP is negligible, and that dermal absorption of NPEs through human and animal skin is less than 1% (Ref. 15). The petitioners cited a study done on human placental tissue suggesting that NP may have some effect on trophoblastic cells of the placenta, and specifically requested that a similar study be repeated. EPA does not believe that repeating this non-standard study or attempting to design a similar one would add to the understanding of these chemicals, because existing studies on whole organisms have already more fully addressed reproductive and other health effects (Ref. 16). Reproductive studies of NP in mammals have been conducted (Refs. 17 and 18), as well as other studies which have examined the estrogenic effects of NP in mammals (e.g., uterotrophic assay) (Refs. 19, 20, and 21), and, on the basis of these data,

EPA believes it has sufficient information to evaluate NP's reproductive risks to human health without conducting a non-standard placental study of the type requested by petitioners. With regard to assessing NP and NPE exposure to the general U.S. population, EPA notes that the Centers for Disease Control and Prevention (CDC) indicated through a notice published in 2003 that NP has already been slated for inclusion in the *National Report on Human Exposure to Environmental Chemicals*, and there is thus no need for EPA to duplicate that activity (Ref. 22). For these reasons, EPA cannot conclude that the available information relevant to this requested testing is insufficient to permit a reasoned evaluation of the health or environmental effects of these chemicals or that the requested testing is necessary, and EPA, therefore, denies these requests for testing under TSCA section 4.

Petitioners' sixth request was that EPA conduct an epidemiology study of industrial laundry workers who may be exposed to NP and NPEs in detergents. Before an epidemiology study can be effectively designed or conducted, however, there needs to be evidence that there are sufficient exposures to a substance to warrant a study of human health effects potentially attributable to those exposures. As noted in the comments submitted by the Uniform and Textile Service Association (UTSA) and the Textile Rental Services Association (TRSA), approximately 90% of industrial laundries use injected liquid detergent (Ref. 23). Given the low volatility (Ref. 24) and the negligible dermal absorption of NP and NPE (Ref. 15), these industrial laundry operations would not present significant exposure potential. Accordingly, there is no evidence to support a conclusion that significant exposures exist that would warrant an epidemiological study in this overall industry. However, for the approximate 10% of industrial laundry operations and an unknown number of institutional laundry operations that may use powdered detergent, EPA considers that there is potential for inhalation exposure to dust containing NP and NPE by workers and that the number of potentially exposed workers involved could be substantial (Ref. 25). As these concerns are based on estimates and not actual exposure monitoring data, they would not support a conclusion that there are sufficient exposures to warrant an epidemiology study. However, EPA considers that obtaining additional exposure information may be warranted

to reasonably assess the potential for risk associated with this one exposure scenario. Accordingly, EPA denies the petitioners' specific request for an epidemiology study, but plans to include in the ANPRM a discussion of the need for data concerning NP and NPE exposures of laundry workers where powdered detergents are used, and to solicit comment on the best means to obtain that information (e.g., whether through requiring an exposure study, workplace exposure monitoring, the voluntary submission of existing monitoring data, or other means).

Finally, the petitioners' seventh request concerned ordering a nationwide study of residential exposures based on one study which found levels of NP and NPEs in dust and indoor air in all homes in the study. However, in both the study cited by petitioners and in a second study that found NP or NPEs in only 10% of the homes studied (Refs. 26 and 27), the levels of NP found were far below any level of concern suggested in reviews (e.g., Ref. 16). Neither study could be assumed to be representative of households across the United States, but both studies would suggest that residential indoor air and dust do not contribute significantly to household exposure. Therefore, EPA cannot conclude that the available information relevant to this requested testing is insufficient to permit a reasoned evaluation of the health effects of these chemicals. Similarly, EPA believes there is no evidence indicating that exposures of the general population to NP and NPEs are of concern at the present, and notes that the CDC human biomonitoring work will provide nationally representative data on the levels of general population exposures to NP irrespective of exposure source. Accordingly, EPA denies the request for a nationwide residential exposure study under TSCA section 4.

#### *C. Denial of Requests to Issue TSCA Section 6 Control Rules*

EPA has concluded that the petitioners have not set forth the facts establishing the need for the control actions requested under TSCA section 6. Although the petition asserts that an unreasonable risk exists, the petition does not present a reasonable basis to conclude both that the chemicals present or will present an unreasonable risk and that the specific actions requested by petitioners would be necessary to protect adequately against such risk using the least burdensome requirements. Accordingly, EPA denies the petitioners' requests for control actions under TSCA section 6.

The petitioners requested that EPA issue TSCA section 6 actions to require labeling, not just Material Safety Data Sheets (MSDSs), on all products containing NP and NPE; to restrict the use of NP and NPE where the user (including the 25% of U.S. households that rely on septic systems) cannot verify that the chemical will receive proper/effective treatment at a well-managed sewage treatment plant from an activated sludge treatment process designed to nitrify; to ban the use of the chemicals in industrial and consumer detergents in favor of existing, less toxic alternatives; and, similar to Canada, to require facilities that use 2,000 kg or more of NP or NPEs to develop formal pollution prevention plans, and to consider safer substitutes consistent with OPPT's Safer Detergents Stewardship Initiative (SDSI).

As noted in Unit III.B., in order to issue a rule under TSCA section 6, EPA must affirmatively find that the risks are unreasonable, and in making that determination, must consider a number of specified issues. These relate not merely to the effects of the chemical(s), but also to:

1. The benefits of the substance(s) for various uses and the availability of substitutes for such uses.
  2. The reasonably ascertainable economic consequences of the control mechanisms proposed to control the risk, including the effect on the national economy and small business and technical innovation.
- These considerations are integral to the determination that a substance presents an unreasonable risk, and the petitioners have not presented sufficient facts to allow EPA to evaluate the issues. It is not sufficient in a petition under TSCA section 21 to assert that an unreasonable risk exists without providing the facts that would support that assertion.

For example, in presenting their argument for actions under TSCA section 6, the petitioners failed to provide information that would permit consideration of the effect of their requested controls on the national economy, small business and technological innovation, the environment, and public health. Petitioners asserted that the costs of their requested controls would be small and that the benefits of their controls would reduce risk, but provided no data to substantiate either their estimates of cost or of the efficacy of their proposed control actions.

In addition, petitioners did not address the extent to which actions taken under other statutes or voluntary programs may already be addressing the

risk that may be presented by these chemicals, and whether those other statutes or voluntary programs may provide more appropriate tools than TSCA section 6 action to control risk to the extent necessary as additional data are generated on chemical effects and exposure. EPA has addressed NP and, to some extent, NPE in recent regulatory actions with respect to water quality criteria (Refs. 3 and 28) and to the reassessment of tolerances for pesticide inerts on food (Ref. 29). EPA also sought public comment in May 2007 on SDSI (Ref. 30). SDSI is intended to complement the water quality criteria for NP by promoting the voluntary conversion by the detergent industry to alternative surfactants that break down quickly to less toxic compounds. EPA must assess those public comments and the potential of SDSI to impact the need for any further regulatory controls.

The data and information supplied in the petition and the information provided in public comments do not provide a reasonable basis to conclude that NP or NPE pose an unreasonable risk to health or the environment. Consequently, EPA has determined that petitioners have failed to provide sufficient justification for any of their requests for control actions under TSCA section 6 of TSCA, and EPA is denying the request that EPA initiate actions under TSCA section 6.

#### IV. Comments Received

EPA published a notice in the **Federal Register** issue of July 10, 2007, announcing receipt of the petition and inviting public comment on or before July 25, 2007 (Ref. 31). EPA received ten timely comments from one individual, one petitioner, one State agency, and seven nonprofit trade or professional associations, and about 1,900 mass-mailed comments from private citizens through a mass comment campaign evidently sponsored by one or more of the petitioners. EPA also received a request for an extension of the comment period on July 25, 2007, submitted by UNITE HERE and the Sierra Club, two of the petitioners. The request for extension was denied because of the schedule for response mandated by TSCA section 21, although EPA indicated that late comments would be considered to the extent possible. One late comment was submitted on August 1, 2007, by another trade association. One State agency submitted a late letter addressed to the Administrator which was received on August 6, 2007, and was directed to the docket as a late comment.

The petitioner (the Environmental Law and Policy Center), the individual,

the two State agencies (the New York State Department of Environmental Conservation and the Illinois Environmental Protection Agency), and the mass mailing campaign supported the petition, without presenting additional significant substantive data apart from an additional reference provided by the petitioner. This reference concerned data already in EPA's possession.

All but one of the trade or professional organizations opposed the petition on the grounds that existing data were already sufficient to assess the chemicals and that no unreasonable risk was demonstrated in the petition. Five of the organizations (the UTSA, the TRSA, the Soap and Detergent Association, the Consumer Specialty Products Association, and the Alkylphenols and Ethoxylates Research Council) submitted detailed comments with references to data. These data were already in EPA's possession. The remaining opposing organization (CropLife America) and the association submitting late comments (the Chemical Producers and Distributors Association) supported the position expressed by the Alkylphenols and Ethoxylates Research Council.

The National Association of Clean Water Agencies (NAWCA) did not comment on the substance of the petition, but indicated that any action taken by EPA in response to the petition should not place the burden for response on the nation's wastewater treatment utilities.

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#### List of Subjects

Environmental protection, Hazardous substances, Nonylphenol, Nonylphenol Ethoxylates.

Dated: August 29, 2007.

**James B. Gulliford,**

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## FEDERAL COMMUNICATIONS COMMISSION

### Notice of Public Information Collection(s) Being Submitted to the Office of Management and Budget, Comment Requested

August 28, 2007.

**SUMMARY:** The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden, invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of