and effective in protecting the safety and health of workers, the environment, and preventing incidents. These evaluations or visits may be random or based upon the OCS lease operator's or contractor's performance.

(b) The MMS or its authorized representative may evaluate your SEMS program, including documentation of contractors, independent third parties, and designated and qualified personnel, and audit reports to assess your SEMS program.

(1) You must be prepared to explain and demonstrate the procedures and policies included in your SEMS program and produce evidence to support your explanation.

(2) The MMS or its authorized representative may conduct a site visit on your facility to verify that personnel are following your SEMS program and can explain and demonstrate the procedures and policies included in your SEMS program and produce evidence to support their explanation for a specific task.

(3) If MMS directs you to do an evaluation, you will be responsible for all costs associated with the evaluation of your SEMS program.

§ 250.1914 What happens if MMS finds shortcomings in my SEMS program?

If MMS determines that your SEMS program is not in compliance with this subpart, we may initiate one or more of the following enforcement actions:

(a) Issue an Incident(s) of Noncompliance;

(b) Require you to revise and submit to MMS your plan to address identified deficiencies in your SEMS program;

(c) Assess civil/criminal penalties; or

(d) Initiate probationary or disqualification procedures from serving as an OCS operator.

§ 250.1915 What are my responsibilities for submitting OCS performance measure data?

You must submit Form MMS–131 on an annual basis, for the previous calendar year, by March 31 of each year.

[FR Doc. E9–14211 Filed 6–16–09; 8:45 am]

BILLING CODE 4310–MR–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[EPA–HQ–OPPT–2007–0490; FRL–8416–8]

RIN 2070–AJ34

Testing of Certain Nonylphenol and Nonylphenol Ethoxylate Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking.

SUMMARY: On June 6, 2007, the Environmental Law and Policy Center, the Sierra Club, the Pacific Coast Federation of Fishermen's Associations, the Washington Toxics Coalition, Physicians for Social Responsibility, and UNITE HERE (hereinafter ''petitioners''), petitioned EPA under section 21 of the Toxic Substances Control Act (TSCA) to initiate rulemaking proceedings under section 4 and section 6 of TSCA for the substances nonylphenol (NP) and nonylphenol ethoxylates (NPEs). EPA granted the petitioners' request for chronic aquatic toxicity testing and a few other aspects of the petitioners' TSCA section 4 request, but denied all of the petitioners' section 6 requests. Subsequently, on October 24, 2007, the petitioners filed suit in the U.S. District Court for the Northern District of California challenging EPA's denial of their TSCA section 21 petition. The lawsuit was mediated and, in an agreement signed on December 30, 2008, the parties settled the case. EPA is now providing this advance notice of proposed rulemaking (ANPRM) for aquatic and sediment toxicity testing under TSCA section 4 for these substances, and is also requesting comment on gathering data under TSCA and through other means to facilitate the evaluation of industrial laundry worker exposure to NPEs.

DATES: Comments must be received on or before September 15, 2009.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2007–0490, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Hand Delivery*: OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2007–0490. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2007–0490. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

Docket: All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., 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.

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*.

For technical information contact: 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) 564–8173; e-mail address: *ccd.citb@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be interested in this action if you manufacture (defined by statute to include import) or process 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II.B. and Unit II.D.1. 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. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What is the Purpose and Background of this ANPRM?

EPA is publishing this ANPRM as a follow-up to its response to certain TSCA section 4 test rule development requests made to EPA by the petitioners under TSCA section 21. Under TSCA section 21, any person may petition EPA to initiate a rulemaking proceeding for the issuance, amendment, or repeal of a rule under TSCA sections 4, 6, or 8 or an order under TSCA sections 5(e) or 6(b)(2). In the petition filed under TSCA section 21 in June 2007, the petitioners' requested that EPA require manufacturers and importers to conduct certain health and safety studies under TSCA section 4, and also requested certain TSCA section 6(a) actions for NP and NPEs (Ref. 1).

In its response to the TSCA section 21 petition (Ref. 2), EPA agreed that there may be a need for aquatic chronic toxicity testing for the short-chain NPEs. However, as EPA noted in its response, the particulars of a proposed testing program to evaluate aquatic toxicity of NPEs are uncertain, including which, and how many test chemicals and test species to include. In regard to an additional TSCA section 4 request, EPA denied that epidemiological testing is necessary, but did conclude that there may be a need for data to determine exposure to industrial laundry workers. However, EPA believes that additional information is needed to resolve:

1. Whether an exposure study (or studies) of industrial laundry workers' exposure to NPEs is warranted, and if so,

2. What kind of exposure study(ies) should be performed.

The TSCA section 21 petition and EPA's response, described in a **Federal Register** document that published on September 5, 2007, are available in the docket for this action (Refs. 1 and 2).

On October 24, 2007, the petitioners filed suit in the U.S. District Court for the Northern District of California (Ref. 56) challenging EPA's denial of the requests in the TSCA section 21 petition. This lawsuit was mediated and, in an agreement signed on December 30, 2008, the parties settled the case (Ref. 57). As part of the settlement, the parties agreed to ask the Court to dismiss the case with prejudice within 10 days of the publication of this ANPRM. Copies of the original filing and the final settlement agreement are available in the docket for this action (Refs. 56 and 57).

The purpose of this ANPRM is to solicit public input and obtain additional information relevant to whether and what kind of testing to propose concerning aquatic toxicity testing of NP and NPEs, and also to solicit comment relevant to establishing the necessity for, and the type of studies useful to, determining exposure of industrial laundry workers to NPEs. EPA is also soliciting comment on the cost of the proposed testing and the

capacity of laboratories to conduct the testing.

B. What are the Chemical Substances of Concern to EPA in this ANPRM?

The chemicals of concern in this ANPRM are NPEs, especially the short-chain NPEs, and NP. NP has little direct use itself, but is used as an intermediate to produce other chemicals, especially long-chain NPEs (Ref. 3). NPEs are manufactured by combining NP with ethylene oxide in an iterative process forming a mixture of NPEs of various chain lengths of 4 to 80 ethoxylate (EO) groups (e.g., NP4EO to NP80EO) (Refs. 3 and 4). Commercially, the commonly used NPEs have chain lengths of 8 to 12 EO groups (Ref. 5). Commercial mixtures of NPEs may contain a mixture of NPEs of various chain lengths; and NPEs may occur in either straight, or, more typically, branched forms. Different chain lengths have different properties and determine the particular industrial application and uses of the NPE substances. Common uses of NPEs include such consumer products as laundry detergents, shampoos, household cleaners and latex paints. Industrial uses include their use as surfactants, detergents, wetting agents and defoamers, among other uses (Refs. 3, 4, 6, and 7).

C. What Testing is EPA Considering in this ANPRM?

As described in this ANPRM, the testing EPA is considering is focused on aquatic toxicity testing for the short-chain NPEs, i.e., NP with one or two EO groups attached (NP1EO and NP2EO) and NP. As discussed in more detail in this unit, NP1EO, NP2EO, and NP occur in the environment mainly as degradation products of the longer-chain NPEs. In its response to the petitioners, EPA agreed that data concerning the toxic effects of the short-chain NPEs appear to be limited for aquatic organisms. In addition, for NP and short-chain NPEs, EPA concluded that there may be insufficient data to evaluate the effects of these substances on sediment-dwelling organisms. Data that are available indicate that these substances are highly toxic to fish and invertebrates, causing lethality on an acute basis and effects on growth, reproduction, and survival with low-level chronic exposures (Refs. 31 and 32). While data exist that are indicative of these effects, for the short-chain NPEs, and also for sediment-dwelling organisms, data may be insufficient for EPA to adequately evaluate the risk to aquatic and sediment-dwelling organisms from exposures to NP and short-chain NPEs. EPA also recognizes that at least part of the toxic mode of action for these substances may include disruption of the organism's endocrine system. For purposes of risk assessment, the testing EPA is considering in this ANPRM may adequately account for these effects. However, as additional data and test methods become available, EPA may propose testing protocols to better address endocrine disruption effects specifically.

NPEs and NP as a class of compounds are considered to be inherently, though not readily, biodegradable and, compared to some other surfactants, are relatively resistant to biodegradation (Refs. 4 and 6). In the environment and in wastewater treatment facilities (WWTFs), the long-chain NPEs degrade relatively quickly when compared to short-chain NPEs and NP (Refs. 8–12). Short-chain NPEs are more resistant to further degradation to NP (Ref. 13). With sufficient time NP is ultimately degraded to CO_2 and water (mineralization), but this process is much longer that the degradation of NPEs to NP (Refs. 3 and 13–15). As a result, although most NPEs are used and released as long-chain NPEs, concentrations of short-chain NPEs and NP are relatively high compared to the long-chain NPEs in WWTF effluent and in environmental samples (Refs. 3, 4, and 16–24).

The following studies are illustrative of sampling results for these compounds in U.S. waterways:

- A study by Rice et al. (2003) examined a 74 mile stretch of the Cuyahoga River, Ohio. They found that urbanized areas typically contain higher levels of NP and NPEs, with maximum concentrations found in water samples near WWTF discharge sites. At the sampling site closest to the Akron WWTF discharge location, 2.1 miles downstream, they found NP, NP1EO, NP2EO, and NP3EO at concentrations of 0.47, 0.60, 1.50, and 2.40 microgram/Liter (µg/L), respectively. However, the combined NP to NPE3EO concentrations in water samples at 7 additional sites along the river were much lower, with total concentrations ranging from only 0.13 to 1.0 µg/L (Ref. 22).
- Similarly, Barber et al. (2000) found detectable levels of combined NP, NP1EO, and NP2EO of 3.36 µg/L (fall samples) and 3.20 µg/L (spring samples) in the Des Plaines River, which is dominated by wastewater. However, these compounds were not detected further downstream in the Illinois River (the Des Plaines and Kankakee Rivers combine to form the Illinois R.), which receives much less WWTF effluent (Ref. 25).

More extensive surveys of NPEs in U.S. waterways have also been undertaken:

- A comprehensive monitoring study of NP and NPEs in 30 U.S. rivers sponsored by the Chemical Manufacturers Association (now the American Chemistry Council (ACC)), was designed with the stated goal of characterizing the upper range of environmental NP and NPE concentrations in U.S. rivers (Refs. 21 and 49). This study found average levels of NP(3–17)EO (combined), NP2EO, NP1EO, and NP of 2.0 µg/L, 0.10 µg/L, 0.09 µg/L, and 0.12 µg/L, respectively, in water samples. The highest levels found were approximately 15 µg/L for NP(3–17)EO and 1 µg/L for each of the other substances measured. Most of the water samples contained non-detectable levels of NP and NPEs (level of detection approximately 0.1 µg/L for NP, NP1EO and NP2EO, and 1.6 µg/L for total NP(3–17)EO) (Ref. 21).
- In another study of 139 U.S. streams in 30 states conducted by the U.S. Geological Survey, NP, NP1EO, and NP2EO were 3 of 95 organic wastewater contaminants sampled for. Samples were taken downstream of areas anticipated to contain pollution from intense urbanization and livestock production. NP was one of the most frequently detected compounds (51%). NP1EO and NP2EO were also detected, though slightly less frequently (46% and 37%, respectively). For NP, NP1EO, and NP2EO the maximum detected concentration levels were 40 µg/L, 20 µg/L, and 9 µg/L, respectively, with the median estimated concentration of each substance being about 0.8 µg/L for NP, and 1 µg/L for NP1EO and NP2EO (Ref. 18).

NP and NPEs have also been reported in sediments. Because of their significant hydrophobicity, which increases with decreasing chain length, and relative resistance to degradation, which also increases with decreasing chain length, NPEs and especially NP and the short-chain NPEs tend to preferentially partition from water and accumulate in sediments at levels much higher than those reported in water (Refs. 3, 4, 6, 26, and 27). For example, Naylor et al. (1992) found that in sediment samples NP and NP1EO predominated (average levels of 162 µg/kilogram (kg) and 18.1 µg/kg, respectively), with the highest sediment levels being about 3,000 µg/kg for NP and 175 µg/kg for NP1EO (Ref. 21). Bennett and Metcalfe (1998, 2000) found NP to be widely distributed in lower Great Lakes sediments with concentrations as high as 37,000 µg/kg in sediments near sewage treatment plants (Refs. 28 and 29). Rice et al.

(2003) measured sediment concentrations of NPEs and NP of 1,020 µg/kg dry weight in the Cuyahoga River, Ohio (Combined NP and NP(1–5)EO) (Ref. 22). Furthermore, in contrasting their observations with other published results, Rice et al. (2003) concluded that sediment levels of NPEs in the Cuyahoga River are low compared to some other areas; they noted, for example much higher levels were reported for the Detroit, Rouge, and Chicago Rivers (e.g., maximum reported levels of NP and/or NPEs from 49,000 to 60,000 µg/kg). In a marine/estuarine environment (Bernard Bayou, Mississippi), sediment concentrations ranged from 78 to 915 µg/kg for NP (average 509 µg/kg), and 5 to 89 µg/kg for NP1EO (average 11 µg/kg) (Ref. 49).

In WWTFs the degradation process of NPEs may vary depending on the efficiency of the WWTF and even according to the season of the year. However, even in cases where biodegradation of the long-chain NPEs is slowed (e.g., in winter or where wastewater treatment is poor), studies indicate that NP and the short-chain NPEs are still the predominant substances found after treatment (Refs. 3, 9, and 30).

D. What are the Issues for Comment Concerning Aquatic Toxicity Testing?

EPA has identified a number of issues, on which it is specifically soliciting comment in regard to proposing aquatic toxicity testing for NP and NPEs. However, this is not intended as an exclusive list of issues and commenters are encouraged to provide comments on any issue pertaining to the aquatic toxicity of NP and NPE short-chain isomers, and the testing that may be necessary or appropriate. The issues on which EPA is specifically soliciting comments are:

- Selection of test substance identity and purity;
- Selection of extent of acute and chronic aquatic tests and test species;
- Selection of particular aquatic toxicity tests and test species for NPEs;
- Testing of NP in a saltwater fish species;
- Testing of NP and NPEs in freshwater and marine sediment; and
- Proposed testing for NP1EO and NP2EO as it relates to development of water quality criteria.

In the discussions in this unit, EPA indicates its preliminary considerations regarding these issues:

1. *Selection of test substance identity and purity*. Currently, the aquatic toxicity testing EPA is considering would focus on testing NP and the short-chain NPEs, i.e., nonylphenol with one or two ethoxylates groups attached. EPA is soliciting comment on the most appropriate selection and purity of NP and NPEs to test. At this time, considering presently available data on NP and NPEs, EPA believes that testing of NP (phenol, 4-nonyl-branched: CAS number 84852–15–3) and NP1EO and/or NP2EO of 95% purity (laboratory grade) is appropriate for purposes of sufficiently predicting environmental risks from NP and NPEs as a chemical category. As noted in Unit II.C., NP1EO, NP2EO and NP occur in the environment mainly as degradation products of the longer-chain NPEs and, because of their relative resistance to degradation compared to the longer-chain NPEs, these short-chain NPEs are commonly found in the aquatic environment (Refs. 22, 25, and 31). NPE toxicity also seems to increase with decreasing chain length (Refs. 32–34). Available toxicity studies indicate that the short-chain NPEs, for example, are about 100 times more toxic than the long-chain NPEs, and NP appears to be about 1.5 to two times more toxic than the short-chain NPEs (Refs. 3 and 35). In the environment, the alkylphenols are combinations of various isomers and congeners, including NP, which is a mix of substances in which the nonyl group may be branched or linear and which may be attached to the phenol ring ortho, meta, or para to the hydroxyl group (Ref. 4). The most predominant commercial NP substance for which EPA has developed aquatic life ambient water quality criteria is phenol, 4-nonyl-branched (CAS number 84852–15–3), but tests on NP with CAS number 25154–52–3 (phenol, nonyl) were also used in developing these criteria (Ref. 4). Determining which test substance to specify for testing is a more complex issue in regard to the short-chain ethoxylates. On the TSCA inventory, both NP1EO (CAS number 27986–36–3) and NP2EO (CAS number 27176–93–8) are described with the term ''unspecified isomer lot.'' EPA has also identified NP1EO (CAS number 104–35–8) and NP2EO (CAS number 27176–93–8) whose name and CAS numbers indicate linear forms of these substances (although the actual structure may be branched); the NP1EO so identified is not present on the TSCA inventory; the NP2EO is.

With regard to who might ultimately be responsible for testing of these substances, the approach that EPA is considering proposing is that all manufacturers and processors of NP and NPEs of any chain length would be responsible for the testing. However, EPA solicits comment on such an approach.

2. *Selection of extent of acute and chronic aquatic tests and test species*. For substances that are broadly distributed in the environment, as is the case for NP and NPEs, EPA's OPPT, in assessing hazard to substances which are considered highly toxic, and EPA's Office of Water (OW), in determining ambient water quality criteria, typically review test data for both freshwater and saltwater organisms (fish, invertebrates, and plants) in order to adequately predict aquatic toxicity to environmental species (Refs. 36–38 and 50 to 51). To further elucidate the aquatic toxicity of NP and NPEs, EPA is considering proposing a number of aquatic and sediment toxicity tests in fish, invertebrates and algae. Specific testing is discussed in more detail in this unit.

The petitioners requested testing of mixtures. EPA responded that, for purposes of evaluating the effects of mixtures of NP and NPEs, an assumption of additive toxicity was reasonable and a more pragmatic way to account for the toxicity of mixtures of these substances to aquatic organisms (Refs. 1 and 2). This is because if effects are additive, the effects of mixtures can be effectively predicted from toxicity studies done on single substances. Two recent papers have examined the issue of additive toxicity for NP and NPEs. These papers present test results for mixtures of NP and the short-chain NPEs on fathead minnows and two species of daphnids, planktonic freshwater crustaceans also known as water fleas (Refs. 52 and 53). TenEyk and Markee (2007) concluded from testing with fathead minnows (*Pimephales promelas*) and water fleas (*Ceriodaphnia dubia*) that both potential additivity and synergism (where toxicity of the mixture is greater than additive) were observed (Ref. 52). Conversely, in tests with another water flea species (*Daphnia magna*), Sun and Gu (2005) concluded that potential antagonism (where toxicity of the mixture was less than additive) was seen (Ref. 53). EPA notes that these testing results indicate the substantial difference in the conclusions regarding the type of interaction (antagonism vs. additivity vs. synergism) that can potentially occur due to any number of factors related to biology, chemistry, experimental variables, etc. However, in considering the limitations associated with the study designs, EPA notes that, in both studies, the deviations observed from a simple additivity interaction are sufficiently small (a factor of approximately two or less) as to make additivity a reasonable

assumption for any evaluation of these compounds at this time. Two–fold is well within the range of inter-laboratory variability that one might expect in the results of testing a single chemical in the same species from one laboratory to another, and is far lower than the variability observed for toxicity of the same chemical to different aquatic species, which, in the case of NP, can exceed 100–fold (Refs. 32 and 55).

Therefore, it is EPA's current view that testing of individual NP and NPE substances as EPA is considering proposing in this ANPRM, will provide sufficient information needed to evaluate the toxicity of mixtures of these substances (for example, by using a toxic equivalent factor (TEF) approach). However, EPA is soliciting comment on whether testing intended to address the potential for additive toxicity should be conducted consistent with the protocol used in the TenEyck and Markee study (Ref. 52), as suggested by the petitioners. EPA is also soliciting comment on alternative approaches to investigating the potential toxicity of mixtures of NP and the various short-chain NPEs.

3. *Selection of particular aquatic toxicity tests and test species for NPEs.* To further determine the aquatic toxicity of NPEs, EPA is considering proposing chronic testing in freshwater fish, both warm and coldwater species (e.g., fathead minnow, *Pimephales promelas*, and rainbow trout, *Oncorhynchus mykiss*); chronic testing in a freshwater invertebrate (e.g., *Daphnia magna*); and testing in freshwater algae (e.g., *Pseudokirchneriella subcapitata*; formerly *Selenastrum capricornutum*). EPA is also considering testing in a saltwater fish (e.g., sheepshead minnow, (*Cyprinodon variegatus*), chronic testing in a saltwater invertebrate (e.g., mysid shrimp, *Mysidopsis bahia*), and testing in saltwater algae (e.g., *Skeletonema costatum*)). In order to set appropriate test concentration levels, and to develop-acute-to-chronic ratios, EPA is also considering acute testing be performed by the same laboratory doing the chronic fish and invertebrate testing.

4. *Testing of NP in a saltwater fish species.* EPA has developed water quality criteria (WQC) for NP (Ref. 4). However, as EPA noted in that document, the WQC for NP (CAS number 84852–15–3) was developed without adequate chronic toxicity data for a saltwater fish species. EPA is therefore considering proposing that acute and chronic toxicity testing of NP be performed in a single laboratory in order to fill that missing chronic toxicity data need, and also to calculate an acute-to-chronic ratio. EPA is considering proposing that the sheepshead minnow be the test species for this possible testing requirement.

5. *Testing of NP and NPEs in freshwater and marine sediment.* EPA noted in its response to the NP-NPE TSCA section 21 petition that information on the toxicity of NP in sediment, in both freshwater and marine/estuarine habitats, is limited and that it would consider additional testing under TSCA section 4 to obtain needed data. EPA is considering proposing acute and chronic sediment toxicity testing in freshwater and marine species of benthic invertebrates for NP, NP1EO, and/or NP2EO, where adequate data are lacking. Specifically, EPA is considering proposing the amphipod (*Hyalella azteca*) as the freshwater test species (acute and chronic testing) (Ref. 39). EPA is also requesting, as per the discussion in Unit II.D.2., comment on whether to require section 4 testing of NPE and NP on a sediment organism, e.g., *Hyalella azteca*, in order to fill the information gaps on additive toxicity. Regarding the marine environment, EPA is considering proposing testing in two species: acute testing in a marine amphipod (*Rhepoxynius abronius*), which, besides being a purely marine species, has a large data base of toxicity testing available; and acute and chronic testing in an estuarine amphipod, (*Leptocheirus plumulosus*) (Refs. 40 and 41). EPA would consider using the results from both *Leptocheirus* and *Rhepoxynius* to estimate chronic toxicity to *Rhepoxynius*, for which a chronic toxicity test method is not available.

6. *Proposed testing for NP1EO and NP2EO as it relates to development of water quality criteria.* EPA has derived recommended ambient water quality criteria (AWQCs) only for NP (Ref. 4). An EPA-recommended AWQC is a level of a pollutant or other measurable substance in water that, when met, will protect aquatic life and/or human health. EPA publishes recommended AWQCs pursuant to Section 304(a) of the Clean Water Act, which directs EPA to publish criteria accurately reflecting the latest scientific knowledge on such factors as ''the kind and extent of all identifiable effects . . . expected from the presence of pollutants in any body of water.'' 33 U.S.C 1314(a)(1)(A). As discussed in this unit, NP is more persistent and toxic, and frequently more abundant in the environment, than NPEs. Because of its relative persistence and toxicity compared to NPEs, most research has focused on NP as a chemical substance of concern. For these same reasons, development of data for NP was considered of priority importance for derivation of AWQCs. (Development of AWQC generally involves extensive and specific test data (Refs. 4 and 38)). In this ANPRM, EPA is considering proposing more limited testing that would sufficiently characterize the toxicity of NP1EO and NP2EO to enable a reasoned assessment of risk from these substances. However, the data developed could also be useful to OW should they pursue development of NPE AWQCs.

E. What are the Issues Concerning Exposure of NPEs to Industrial Laundry Workers?

The petitioners requested that EPA conduct an epidemiology study of industrial laundry workers who may be exposed to NP and NPEs in detergents. As noted in EPA's response to the petition, before an epidemiology study can be effectively designed or conducted, there needs to be 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. 42). Given the low volatility (Ref. 43) and negligible dermal absorption of NP and NPE (Ref. 44), EPA does not expect that where liquid detergents are used these industrial laundry operations will present a significant exposure potential to workers. However, as agreed to in the Settlement Agreement (Ref. 57), EPA is soliciting comment on that conclusion in this ANPRM. Additionally, EPA is soliciting information on specific circumstances or scenarios which may result in workers being exposed. Examples included exposure scenarios resulting from spills. EPA would be interested in the extent to which those types of exposures would present risks to workers. EPA would also be interested in receiving comments on the best ways to obtain data or information on such exposures.

For the approximately 10% of industrial laundry operations and an unknown number of institutional laundry operations that may use powdered detergent, EPA believes 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. 45). As these concerns are based on estimates, 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 exposure scenario in particular.

EPA has examined the regulatory status, as well as other studies, of various components of detergents that are used in consumer, industrial, and institutional laundry operations (Refs. 46, 47, and 48). Exposure limits for subtilisins, enzymes used in detergent formulations, have been established by the American Conference of Industrial Hygienists (ACGIH) and the National Institute for Occupational Safety and Health (NIOSH). Air monitoring to ensure the levels are maintained is recommended and personal monitoring equipment for subtilisins or other common enzyme detergents is available (Ref. 47). In addition, the Organization for Economic Co-operation and Development (OECD) Screening Information Data Set (SIDS) report on linear alkyl sulfonates, another common laundry detergent component, suggests that the hazard warnings and routine practices (protective equipment use and rinsing of residuals from contact) will sufficiently limit exposure and subsequent absorption (Ref. 48). The potential for exposure to NP based chemicals in detergents should already be mitigated by the policies in place for the other detergent components. However, based on EPA's draft engineering report (Ref. 45), EPA believes that specific monitoring for NP or NPE, using the analogous methodology for monitoring enzyme exposure, may be warranted to ensure that these routine practices are also protecting from NP exposures.

Accordingly, while EPA denied the petitioners' specific request for an epidemiology study, EPA is soliciting comment on the best means to obtain information on NP and NPE exposures of laundry workers, especially where powdered detergents are used (e.g., whether through requiring an exposure study, workplace exposure monitoring, the voluntary submission of existing monitoring data, or other means). In addition, although EPA does not believe it has evidence sufficient to support the same level of concern for liquid detergents as for powdered detergents, EPA is soliciting comment on whether and how to obtain data on specific scenarios that may result in exposure to laundry workers from liquid detergents, as well as powdered detergents.

F. What is the Agency's Authority for Taking this Action?

EPA is issuing this ANPRM on certain health and environmental effects testing for certain NP and NPE chemical substances under TSCA section 4(a) (15 U.S.C. 2603(a)).

Section 2(b)(1) of TSCA (15 U.S.C. 2601(b)) states that it is the policy of the United States that ''adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture [which is defined by statue to include import] and those who process such chemical substances and mixtures[.]'' To implement this policy, TSCA section 4(a) provides that EPA shall require by rule that manufacturers and processors of chemical substances and mixtures conduct testing if the Administrator finds that:

(1)(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture of any combination of such activities on health or the environment can reasonable be determined or predicted, and

(iii) testing of such substances or mixture with respect to such effects is necessary to develop such data; or

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonable be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; and

(2) in the case of a mixture, the effects which the mixture's manufacture, distribution in commerce, processing, use or disposal or any combination of such activities may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture[.]
(15 U.S.C. 2603(a))

If EPA makes these findings for a chemical substance or mixture, the Administrator shall require that testing be conducted on that chemical substance or mixture. The purpose of the testing would be to develop data about the substance's or mixture's health and environmental effects for which there is an insufficiency of data and experience, and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of the substance or mixture, or any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment. (15 U.S.C. 2603(a))

Once the Administrator has made the relevant findings under TSCA section 4(a), EPA may require any type of health or environmental effects testing necessary to address unanswered questions about the effects of the chemical substance. EPA need not limit the scope of testing required to the factual basis for the TSCA section 4(a)(1)(A) or (B) findings as long as EPA also finds that there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and that testing is necessary to develop such data. This approach is explained in more detail in EPA's TSCA section 4(a)(1)(B) Final Statement of Policy published in the **Federal Register** issue of May 14, 1993 (58 FR 28736, 28738–28739) (B Policy).

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IV. Do Any Statutory and Executive Order Reviews Apply to This Action?

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), it has been determined that this is a ''significant regulatory action'' because the initiation of a new rulemaking proceeding may raise novel legal or policy issues. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

Because this action does not propose or impose any requirements, other statutory and Executive Order reviews that apply to rulemaking do not apply. Should EPA subsequently determine to pursue a rulemaking, EPA will address the statutes and Executive Orders as applicable to that rulemaking.

Nevertheless, the Agency welcomes comments and/or information that would help the Agency to assess any of

the following: The potential impact of a rule on small entities pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*); availability of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note); environmental health or safety effects on children pursuant to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19985, April 23, 1997); or human health or environmental effects on minority or low-income populations pursuant to Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). The Agency will consider such comments during the development of any subsequent rulemaking.

List of Subjects in 40 CFR Part 799

Environmental protection, Chemicals, Hazardous substances, Nonylphenol, Nonylphenol ethoxylates, Reports and recordkeeping requirements.

Dated: June 10, 2009.

James Jones,

Acting Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

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