June 5, 2007

Stephen Johnson, Administrator
Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Re: Citizen Petition to EPA Regarding Nonylphenol and Nonylphenol Ethoxylates

Dear Administrator Johnson:

Male fish produce female egg proteins when exposed to low levels of nonylphenol ("NP") and nonylphenol ethoxylate ("NPE") products.[1] Yet, the U.S. Environmental Protection Agency ("EPA") claims it is unable to set water quality criteria to prevent this unnatural result because it does not have compelling evidence that male fish making female egg proteins is bad for fish growth, reproduction or survival. EPA acknowledges the need for more research.[2]

Fish may not be alone in responding in potentially dangerous ways to NP. Research published in the September 2006 edition of *Toxicological Sciences* shows that human placenta responds to NP in the first trimester.[3] The result may be early termination of pregnancy and fetal growth defects.[4]

The potential for harm is salient. American manufacturers make more than 200 million pounds of NP each year, which is used to produce almost 400 million pounds of NPE products.[5] Most of the NPE is used in a variety of residential and commercial cleaning products and is discharged to the

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[1] U.S. Environmental Protection Agency, Office of Water, Office of Science and Technology, Ambient Aquatic Life Water Quality Criteria Nonylphenol, December 2005, EPA-822-R-05-005.("EPA Criteria Document") www.epa.gov/waterscience/criteria/aqlife.html Section 1.4

[2] Id.at page 7.

[3] Bechi, N., Estrogen-Like Response to p-Nonylphenol in Human First Trimester Placenta and BeWo Choriocarcinoma Cells, Toxicological Sciences, 93(1), 75-81 (September, 2006).http://toxsci.oxfordjournals.org/cgi/content/full/93/1/75.

[4] Id at 79. Potential adverse effects of NP and NPEs on human health is also discussed in Vazquez-Duhalt, Nonylphenol, an integrated vision of a pollutant, Applied Ecology and Environmental Research 4(1):1-25 ISSN1589 1623, http://www.ecology.kee.hu/pdf/0401_001025.pdf. Widespread exposure of the U.S. population to NP has been demonstrated. Calafat, A., Kuklenyik Z., Reidy J., Caudill S., Ekong J., Needham L. 2005. Urinary Concentrations of Bisphenol A and 4-Nonylphenol in a Human Reference Population. Environmental Health Perspectives Vol. 113, p. 391. NP at high doses has been linked to breast cancer in mice. BBC News. 2005. Chemical Link to Breast Cancer.http://news.bbc.co.uk/1/hi/health/4676129.stmin 6/2005.

[5] EPA Criteria Document pp. 1-2; USEPA Region 5 Powerpoint presented August 2006 at Chicago, Illinois to the Uniform and Textile Association ("2006 R5 Powerpoint") p. 3. NP was one of the most frequently detected compounds in U.S. waters in a United Geological Survey study. U.S. Geological Survey. 2002. *What's in the Water? USGS Releases First Nationwide Look at Pharmaceuticals, Hormones, and Other Organic Contaminants in U.S. Streams.* News Release.

sewer.[6] In water and sewage treatment plants, NPE degrades into NP, short chain NPEs and related compounds, and the effect of NP and other NPE breakdown products in combination is more detrimental to the environment than NP alone.[7] Because of the widespread use of NP and NPE, it is simply impossible to rely on sewage treatment to reduce these compounds to a level at which there will be no adverse effects on the environment.[8]

EPA's Office of Pollution Prevention and Toxics ("OPPT") has recognized the problem. Through its Design for the Environment ("DFE") program, OPPT launched the Safer Detergents Stewardship Initiative ("SDSI"). In introducing the SDSI, EPA stated that:

> EPA is developing the Safer Detergents Stewardship Initiative (SDSI) to recognize companies, facilities, and others who voluntarily phase out or commit to phasing out the manufacture or use of nonylphenol ethoxylate surfactants, commonly referred to as NPEs. These surfactants are used in detergents in cleaning and other products. Both nonylphenol ethoxylates and their breakdown products, such as nonylphenol, can harm aquatic life.[9]

There are alternatives to the use of NP and NPE. Alcohol ethoxlyates ("AEs") are alternatives to NPEs that are readily biodegradable and significantly less toxic.[10] In fact, EPA has acknowledged the greater safety of these products and states that "[t]hese safer alternative surfactants are comparable in cost and are readily available."[11] Risk assessments based on their use in Europe have concluded that AEs pose a reasonable margin of safety and low concern for the aquatic environment.[12]

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[6] Dickey, Philip, Troubling Bubbles, Washington Toxics Coalition (1997) pp 67-84.

[7] TenEyck, M and Markee, T (2006) Additive Toxicity of Nonylphenol, Nonylphenol Monoethoxlyate, and Nonylphenol Diethoxylate to Selected Freshwater Species, Pimephales promelas (Fathead Minnow) and Ceriodaphnia dubia. [accepted for publication in Archives of Environmental Toxicology and Chemistry]; see also www.epa.gov/R5water/wqb/presentation/teneyck_presentation.pdf; Brian, J.V., Harris C.A., Scholze, M., Backhaus, T., Booy, P., Lamonee, M., Pojanu, Giulio, Jonkers, Neils, Runnalls, T., Bonfu, A., Marcomini, A., and Sumpter, J.P. (2005). Accurate Prediction of the Response of Freshwater Fish to a Mixture of Estrogenic Chemicals, Env. Health Prospectives, Vol. 113, p 721.

[8] Bistodeau, T.J., Barber, L.B., Bartell, S.E., Cediel, R.A., Grove, K.J., Klaustermeier, J., Woodard, J.C., Lee, K.E., Schoenfuss, H.L., 2006. Larval exposure to environmentally relevant mixtures of alkylphenolethoxylates reduces reproductive competence in male fathead minnows. Aquatic Toxicology, vol 79, pp. 268-77. (exposure to mixture of NP and other substances at concentrations likely to be present in Midwest sewage treatment plant effluent found toxic to male fathead minnows)

[9] See Safer Detergents Stewardship Initiative, www.epa.gov/opptintr/dfe/pubs/projects/formulat/sdsi.htm ("SDSI website")

[10] See, e.g., Toxecology Environmental Consulting Ltd. (2002) Alternatives to Nonylphenol Ethoxylates: Review of Toxicity, Biodegradation, & Technical-Economic Aspects. Prepared for Environment Canada.

[11] See SDSI website at http://www.epa.gov/dfe/pubs/projects/formulat/sdsi.htm

[12] See, e.g., Belanger, S.E. et al. (2006), Aquatic risk assessment of alcohol ethoxylates in North America and Europe, Ecotoxicology and Environmental Safety, 64:85-99.

Recognizing the harms caused by NP and NPE and the availability of alternatives, Europe and Canada have taken action to restrict NP.[13] Several leading companies also have taken a stand. Procter & Gamble has banned nonylphenol ethoxylates from its high-volume laundry and cleaning products.[14] Unilever has stopped using NPEs.[15] On October 30, 2006, Wal-Mart included nonylphenol ethoxylates as one of the first three chemicals of concern the company seeks to phase-out of its stores.[16]

Representatives of nonylphenol ethoxylate manufacturers, users and raw materials suppliers naturally object to EPA's DFE program, the European and Canadian restrictions, and Wal-Mart's decision.[17] They cite research that NP is less potent than natural hormones from human waste.[18] They claim that NPEs are "well-studied, safe, cost-effective and reliable cleaning ingredients."[19]

Sierra Club, Environmental Law & Policy Center of the Midwest, the Pacific Coast Federation of Fisherman's Association, Washington Toxics Coalition, Physicians for Social Responsibility, and UNITE HERE ("Petitioners") disagree.[20] While there are still important gaps in the research, new research evidences an impact on humans at levels much lower than previously studied and demonstrates that more research is needed. NP and NPEs are discharged in quantities several orders of magnitude higher than natural hormones. The combined effect of NP and NPE breakdown products

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[13] See http://eescopinions.eesc.europa.eu/eescopiniondocument.aspx?language=en&docnr=399&year=2003; *Canadian Environmental Quality Guidelines – Nonylphenol and its Ethoxylates* at www.ec.gc.ca/ceqg-rcqe/English/Html/GAAG_NPE_SEQG.cfm ; Reneer, R. Environ. Sci. Technol., (1997), 31, 316-20.

[14] See *Use of Nonylphenol and Nonylphenol Ethoxylates in P&G Products* at www.pgperspectives.com/en_UK/productingredient/nonylphenolnonylphenolethoxylates_en.html

[15] See Frequently Asked Questions: "Do you use nonylphenol ethoxylates (NPEs) as surfactants?" at www.unilever.com/ourvalues/environmentandsociety/env_social_report/consumers/chemicalsinproducts/FAQs.asp

[16] See *Wal-Mart Stores, Inc. Launches Innovative Program to Inspire Use of Preferred Substances in Chemical Intensive Products* at www.walmartfacts.com/articles/4556.aspx.

[17] See statement of Robert Fensterheim http://www.aperc.org/whatsnew.htm

[18] http://www.aperc.org/docs/aperc_statement_on_walmart.pdf

[19] Id.

[20] Petitioners and/or their members commercially fish, swim, drink water, work with, and recreationally fish, canoe, engage in nature study and otherwise use waters that are or may become affected by NP and NPEs and, accordingly, are directly affected by the adverse effects that the manufacture and use NP and NPE are having on the environment. Inspired by nature, Sierra Club's 750,000 members work together to protect our communities and the planet. The Club is America's oldest, largest and most influential grassroots environmental organization. The Environmental Law & Policy Center has worked to improve water quality in numerous states on behalf of its members and clients. The Pacific Coast Federation of Fishermen's Association represents working men and women in the West Coast Commercial Fishing Fleet. Washington Toxics Coalition protects public health and the environment by eliminating toxic pollution. WTC promotes alternatives, advocates policies, empowers communities, and educates people to create a healthy environment. Guided by the values and expertise of medicine and public health, Physicians for Social Responsibility works to protect human life from the gravest threats to health and survival. UNITE (formerly Union of Needletrades, Industrial and Textile Employees) and HERE (Hotel Employees and Restaurant Employees International Union) merged on July 8, 2004 forming UNITE HERE. The union represents more than 450,000 active members and more than 400,000 retireees throughout North America.

are clearly adversely affecting fish reproductive potential based on effluent concentrations and documented effect levels. Action is needed now.

Further, as explained below, the risk posed to the environment by NP and NPE cannot be addressed adequately under federal laws other than the Toxic Substances Control Act ("TSCA"). *See generally*, 15 U.S.C. § 2608(b). Much NP and NPE reach the environment through unregulated non-point sources and combined sewer overflows that are unlikely to be abated in the foreseeable future. Still further, even sewage treatment plants that provide tertiary treatment and nitrify ammonia do not break NP and NPE down to the extent necessary to protect the environment. In light of these limits, EPA needs to rely on pollution prevention rather than treatment to address the problem.

Petitioners ask that EPA, pursuant to Section 21 of TSCA,[21] take action regarding nonylphenol and nonylphenol ethoxylates. Specifically, Petitioners request that EPA exercise its authority under TSCA Section 4 and 6(a) to:

1. Require manufacturers and importers to conduct specific health and safety studies;
2. Require labeling on all products containing NP and NPE; and
3. Limit the use of NP and NPE where the use presents an unreasonable risk to public health and the environment, given available alternatives.

The basis for these actions is set forth below.

BACKGROUND

Indentification of Nonylphenol and Nonylphenol Ethoxylates

According to EPA,

> Nonylphenol is an organic chemical used primarily as an intermediate to produce nonionic surfactants of the nonylphenol ethoxylate type. It is produced in large quantities in the United States. It is toxic to aquatic organisms and is found in ambient waters. Environmental exposure occurs mainly from its release as a breakdown product from industrial and domestic sewage treatment plant effluents. Nonylphenol

[21] 15 U.S.C.§ 2620 (Toxic Substance Control Act, Section 21) (2006). It states that (a) "Any person may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 2603, 2605, or 2607 of this title or an order under section 2604(e) or 2605(b)(2) of this title."

> is moderately soluble and resistant to natural degradation in water. Because of nonylphenol's toxicity, chemical properties, and widespread use as a chemical intermediate, concerns have been raised over the potential risks to aquatic organisms posed by exposure to it.[22]

Petitioners here define nonylphenol according to the CAS numbers identified in the 2005 EPA Criteria Document. The EPA Criteria Document states that "commercial nonylphenol is most accurately described by CAS number 84852-15-3 (phenol, 4-nonyl-branched), but CAS numbers 104-40-5 (phenol, 4-nonyl-) and 25154-52-3 (phenol, nonyl) have also been used to describe these compounds commercially."[23] The EPA Criteria Document further states that

> Nonylphenol is produced in large quantities in the United States. Production was 147.2 million pounds (66.8 million kg) in 1980 (USITC 1981), 201.2 million pounds (91.3 million kg) in 1988 (USITC 1989), 230 million pounds (104 million kg) in 1998 (Harvilicz 1999), and demand is increasing about 2 percent annually.[24]

Petitioners rely on these figures to evidence the large scale of NP production.

Petitioners here define nonylphenol ethoxylates as the set of chemicals with between one and 100 ethoxylates attached to nonylphenol. This group of chemicals is also known as nonylphenol polyethoxylates. In 2003, approximately 391 million pounds of NPEs were produced.[25]

Known effects of NP and NPEs in water bodies

The EPA Criteria Document recognizes that NP is highly toxic, even considered in isolation from the other NPE breakdown products with which it is found in the environment. Established water quality criteria are as follows: freshwater acute and chronic criteria of respectively 28 μg/L and 6.6 μg/L, and saltwater acute and chronic criteria of respectively 7.0 μg/L and 1.7 μg/L. (EPA Criteria Document p. 34)[26]

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[22]EPA Criteria Document p. 1.
[23] Id.
[24] Id.
[25] 2006 R5 Powerpoint p.3
[26] Environment Canada, after an extensive study of NP and NPE effluent concentrations and toxicity, concluded that use restrictions need to be imposed based on toxicity of NP and the short chain ethoxylates and established a water quality guidance for NP of 1.0 μg/L for freshwater and 0.7 μg/L saltwater. Canadian Council of Ministers of the Environment, Canadian Water Quality Guidelines for the Protection of Aquatic Life Nonylphenol and its Ethoxylates (2001). Environment Canada assumed that NP1EO and higher chain ethoxylates were approximately one-half as toxic as NP and

Further, NP and NPE have effects on aquatic life in addition to direct toxicity. NP and its lower ethoxylates are endocrine disrupting chemicals with estrogenic properties.[27] NP and NP2EO have been shown to bind to the estrogen receptor.[28] They also have been linked to:

- Elevated vitellogenin (the major constituent of the yolk in oocytes and a biomarker for estrogenicity) in male rainbow trout, flounder, Atlantic salmon, and eelpouts;[29]
- Reduced gonadosomatic indices and severe histological effects on testicular structure in male eelpouts;[30]
- Reduced Atlantic salmon abundance, as well as variations in three key steroidogenic proteins, and xenobiotic and steroid metabolizing cytochrome P450 isozyme levels in the brain of exposed juvenile salmon;[31]
- Estrogenic effects on amphibians;[32] and
- Toxic effects to marine oysters.[33]

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that the toxicity was additive. (2006 R5 Powerpoint p. 11). The use restriction was based on the total concentration of NP and of NPEs and cumulative toxicity (TEQ).
Unlike the Canadian assessment EPA's water quality criteria is only for NP. EPA recently supported an acute toxicity study on the individual and additive toxicity of NP, NP1EO and NP2EO to fathead minnows and Ceriodaphnia that documented that the acute toxicity of NP1EO and NP2EO to fatheads, was approximately 2/3 and ½ that of NP. Ten Eyck (2006) Further, the combined effects were at least additive in terms of toxicity.
When Region 5 staff compared effluent concentrations with expected cumulative toxicity, they found that many of the limited number of effluents they compared would be toxic. (2006 R5 Powerpoint pp.7, 14, 24, 26, 37,38, 43, 45) Of particular concern would be effluent concentrations for discharges to saltwater since the WQC for salt water is much lower than it is for freshwater. Finally, a recent study funded by the State of Minnesota documented that fathead minnow larvae exposed to twice the average concentration of all NPE in a Minnesota effluent for 30 days exhibited 100 percent mortality. Bistodeau (2006) In this regard, it is noteworthy that this species is not particularly sensitive to NP based on comparison of toxicity with other species reported in the EPA Criteria Document.

[27] Environment Canada, National Guidelines and Standards Office, "Canadian Environmental Quality Guidelines for Nonylphenol and its Ethoxylates." ("CEQG for NP and NPEs") Aug. 2002, at p. 30; Thorpe, K.L., T.H. Hutchinson, M.J. Hetheridge, M. Scholze, J.P. Sumpter, and C.R. Tyler. (2001) Assessing the biological potency of binary mixtures of environmental estrogens using vitellogenin induction in juvenile rainbow trout (Oncorhynchus mykiss). *Environ Sci Technol.* 2001 Jun 15; 35(12): 2476-2481.

[28] White, R., S. Jobling, S. Hoare, J. Sumpter, M. Parker. (1994). Environmentally persistent alkylphenolic compounds are estrogenic. *Endocrinology*. 135(1): 175-182.

[29] See Environment Canada and Health Canada, Priority Substances List Assessment Report: Nonylphenol and Its Ethoxylates," Apr. 2001 ("NP PSLAR") (noting paucity of data for conducting health health risk characterization); Christiansen et al. 1998a, Bjerregaard et al 1998, Yadetie, Christiansen et al. 1998b; Arukwe, A. 2005. Modulation of the StAR protein and P450scc in the brain of juvenile Atlantic salmon (Salmo salar) is a novel aspect of nonylphenol toxicity. Environ. Sci. Technol., 39 (24), 9791 -9798; Fairchild, W.L., E.O. Swansburg, J.T. Arenaut and S.B. Brown. (1999) Does an association between pesticide use and subsequent declines in catch of Atlantic Salmon represent a case of endocrine disruption? Environ. Health Perspect. 107: 349-357.

[30] Id.

[31] Id.

[32] Mackenzie CA, Berrill M, Metcalfe C, Pauli BD, (2003) Gonadal Differentiation in Frogs Exposed to Estrogenic and Antiestrogenic Compunds, Env. Toxicology and Chemistry 22:2466-2475.

There is evidence that NP and NPE also are affecting aquatic life through long term and indirect effects that do not appear in studies designed to measure direct toxicity and endocrine disruption.[34]

The 2002 Canadian risk assessment documents effluent concentrations of NPEs in a number of Canadian sewage plant and industrial outfalls.[35] EPA Region 5 has summarized effluent concentrations in a number of sewage treatment and paper mill effluents in Connecticut, Illinois, Ohio and Wisconsin.[36] The levels found in these states are significant even if NP alone is considered in comparison to the chronic U.S. EPA criteria. However, it is noteworthy that a U.S. EPA presentation on the concentrations demonstrates that effluent concentrations of nonylphenol monoethoxylate (NP1EO) and nonylphenol diethoxylate (NP2EO) combined are typically at least an order of magnitude higher than NP. This means that the toxic and estrogenic effect on aquatic life is probably a very substantial multiple of the effect that would be expected considering NP alone.[37]

THE TESTS THAT SHOULD BE REQUIRED UNDER TSCA SECTION 4

Petitioners request that EPA exercise its authority under TSCA Section 4 and require manufacturers and processors of nonylphenol and nonylphenol ethoxylates to conduct specific tests regarding these chemicals.

In light of the research gaps and scientific data that is needed, EPA is required to make the "B" findings for a Section 4 test rule. In the EPA Criteria Document, EPA found that over 230 million

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[33] Natural Environmental Research Council. 2003. *Pollutant Threat to Oyster Industry,*Royal Holloway, University of London. Retrieved from http://www.nerc.ac.uk/publications/latestpressrelease/2003-13-oysters.asp; Nice, H., D. Morritt, M. Crane and M. Thorndyke. 2003. *Long-term and Transgenerational* Effects of Nonylphenol Exposure At a Key stage in the Development of Crassostrea gigas. Possible Endocrine Disruption? Marine Ecology Progress Series, Vol. 256, p. 293.

[34] Liney KE, Hagger JA, Tyler CR, Depledge MH, Galloway TS, and Jobling S, (2006) Health Effects in Fish of Long-Term Exposure to Effluents from Wastewater Treatment Works, Environ Health Perspect. 114: 81-9.

[35] Canadian Environmental Quality Guideline for Nonylphenol and its Ethoxylates, ISSN1497-2689 (August 2002) p. 11

[36] 2006 R5 Powerpoint pp. 24, 37, 43, 45; See also, http://www.epa.gov/R5water/wqb/swims.htm#advanced (presentation by T. Nettesheim and E. Murphy given January 31, 2007 to SWiMs meeting in Chicago)

[37] Winter effluent concentrations may be several times higher than summer concentration due to poorer treatment in winter months due to lower treatment temperatures. 2006 R5 Powerpoint pp. 15, 20-22) Unfortunately, it is also true that sewage treatment plant temperatures are higher than receiving stream temperatures in winter months. This is important due to the fact that many fish are attracted to warmer water in winter months and thus to higher concentrations of NPE. Of particular concern is that fish will be exposed to endocrine disruption effects of NPEs at a time when gonads should be developing for the spring reproductive period. The situation is worst in effluent dominated streams where the effluent represents most of the flow in a stream for a portion of the year. Under these conditions, toxicity and endocrine disruption is expected to be widespread. A significant percentage of regulated discharges in the U.S. are now made to effluent-dominated streams and the situation is expected to increase in frequency. Brooks B., Riley T., Taylor R., (2006) Water quality of effluent-dominated ecosystems: ecotoxicological, hydrological, and management considerations, Hydrobiologia 556:365-79.

pounds of the chemical are produced annually. This amount is more than 230 times the threshold for significant quantities that EPA uses in its "B Policy."[38] An industry study has found that activated sludge wastewater treatment plants remove 90 to 95% of primary compounds.[39] Importantly, however, this study also found that NP1EO and NPE2EO often remain after treatment. In any case, even if all of the approximately 400 million pounds of the NP and NPEs produced each year received 95% treatment, more than 10 million pounds of the chemicals would be released into the environment each year. This figure is more than 10 times the threshold for a significant environmental release of one million pounds established by EPA in its "B Policy."[40]

Seven categories of tests are needed to determine the extent of the effect of these chemicals on aquatic life and the risk of exposure to these chemicals on persons working with them and other populations. Petitioners request that EPA treat each of the requested tests separately.

1. Filling the Gaps for Chronic Toxicity of NPE Oligomers

Aquatic toxicity of nonylphenol ethoxylates increases with decreasing length of the ethoxylate chain. To date, there is a lack of data on chronic toxicity of short-chain NPE. Such data is necessary for development of protective chronic water quality criteria and standards that account for the full range of negative impacts from NP and NPEs.

2. Filling the Gaps Regarding the Additive Toxicity of NP and NPE Oligomers to Species

Research supports that NP, NP1EO and NP2EO occur in mixtures in the aquatic environment. These substances have a common mode of toxicity, narcosis, such that their effects are treated properly as additive.[41] Thus, to adequately protect water quality, criteria and standards should be set by summing the impacts of these chemicals. In order to set a water quality standard based on additivity, states such as Illinois require studies of combinations of substances on at least three species of ecologically diverse taxa. See, e.g., 35 Ill. Admin. Code 302.621(b). EPA recently released a study

[38] U.S. EPA, May 14, 1993 (58 FR 28736). See www.epa.gov/opptintr/chemtest/bfinal.pdf

[39] Melcer, Henryk, *et.al.*, *The Removal of Alkylphenol Ethoxylate Surfactants in Activated Sludge Plants*, presentation at the Water Environment Federation Technical Exhibition and Conference, October 24, 2006. See www.aperc.org/wef_slides_final.ppt#1

[40] U.S. EPA, May 14, 1993 (58 FR 28736); See www.epa.gov/opptintr/chemtest/bfinal.pdf

[41] Environment Canada, National Guidelines and Standards Office, "Canadian Environmental Quality Guidelines for Nonylphenol and its Ethoxylates." ("CEQG for NP and NPEs") Aug. 2002, at p. 34.

on the additive acute toxicity of NP, NP1EO and NP2EO to *Pimephales promelas* (fathead minnow) and *Ceriodaphnia dubia.*[42] Petitioners request that EPA require research on a third species from a different taxa, e.g., *hyalella azteca* (an amphipod), to serve as the basis for additive NP and NPE water quality standards.

As noted above, research is needed on the chronic toxicity of various NPEs. Chronic toxicity studies should be carried out on mixtures as well as individual NPEs on a variety of aquatic species.

3. Research on Individual Endocrine Disruption Impacts and on the Relationship Between Individual Endocrine Disruption Impacts and Population-Level Impacts

As shown above, there is abundant evidence of the estrogenic effects of NP and NPE. However, few studies exist on the long-term, population-level ramifications of endocrine disruption in general, including that from NP and NPEs. This research is necessary to determine the extent of the ecological effect of various concentration levels and to set environmental standards that protect populations.

In setting the water quality criteria for NP, EPA recognized that there was much evidence in the record showing effects of NP and NPE on wildlife, but decided that additional research was needed before that data could be used in setting standards. Thus, EPA excluded many significant studies regarding nonylphenols and nonylphenol ethoxylates that showed a substantial impact on the biochemical processes in aquatic species because these studies did not also contain compelling evidence of tangible reproductive, survival, and growth impacts. For example, in the EPA Criteria Document, EPA states that:

> The majority of studies using aquatic species models report results for molecular or biochemical endpoints such as induction of the egg protein, vitellogenin, or are in vitro studies such as receptor binding assays. These types of studies and endpoints do not meet the data acceptability requirements outlined in EPA's *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* (Stephan et al. 1985) and hence were not used [sic] deriving ambient water quality criteria.[43]

[42] Ten Eyck, M and Markee, T (2006)
[43] EPA Criteria Document at 6.

Accordingly, it is clear that additional tests are needed to better understand tangible changes in the biochemistry of aquatic species observed in many published studies and the effects of those changes on the reproductive and growth endpoints that EPA uses to establish water quality criteria.

Important areas for research on the population-level impact of endocrine disruption from NP and NPEs include:

- Whether links exist between the vitellogenin response and semen quality, testicular development, histological changes, and offspring sex ratio and development;
- Whether noted population effects associated with NP are due to endocrine disruption; and
- Multigenerational toxicity tests with suspected endocrine disrupters.

The results of these studies will aid in filling the research gap noted by EPA.

4. Testing for vitellogen gene expression

EPA's Office of Research and Development has developed a vitellogenin gene expression assay as an indicator of estrogen exposure. In a recent report on significant research findings, EPA identified success in the assay.[44] Petitioners ask that EPA require that the assay be applied to NP and each individual NPE. This information will be essential to developing a more subtle understanding of the contribution of each type of NPE to overall toxicity.

5. Testing Related to Levels of NP and NPE in Humans and Estrogenic Effects on Humans

Data on human exposure to NP and NPE are scarce.[45] Research that does exist on levels of NP in humans is limited by testing of a single isomer, as well as the lack of knowledge regarding the relevance of an oxidative metabolism pathway for NP in humans.[46] Another gap in current knowledge

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[44] EPA, Report on vitellogenin gene expression in minnows and pearl dace from control (non-dosed) and lakes dosed with EDCs in the Canadian Experimental Lake Area, 5/17/05 See http://www.epa.gov/nerl/research/2004/g4-15.html

[45] Calafant A., Kuklenyik, J., Caudill, S. Ekong J. and Needham L.(2005); Analysis of many drinking water samples in the U.S. has found an overall average concentration of alkylphenolic compounds of 1 µg/L. U.S. EPA. 2001. *Removal of Endocrine Disruptor Chemicals Using Drinking WaterTreatment Processes.* Retrieved from http://www.epa.gov/ORD/NRMRL/Pubs/2001/edc/625r00015.pdf

[46] Id.

is the extent of dermal absorption of NP and NPEs contained in consumer products.[47] Thus, Petitioners request that EPA require research to establish the relevance of oxidative metabolism of NP in humans and to identify the urinary metabolites of NP commercial mixtures. Petitioners also request research on dermal absorption of NP and NPEs, as well as of NP and NPE exposure in a nationally representative sample of the U.S. population.

While a body of research exists on estrogenic impacts of NP and NPEs on animals, a gap exists in terms of the impact of NP and NPEs on development of the human placenta. A recent study from Italy suggests that the human trophoblast may be highly responsive to NP, raising potential concerns about maternal exposure in early gestation.[48] Petitioners request that the EPA require testing on the effect of NP on human placenta development similar to the Italian study.

6. Testing for Health Impacts on Workers Handling the Chemicals at Industrial Laundries

The epidemiological literature on NP and NPEs is inadequate to gauge the extent of the threat to persons working with these chemicals.[49] In terms of occupational analysis of NP and NPE, the European Union's risk assessment focused on estimating exposures among workers involved in manufacturing NP, using NP as an intermediate, manufacturing specialty paints, and using specialty paints.[50] Canada, in turn, has conducted a general population human health risk assessment.[51] Notably missing from these sources is research on the potential impacts to industrial laundry workers, who are likely exposed to NPE in significantly greater quantities than the general public through their contact with NPE-containing cleaning products.

There is significant potential for human exposure to the chemicals in the workplace. In May 2004, the U.S. Department of Labor's Bureau of Labor Statistics estimated that there were 203,920 people employed in production occupations in drycleaning and laundry services with 108,040 front-line workers.[52] The number of people who work in industrial laundries that use the chemicals is more

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[47] See NP PSLAR at p. Chapter 3.3
[48] Bechi, N. (2006). See http://toxsci.oxfordjournals.org/cgi/content/full/93/1/75.
[49] See NP PSLAR at p. 74.
[50] European Chemicals Bureau, "European Union Risk Assessment Report: 4-nonylphenol (branched) and nonylphenol," (2002), at Chapter 4.
[51] See NP PSLAR.
[52] U.S. Department of Labor, Bureau of Labor Statistics, NAICS 812300. SOC Code Number 51-0000 for Productin Occupations. SOC Code Number 51-6011 for front line workers. See www.bls.gov/oes/2004/may/naics4_812300.htm.

than 200 times the "B Policy" threshold of 1000 workers.[53] Petitioners request that EPA require epidemiological studies on laundry worker potential exposure to NPEs.

7. *Testing for Determine Exposure to NPE in Residential Indoor Air*

Research by Ruthann Rudel at the Silent Spring Institute evaluating indoor air and dust in 120 homes in Cape Cod, Massachusetts measured 4-nonylphenol in the indoor air of 100% of the homes.[54] The median concentration was 110 nanograms per cubic meter. Eighty percent (80%) of the dust samples had measurable levels of 4-nonylphenol. The study concluded that "[a]lkylphenols, particularly 4-nonylphenol (4-NP) and its mono- and diethoxylates, were also among the most abundant compounds detected." The researchers stated that "this result contrasts with conclusions by others that 4-NP is not volatile and would be unlikely to be a significant air contaminant."[55]

Petitioners request that EPA adopt a Section 4 rule requiring manufacturers to conduct testing to assess the concentrations of NP and NPEs in indoor air and dust and to assess the health threats posed by the levels found. With respect to NP and NPEs, there is no reason to suspect that homes in Cape Cod are unusual. Every home in the United States may have these levels. If so, the threat to resident health, especially children who spend so much of their time in the home, greatly exceed EPA's "B Policy" thresholds.

RESTRICTIONS THAT SHOULD BE REQUIRED UNDER TSCA SECTION 6(A)

Petitioners further request that EPA exercise its authority under TSCA Section 6(a) and require manufacturers, processors and users of nonylphenol and nonylphenol ethoxylates to limit their use of these chemicals. Petitioners request that EPA treat each of the requested actions separately and consider them as an entire group.

It is clear that the current unrestricted manufacture and release of NP and NPE poses an unreasonable risk to the environment. It is certainly not reasonable to rely on sewage treatment or NPDES permit limits to control the risks posed by the current manufacture and use of NP and NPE.

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[53] http://www.bls.gov/oes/2004/may/naics4_812300.htm

[54] Rudel, R., Camann, D., Spengler, J., Korn, L., Brody, J., (2003); Phthalates, Alkylphenols, Pesticides, Polybrominated Diphenyl Ethers, and Other Endocrine-Disrupting, Compounds in Indoor Air and Dust, Environmental Science & Technology, Vol, 37, No. 20. p. 4543

[55] Id at 4549.

Studies of the discharge from sewage treatment plants and paper mills show that discharges of NP occur, particularly in the wintertime, approaching or exceeding the 6.6 µg/L EPA chronic quality criterion for NP.[56] However, even if the NP levels in discharges were always well below the chronic criterion, that fact would provide little comfort for a number of reasons. First, numerous studies have found endocrine disruptive effects well below the 6.6 µg/L level.[57] Moreover, as discussed above, the 6.6 µg/L chronic criterion takes into only account NP and not its breakdown products, such as NP1EO and NP2EO. Some of these breakdown products are nearly as toxic as NP and are known to be additive in effect with NP, rendering the criterion inadequately protective. Certainly, the fact that numerous studies have found fish which are severely affected by endocrine disruption effects immediately downstream of well-run sewage treatment plants indicates that the combination of chemicals coming out of the plants is not benign.[58]

Moreover, it is plain that much NPE will be released into the environment without having passed through an activated sludge wastewater treatment plant. Water contaminated by NP and NPE

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[56] 2006 R5 Powerpoint pp. 24, 37, 43, 45; Jobling, S., Sheahan, D., Osborne, J.A., Matthiessen, P., Sumpter, J.P., (1995) Inhibition of Testicular Growth in Rainbow Trout (*Oncorhynchus Mykiss*) Exposed to Estrogenic Alkylphenolic Chemicals. Environmental Toxicology and Chemistry, vol. 15, no.2, pp. 199 (domestic sewage and some industrial effluents may contain up to hundreds of micrograms of alkylphenolic compounds).

[57] E.g. Hemmer, J.H., Hemmer, B.L., Bowman, C.J., Kroll, K..J., Folmar, L.C., Macoovich, D., Hoglund, M.D., Denslow, N.D., 2001. Effects of p-Nonylphenol, Methoxychlor, and Endosulfan on Vitellogenin Induction and Expression in Sheepshead Minnow (Cyprinodon Variegatus). Environmental Toxicology and Chemistry, vol 20, pp. 336-343. (effect seen after exposure to .64 µg/L NP); Miles-Richardson, S.R., Pierens, S.L., Nichols, K.M., Kramer, V.J., Snyder, E.M., Snyder, S.A., Render, J.A., Fitzgerald, S.D., Giesy, J.P., 1999. Effects of Waterborne Exposure to 4-Nonylphenol and Nonylphenol Ethoxylate on Secondary Sex Characteristics and Gonads of Fathead Minnows (pimephales promelas). Environmental Research, Section A80, S122, S137. (cell changes observed after exposure to 1.1 or 3.4 µg/L NP); Schwaiger, J., Mallow, U., Ferling, H., Knoerr, S., Braunbeck, T., Kalbfus, W., Negele, R.D., 2002. How estrogenic is nonylphenol? A transgenerational study using rainbow trout (Oncorhynchus mykiss) as a test organism. Aquatic Toxicology, vol 59, pp. 177-189. (estrogenic effect found after intermittent exposure to 1 µg/L NP)

[58] Endocrine disruption in fish collected in sewage plant effluents in the United States was first documented for carp and walleye collected from the Minneapolis metro plant in the mid 1990's after the first studies were published in Great Britain. Folmar LC, Denslow ND, Rao V, Chow M, Crain DA, Enblom J, Marcin J and Guillette LJ, (1996)Vitellogin Induction and Reduced Serum Testosterone Concentrations in Feral Male Carp (Cyprinus carpio) Captured Near a Major Metropolitan Sewage Treatment Plant, Environ Health Perspect 104:1096-1100;); Sumpter, J., and S. Jobling. 1995. Vitellogenesis as a Biomarker for Oestrogenic Contaminationof the Aquatic Environment. Environmental Health Perspectives Suppl. Vol. 103, p. 173; Numerous other studies have now found these effects in rivers in the United States. Mitichelmore, C.L., Rice, C.P., 2006. Correlations of nonylphenol-ethoxylates and nonylphenol with biomarkers of reproductive function in carp (cyprinus carpio) from the Cuyahoga River. Science of the Total Environment, vol 371, pp. 391-401. (elevated VTG levels in male carp below sewage treatment plants); Cornwall W. and Ervin K., Hormonal Chemicals May be Imperiling Fish, The Seattle Times, Sunday, April 1, 2007; Fahrenhold DA, Male Bass Across Region Found to Be Bearing Eggs Pollution Concerns Arise In Drinking-Water Source, Washington Post Wednesday, September 6, 2006, A01; Stein M. and Moffeit M., Mutant Fish Prompt Concern, Denver Post Oct. 4, 2004; Cone M., Male bottom-dwellers with female sex characteristics are found near outfall pipes in waters off Los Angeles and Orange Counties, LA Times Nov 14, 2005. See also, Bistodeau, T.J., Barber, L.B., Bartell, S.E., Cediel, R.A., Grove, K.J., Klaustermeier, J., Woodard, J.C., Lee, K.E., Schoenfuss, H.L., 2006. (Larval exposure to environmentally relevant mixtures of alkylphenolethoxylates reduces reproductive competence in male fathead minnows

can enter the nation's waters via by-passes, combined sewer overflows, septic systems, or surface run-off. Still further, much of the wastewater that is treated does not receive treatment to nitrify ammonia although it is clear that this level of treatment is required to achieve anything close to the figure of 95% reduction in NP that has been touted by the industry and some sewage treatment plant operators.[59]

1. *Require labeling on all products containing the chemicals*

Chemical users, workers and the public need to know when a product contains nonylphenols and nonylphenol ethoxylates so they can take appropriate precautions in handling the product, both for their own protection and to keep it out of the water. Material safety data sheets are not sufficient to alert the worker to the potential danger. Labels must accompany the products themselves. A labeling requirement would impose a small and manageable burden on the industry. It would empower users to take steps to prevent the well-documented unreasonable risk posed by the chemicals. While water quality criteria are essential (and need to be revised to reflect the latest science), they are only useful in setting limits in NPDES permits and devising TMDLs. Given the widespread and pervasive use of the chemicals, there are inadequate tools to ensure compliance with aquatic life water quality criteria. EPA needs to enable compliance with enhanced labeling requirements.

2. *Restrict the use of the chemicals where the user cannot verify that the chemical will receive proper treatment from an activated sludge treatment process designed to nitrify*

Advocates for the ongoing and unrestrained use of NPE maintain that NPE can be used safely if these pollutants are subject to effective wastewater treatment at a well-managed plant. Petitioners do not agree. Regardless, it is clear that releases of NPE will very seriously affect the environment when they do not receive this type of sewage treatment. Therefore, EPA should prohibit the industrial, commercial and consumer use of NPEs where the NPEs that will be released are not likely to receive the necessary treatment. This restriction would apply to uses where the release will go to a plant that is not equipped to nitrify and uses where wastewater entering the sewer is not assured of receiving treatment.

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[59] 2006 R5 Powerpoint pp. 18-23.

Wastewater commonly does not receive treatment. In fact, EPA itself has documented that significant quantities of wastewater never receive treatment. In its report to Congress on combined and sanitary sewage overflows, EPA estimated that combined sewage overflows in 32 states and the District of Columbia discharge 850 billion gallons per year. In addition, EPA estimated that between 23,000 and 75,000 sanitary sewage overflow events occur per year in the United States, discharging a total volume of three to 10 billion gallons per year.[60] In addition to these scenarios, the proposed restriction would apply to the approximately 25 percent of U.S. households which rely upon septic systems, as research indicates that septic systems may not provide effective treatment.[61]

EPA should define a well-managed treatment plant as a treatment plant that:

- Is not the subject to a consent decree unless the consent decree has been fully implemented;
- Is not the subject of a notice of violation issued by an agency that has authority to implement the Clean Water Act; or
- Has not had the wastewater treatment plant operator license of its employee or contractor revoked.

Furthermore, the chemical is not receiving adequate treatment if one of the following applies:

- The treatment plant does not have treatment standards for ammonia based on tertiary treatment; or
- The treatment plant and associated collection system experiences more than five days of sewer overflows or treatment bypasses on average in the previous five years.

Putting the burden on the user to work with the municipality that manages the user's wastewater is a small burden since the parties should already be communicating and the municipal treatment plant should be able to easily ascertain its status.

3. Ban the use of the chemicals in industrial and consumer detergents

A ban on the use of NP and NPEs in industrial and consumer detergents is justified. In July 2003, the European Union passed directive 2003/53/EC, which restricts the marketing and use in Europe of products and product formulations that contain more than 0.1% of NPE or NP. These

[60] U.S. EPA, Report to Congress, Impacts and Control of CSOs and SSOs. August, 2004, at pp. ES 4-5.
[61] Swartz, Christopher H., *et.al.*, 2006. "Steroid Estrogens, Nonylphenol Ethoxylate Metabolites, and Other Wastewater Contaminants in Groundwater Affected by a Residential Septic System on Cape Cod, MA," Environ. Sci. Technol.,.40 (16), 4894-4902.

restrictions cover laundry products. As noted above, Procter & Gamble and Unilever have banned using NPEs in their products. A report written for Environment Canada explained that alcohol ethoxylates ("AE") are far safer than NPE for the environment and can be substituted for a wide range of detergent products:

> There are wide variety of different surfactants that can be used as substitutes for NPE, including a range of AE with varying technical properties, specialty surfactants for specialized applications, and various surfactant blends. These materials are available to Canadian end-users of surfactants through a number of domestic surfactant producers and various US-based producers via several chemical distributors.[62]

As a less toxic alternative is readily available and already in use by some manufacturers, EPA should ban the use of NP and NPEs in industrial and consumer detergents.[63]

4. Require pollution prevention planning by facilities that use 2000 kg or more of NP or NPEs

Canada requires facilities that use 2000 kg or more of NP or NPEs to develop formal pollution prevention plans.[64] EPA should follow this model and require similar planning. The plans would need to consider safer substitutes consistent with OPPT's SDSI project.

CONCLUSION

Petitioners applaud EPA's Safe Detergent Stewardship Initiative, but greater efforts must be taken to address harms from NPEs.

The Sierra Club, Environmental Law & Policy Center of the Midwest, the Pacific Coast Federation of Fishermen's Associations, Washington Toxics Coalition, Physicians for Social Responsibility and UNITE HERE request that EPA act in the manner described above to protect the environment from serious reproductive problems related to the use, treatment and disposal of nonylphenol and nonylphenol ethoxylates.

Petitioners look forward to EPA's response to this petition within 90 days, as required by TSCA, 15 U.S.C. § 2620(b)(3).[65]

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[62] Toxecology (2002) p. 4.
[63] Toxecology Environmental Consulting Ltd. (2002)
[64] Canada Gazette Vol 138, No. 49. December 2004.

Please address your response to this Petition to:

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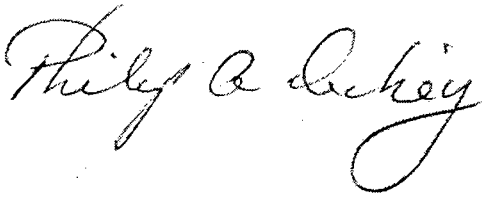
Chicago, Illinois 60601-2110

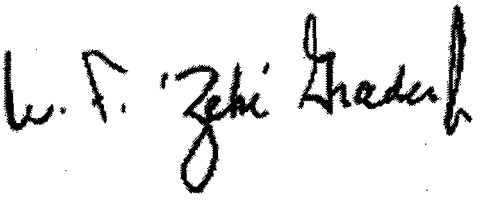
Sincerely,

Ed Hopkins
Tom Neltner
Sierra Club

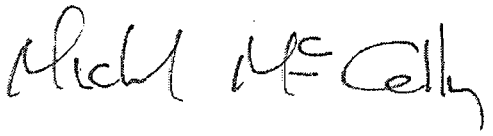
Albert Ettinger
Meleah Geertsma
Environmental Law & Policy Center



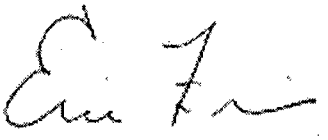
Philip Dickey
Washington Toxics Coalition



Zeke Grader
Pacific Coast Federation of Fisherman's Associations



Michael McCally
Physicians for Social Responsibility



Eric Frumin
UNITE HERE

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[65] 15 U.S.C.§ 2620(b)(3) (Toxic Substance Control Act, Section 21(b)(3)) (2006)