# APE RESEARCH COUNCIL

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Re: To Our Customers and Others Interested in the Safe Use of Nonylphenol (NP) and Nonylphenol Ethoxylates (NPEs)

Dear Valued Customer:

The Alkylphenols & Ethoxylates Research Council (APERC) is composed of manufacturers, processors, users and raw material suppliers of alkylphenols (APs), alkylphenol ethoxylates (APEs) and other derivatives. For the past 12 years, APERC and its predecessor organization, the Alkylphenols and Ethoxylates Panel of the Chemical Manufacturers Association, now the American Chemistry Council, have been conducting research studies and providing science-based information regarding the health and environmental safety of APs and derivatives. Recently, there has been heightened attention on nonylphenol (NP) and nonylphenol ethoxylates (NPEs) regarding a proposed regulatory classification in Canada[1] and restrictions on discharges to public sewers in the City of Toronto.[2] Consequently, we thought it might be worthwhile to review the scientific basis for these actions and the key information available on NP and NPEs.

NP is a highly effective intermediate that has been safely used for more than 50 years to produce high performance products such as surfactants, lube oil additives, stabilizers for rubbers and plastics, dispersants, emulsifiers, and plasticizers for resins. The largest use of NP is in the manufacture of NPEs.

NPEs are highly effective surfactants that have also been safely used for more than 50 years in a number of industrial sectors including textiles, pulp and paper, paints, adhesives, resins and protective coatings. NPEs are also used in a variety of cleaning products and detergents for home and institutional use.

Numerous scientific studies on the health and safety of NP and NPEs have been conducted, and new research, including major studies sponsored by APERC,[3] continues to be presented at scientific conferences and published in the scientific literature. Eleven key studies along with a summary of the findings, as well as list of nearly 200 additional peer-reviewed studies, were published in *The Alkylphenols & Alkylphenol Ethoxylates Review*.[4] Overviews of the science have recently been prepared by APERC[5] and the Soap and Detergent Association.[6]

The available scientific literature continues to support a number of important conclusions about the safe use of NP and NPEs:

1) **NP and NPEs are effectively removed from wastewater in well functioning sewage treatment plants.**[7] This is important because many of the products made with these materials are used in "down-the drain" applications. Sewage treatment reduces levels of these and other substances so that the residual levels present in treated wastewater discharged to rivers, lakes or the oceans are harmless.[8,9]

2) **NP and NPEs are biodegradable.** Field studies and laboratory tests show that they can extensively breakdown in the environment anywhere air or oxygen is present.[10] This is particularly true for sewage treatment plants where removal of NPEs due to biodegradation approaches 100%.[7] It also means that the low, residual levels of NP and NPEs in rivers, lakes and oceans receiving treated wastewater will continue to biodegrade.

3) **Environmental monitoring in Canada and the US shows that levels of NP and NPEs in rivers and lakes are low and pose little risk to fish or other aquatic life.** Levels of NP, NPEs and NPE biodegradation intermediates are generally not detected in rivers or lakes in Canada or the US even using sensitive analytical measurement techniques.[11] Where detected, they are below the levels that would harm fish or other aquatic life, or cause estrogen-like effects;[12] exceptions are noted, as might be expected, where untreated or partially treated wastewater is discharged.[13]

4) **NP and NPEs do not build up in the food chain.** Fish and other aquatic organisms rapidly metabolize and excrete these materials so that they do not build up in the food-chain (*i.e.*, as small aquatic organisms are eaten by fish, small fish are eaten by larger fish, etc).[14]

5) **Residual levels of NP and NPEs in biosolids used as fertilizers continue to biodegrade and pose little risk to the soil.** In well functioning sewage treatment plants, a small fraction of the NP and NPEs in the sewage is removed in the biosolids (sewage sludge).[15] Biosolids from treatment plants may be applied to farmland as a fertilizer, put into landfills or incinerated. NP and NPEs in soil have been shown to undergo rapid and extensive biodegradation.[16] Because of this biodegradation, the levels of NP remaining in soil as a result of biosolids application are below the level that would pose a risk to typical soil organisms such as earthworms.[17] Laboratory experiments indicate that NP and NPEs in biosolids amended soil do not leach into lower soil layers towards groundwater.[18] Uptake of NP by crop plants from biosolids applied to soil is unlikely because of the rapid biodegradation of NP and NPEs in soil and the typical fallow period between application of biosolids and planting.[19]

6) **While NP has shown weak hormone-like (estrogenic) characteristics in laboratory experiments, there is no significant risk to human health or the environment.[20]** Tests with laboratory animals demonstrate that NP has weak estrogen-like activity[21] but commercial NPEs do not.[22] Moreover, NP demonstrates this activity only at very high exposure (dose) levels. Maximal estimates of human exposure from normal use of products containing NP are thousands of times lower than the very high doses required to produce hormonal effects.[23] Consequently, use of products made from NP does not pose an estrogenic health risk to humans.

7) **Use of NP and NPEs does not pose a significant risk to human health.** Human exposure to NP and NPEs from the use of products containing these materials, or from indirect environmental exposures is low and considerably below levels that would pose a risk to human health.[24]

Regulatory Activities - Canada

Environment Canada and Health Canada recently completed the public comment period on a draft Priority Substance List (PSL) assessment report on NP and NPEs.[1] A summary of the comments is being compiled and will be posted to the Priority Substance Assessment Program web site (http://www.ec.gc.ca/cceb1/ese/eng/psap.htm). The report will then be finalized and published, likely by the end of 2000.

As expected, the assessment report concludes (pages 10-11):

> *Based on the information available, it is proposed that nonylphenol and its ethoxylates are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger to the environment on which life depends.*
>
> *On the basis of consideration of the margin of exposure between effect levels and reasonable worst-case estimates of intake by the general population from environmental media, NP and NPEs are not considered a priority for investigation of options to reduce human exposure through control of sources that are addressed under CEPA.*

However, the report has generated some concern because it proposes to classify NP and NPEs as "toxic" under the Canadian Environmental Protection Act. This proposed classification is based on observations that some levels of NP and NPEs in effluents of certain textile mills, pulp and paper mills and municipal wastewater treatment plants may exceed levels of concern for these materials. If this classification is retained in the final report, efforts will likely be initiated to reduce emissions from those facilities responsible for the releases.

It seems clear from the findings of the draft report that the focus of any pollution prevention activities should be on minimizing discharges, where possible, and ensuring that all discharges are properly treated.

Recently, APERC initiated an NPE Environmental Management Program.[25] The purpose of the program is to work in partnership with formulators, users and regulators to identify or develop practical methods of reducing environmental exposures as proposed in the PSL assessment report, and meeting proposed water quality guidelines under consideration by the US Environmental Protection Agency. The methods proposed will focus on widely accepted product stewardship practices and up-to-date means for controlling releases. For further details regarding this assistance, please contact APERC using the contact information provided below.

Toronto

In a quite different type of regulatory activity, the City of Toronto has recently passed restrictions on disposal to public sewers of 29 organic substances.[2] The discharge limits on NP, NPEs and other commercially important organic substances are so restrictive as to prevent the use of numerous consumer, institutional and industrial products containing these ingredients.[26] These restrictions are not based on a safety assessment (no assessment was conducted) or any finding of harm to human health or the environment.[27] Consequently, there will be considerable costs imposed by the sewer restrictions[28] without demonstration of any environmental benefit. This is the unfortunate result when environmental regulations are not based on science.

## Concluding Remarks

We hope this review of the scientific and regulatory issues has been useful in addressing your concerns regarding the safety of NP and NPEs that may have been raised by the recent Environment Canada assessment and the City of Toronto action.

If you would like further information on any of the studies discussed in this letter, please contact APERC (1250 Connecticut Avenue, NW, Suite 700, Washington, DC 20036, phone: 202-637-9071, fax: 202-637-9178, e-mail: info@aperc.org) or visit the APERC web site at www.aperc.org. You can also register on the site, to receive future updates.

Sincerely,

*James Harton* *Robert J. Fensterheim*

James Harton
Chair

Robert J. Fensterheim
Executive Director

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[1] A draft PSL assessment report, Nonylphenol and Its Ethoxylates, has been jointly prepared by Environment Canada and Health Canada. A synopsis of the report and an update on its status may be found on the Internet at www.ec.gc.ca/cceb1/eng/public/npe_e.html. APERC comments on the draft PSL2 assessment report can be found on the APERC web site at www.aperc.org.

[2] Information about the sewer-use bylaw may be found at www.city.toronto.on.ca/council/highlight_index.htm or on the APERC web site at www.aperc.org.

[3] C.A. Staples, "A comparison of aquatic risk assessment methodologies – nonylphenol as a test case," platform presentation 6E/002, *Abstracts, Third SETAC World Congress, Brighton, United Kingdom, 21-25 May 2000*, Society of Environmental Toxicology and Chemistry – Europe, Brussels, page 68; C.G. Naylor *et al*., "Comparison of nonylphenol ethoxylates treatability in waste water treatment plants and septic systems," poster 5L/p011, ibid., page 272; B.E. Huntsman *et al*., "Measuring the treatability of nonylphenol ethoxylates in household septic systems," poster 5L/p015, ibid., page 273; C.A. Staple *et al*., "Biodegradation of nonylphenol ethoxylate surfactant in the environment," poster 5L/p023, ibid., page 275; C.G. Naylor *et al*., "Fate of nonylphenol ethoxylate in household septic systems," *Proceedings, CESIO 5th World Surfactants Congress, May 29 – June 2, 2000, Firenze*, FEDERCHIMICA Assobase – P.I.T.I.O., Milan, pages 1645-53.

[4] Volume 1, issue 1 is available at no charge from the APE Research Council, 1250 Connecticut Avenue, NW, Suite 700, Washington, DC 20036, phone: 202-637-9071, fax: 202-637-9178, e-mail: info@aperc.org.

[5] "Alkylphenols and Alkylphenol Ethoxylates, An Overview of Safety Issues," APE Research Council, Washington, DC, January 1999, 12 pages.

[6] "Alkylphenol Ethoxylate," The Soap and Detergent Association, Washington, DC, 1999, 14 pages.

[7] This has been demonstrated in studies in the U.S. of biological (activated sludge) plants treating industrial wastewater and domestic sewage (C.G. Naylor, "Environmental Fate and Safety of Nonylphenol Ethoxylates," *Textile Chemists and Colorists*, volume 27, pages 29-33, 1995; C.G. Naylor, "The Dirt on Detergents," *Industrial Wastewater*, September/October, 1996). Removal efficiencies for NP + NPE(1-17) in treated wastewater (effluent) ranged from 92.5 to 99.8%. Effluent levels of NP ranged from less than 1 to 15 micrograms per liter and for NPE(1-17) from less than 5 to 261 micrograms per liter.

Similar effluent levels have been observed in Canadian biological treatment (activated sludge) plants implying similar removal efficiencies in these treatment plants (data from Figures 3 and 4 of the Priority Substance List Assessment Report, Nonylphenol and Its Ethoxylates, Draft for Public Comment, Environmental Canada, Health Canada, March 2000, pages 27-8). (NP levels ranged from less than 1 to about 4 micrograms per liter, NPE1 and NPE2 levels each ranged from less than 1 to about 10 micrograms per liter, and NP1EC and NP2EC levels ranged from 1 to about 46 micrograms per liter and NPE(3-17) levels of about 5 micrograms per liter.) Note that the effluent from a treatment plant not using biological treatment (Windsor, primary treatment, solids settling and

removal only) had higher levels of NP, NPE1 and NPE2 than the four plants using biological (secondary or tertiary) treatment.
Studies of overloaded (and hence poorly functioning) biological treatment plants in Switzerland have demonstrated lower removals in a monitoring study of sewage treatment plants in the United Kingdom, 4 of 16 plants had NP levels in treated wastewater (effluent) greater than 1 microgram per liter. (M. Ahel *et al*., "Nonylphenolic chemicals revisited in Switzerland: Monitoring waste water effluents and ambient waters before and after risk reduction measures," American Chemical Society Annual Meeting, Boston, MA, August 1998; M. Ahel *et al*., "Behavior of alkylphenol polyethoxylate surfactants in the aquatic environment – I. Occurrence and transformation in sewage treatment," *Water Research*, vol. 28, pages 1131-1142, 1994); (M.A. Blackburn and M.J. Waldock, "Concentrations of alkylphenols in rivers and estuaries in England and Wales," *Water Research*, vol. 29, pages 1623-9, 1995) The plant with the highest NP level (Marley on the River Aire, 330 micrograms extractable NP per liter) uses the less efficient trickling filter biological treatment process (M.S. Holt *et al*., "Monitoring studies in the UK designed for the validation of the geo-referenced exposure assessment tool for European rivers (GREAT-ER)," in *Proceeding, CESIO 5th World Surfactants Congress, May 29 – June 2, 2000, Firenze,* FEDERCHIMICA Assobase – P.I.T.I.O., Milan, pages 1358-69, 2000) and receives industrial wastewater from textile plants (Blackburn and Waldock, op. cit.). The plant with the second highest NP level (Southend on the Thames Estuary, 6.7 micrograms extractable NP per liter) does not use biological treatment and the wastewater is discharged after only primary treatment. The other two plants having NP levels greater than 1 microgram per liter (Horsham on the River Arun, 2.9 micrograms extractable NP per liter, and Tilbury on the Thames Estuary, 1.4 micrograms dissolved NP per liter) use biological treatment process, as did the other 12 plants showing NP levels less than 1 microgram per liter, but the type of biological treatment is not reported by Blackburn and Waldock.

[8] There are many studies available reporting effect levels for short term (acute) or long term (chronic) exposure of fish and other aquatic organisms to NP, but fewer studies on NPEs and the major NPE biodegradation intermediates (NPE1, NPE2, NP1EC and NP2EC) (C.A. Staples *et al*., "Evaluation of aquatic toxicity and bioaccumulation of C8- and C9-alkylphenol ethoxylates," *Environmental Toxicology and Chemistry*, vol. 17, pages 2470-80, 1998; M.R. Servos, "Review of the aquatic toxicity, estrogenic responses and bioaccumulation of alkylphenols and alkylphenol polyethoxylates," *Water Quality Research Journal of Canada*, vol. 34, pages 123-177, 1999).
For NP, safe or predicted no effect concentrations (PNEC) related to chronic exposures can be estimated from the lowest no observed effect concentration (NOEC) in chronic exposure studies. The lowest NOEC for NP in aquatic organisms is 3.9 micrograms per liter. The lowest NOEC for NP in sediment organisms is 20 micrograms per gram. The corresponding NOEC for NPE9, representing NPE(3-17), is 1000 micrograms per liter for aquatic organisms. In the most conservative approach, this NOEC is divided by a 10-fold uncertainty factor to give a PNEC of 0.39 micrograms per liter in water and 2 micrograms per gram in sediment for NP and 100 micrograms per liter for NPE9. An alternate approach takes into consideration the extensive amount of data available on NP to estimate a PNEC that is protective of the entire fresh water environment. Using such an approach and US EPA procedures for setting ambient water quality criteria (AWQC), a PNEC of 9.1 micrograms per liter of NP was calculated (since revised to 5.9 ug/L based on the incorporation of additional information). (C.A. Staples *et al*., "An environmental risk assessment of the biodegradation intermediates of nonylphenol ethoxylates," *Proceedings of the 4$^{th}$ World Conference on Detergents: Strategies for the 21$^{st}$ Century*, A. Cahn, ed., AOCS Press, Champaign, Illinois, pages 298-303, 1998). Using European Union Technical Guidance Document procedures, a PNEC of 2.8 micrograms per liter of NP was calculated in this same study.
Environment Canada has combined both approaches to calculate a NOEC of 10 micrograms per liter for NP (similar to the AWQC value) that is protective of 95% of aquatic organisms and divided this value by a 10-fold uncertainty factor to derive a PNEC for NP of 1 microgram per liter (Priority Substance List Assessment Report, Nonylphenol and Its Ethoxylates, Draft for Public Comment, Environmental Canada, Health Canada, March 2000, pages 54-58). Comparing the available toxicity data on NPEs and NPE biodegradation intermediates with that for NP, Environment Canada has estimated a PNEC value for NPE1 and NPE2 of 2 micrograms per liter each and a PNEC value of 200 micrograms per liter each for NPE9 [NPE(3-17)], NP1EC, and NP2EC (ibid, pages 59-63).
For sediments, Environment Canada used the lowest NOEC value for NP divided by a 10-fold uncertainty factor, *i.e*. a PNEC of 2 micrograms per gram. Comparing the available aquatic toxicity data on NPE1 and NPE2 with that for NP, Environment Canada has estimated a PNEC value for NPE1 and NPE2 of 4 micrograms per gram liter (ibid, page 67).

[9] Potentially harmful substances in untreated sewage include disease-causing microorganisms, ammonia and total biodegradable materials (biochemical oxygen demand or BOD). Ammonia is harmful to fish or other aquatic organisms at free (un-ionized) ammonia concentrations of 10 to 50 micrograms per liter or higher (P.H. Masscheleyn *et al*., "Linear alkylbenzene sulfonate (LAS) environmental properties & risk characterization in the Philippines," Technical Symposium on Surfactants, Manila, the Philippines, September 30, 1999). BOD is harmful at concentrations of 5-10 milligrams per liter or higher because it reduces dissolved oxygen levels that fish and other aquatic organisms depend on to live (Masscheleyn *et al*., op. cit.). Note that BOD includes all biodegradable

materials including alternatives to NP and NPEs. Consequently, substitution for NP or NPEs does not necessarily reduce BOD.

[10] S.S. Talmage, *Environmental and Human Safety of Major Surfactants: Alcohol Ethoxylates and Alkylphenol Ethoxylates*, The Soap and Detergent Association, Lewis Publishers, Boca Raton, Florida, 1994; R. Ekuland *et al*., "Biodegradation of 4-nonylphenol in seawater and Sediment," *Environmental Pollution*, vol. 79, pages 59-61, 1996; C.A. Staples *et al*., "Measuring the biodegradability of nonylphenol ether carboxylates, octylphenol ether carboxylates and nonylphenol," *Chemosphere*, vol. 38, pages 2029-2039, 1999; R.J. Maguire, "Review of the persistence of nonylphenol and nonylphenol ethoxylates in aquatic environments," *Water Quality Research Journal of Canada*, vol. 34, pages 37-78, 1999; Priority Substance List Assessment Report, Nonylphenol and Its Ethoxylates, Draft for Public Comment, Environmental Canada, Health Canada, March 2000, pages 23-29; C.G. Naylor *et al*., "Biodegradation of nonylphenol ethoxylate, I. Synthesis and characterization of $^{14}$C ring-labeled nonylphenol and ethoxylate, II. $^{14}$C ring-labeled nonylphenol ethoxylate in semicontinuous activated sludge, III. $^{14}$C ring-labeled nonylphenol ethoxylate in river water, submitted for publication.

[11] In the thirty-rivers study, NP levels in river water ranged from less than 0.1 to 0.64 micrograms per liter, with 70% of the samples below the method detection limit (MDL); for NPE1, from less than 0.06 to 0.6 micrograms per liter with 67% below the MDL; for NPE2, from less than 0.07 to 1.2 micrograms per liter with 58% below the MDL; and for NPE(3-17), from less than 1.6 to 14.9 micrograms per liter with 76% below the MDL (C.G. Naylor *et al*., "Alkylphenol ethoxylates in the environment," *Journal of the American Oil Chemists Society*, vol. 69, pages 695-703, 1992). In river sediments, NP levels ranged from less than 0.003 to 2.96 micrograms per gram with 28% below the MDL; and for NPE1, from less than 0.003 to 0.175 micrograms per gram with 44% below the MDL.
In a study of the Fox River (Wisconsin), which receives effluent from 15 paper mills and 6 publicly-owned treatment works, NP levels in river water ranged from 0.1 to 0.64 micrograms per liter; for NPE1, from 0.04 to 0.9 micrograms per liter; and for NPE(2-17), from 1.1 to 7.3 micrograms per liter (C.G. Naylor *et al*., "Nonylphenol ethoxylates in an industrial river," *Proceedings, 4th World Surfactants Congress, Barcelona, 3-7 VI 1996*, CED, Barcelona, vol. 4, pages 378-391, 1996). In Fox river sediments, NP levels ranged from less than 0.056 to 1.04 micrograms per gram with 18% below the MDL; and for NPE1, from less than 0.014 to 0.215 micrograms per gram with 9% below the MDL. Sediments from the Grand Calumet river near Gary, Indiana, a superfund site, had NP levels of 6.9 micrograms per gram and NPE1 levels of 0.8 micrograms per gram.
In a study of 8 U.S. rivers, including the Fox and 7 other rivers surveyed in the thirty-rivers study, NP1EC levels in river water ranged from less than 0.04 to 2 micrograms per liter with 60% of the samples below the MDL; and for NP2EC levels from less than 0.2 to 11.8 micrograms per liter with 50% of the samples below the MDL (J.A. Field and R.L. Reed, "Nonylphenol polyethoxy carboxylate metabolites of nonionic surfactants in U.S. paper mill effluents, municipal sewage treatment plant effluents and river water," *Environmental Science and Technology*, volume 30, pages 3544-3550, 1996).
In a study of the Great Lakes basin and the upper St. Lawrence River near municipal sewage treatment plant discharges, pulp mill discharges, large population centers and regions of heavy industry, NP levels in water ranged from less than 0.01 to 0.92 micrograms per liter with 76% below the MDL; for NPE1, from less than 0.02 to 5.1 micrograms per liter with 42% below the MDL; and for NPE2, from less than 0.02 to 10 micrograms per liter, with 68% below the MDL (D.T. Bennie *et al*., "Occurrence of alkylphenols and alkylphenol mono- and diethoxylates in natural waters of the Laurentian Great Lakes basin and the Upper St. Lawrence River," *The Science of the Total Environment*, vol. 193, pages 263-275, 1997). In sediments, NP levels ranged from 0.17 to 72 micrograms per gram; for NPE1, from less than 0.015 to 38 micrograms per gram with 33% of the samples below the MDL; and for NPE2, from less than 0.015 to 6 micrograms per gram with 33% of the samples below the MDL.
Based on the Bennie *et al*. study and additional unpublished data, Environment Canada reports that NP levels in Canadian river, lake and freshwater harbors ranged from less than 0.02 to 4.25 micrograms per liter in 126 samples from 42 sites, NPE1 levels ranged from less than 0.02 to 10.3 micrograms per liter and NPE2 levels from less than 0.02 to 10.4 micrograms per liter in 81 samples from 28 sites, NPE(3-17) levels ranged from 0.11 to 17.6 micrograms per liter in 27 samples from 3 river sites, and NP1EC levels ranged from 0.44 to 3.17 micrograms per liter and NP2EC levels from 0.81 to 4.3 micrograms per liter in 37 samples from a river site (Priority Substance List Assessment Report, Nonylphenol and Its Ethoxylates, Draft for Public Comment, Environmental Canada, Health Canada, March 2000, page 31). In Canadian sediments, NP levels ranged from less than 0.02 to 72.2 micrograms per gram in 58 samples from 23 sites, NPE1 levels ranged from less than 0.02 to 38.1 micrograms per gram and NPE2 levels ranged from less than 0.02 to 6.0 micrograms per gram in 14 samples from 6 sites, and NPE(3-17) levels ranged from less than 0.02 to 0.17 micrograms per gram in 4 samples from one site.

[12] Estrogen-like effects of NP and NPE biodegradation intermediates have reported to occur in aquatic organisms at similar concentrations to those at which chronic effects are reported (Priority Substance List Assessment Report, Nonylphenol and Its Ethoxylates, Draft for Public Comment, Environmental Canada, Health Canada, March 2000, pages 64-7). Consequently, Environment Canada uses the same PNEC for NP (1 microgram per liter) for estrogenic effects as for protecting the aquatic environment from effects of long term exposure to NP. However, there is considerable uncertainty in the literature regarding the relative estrogenic potency of NPEs and NPE biodegradation

intermediates relative to NP. As discussed in the Environment Canada report, this uncertainty confounds the interpretation of environmental levels of these materials. The APE Research Council is conducting research on an urgent basis with a Canadian expert to resolve the uncertainty and allow a more reliable safety assessment for these materials to be conducted.

[13] Comparing measured environmental concentrations in note 12 with NOEC/PNEC values in note 8 reveals that:

1) In the thirty rivers (US) study, all NP and NPE levels are lower than the lowest NOECs for aquatic and sediment organisms and, exc ept for a single NP value in sediment, below the PNECs proposed by Environment Canada;
2) In the Fox River (US) study, all NP and NPE levels are lower than the lowest NOECs for aquatic and sediment organisms and below the PNECs proposed by Environment Canada;
3) In the Grand Calumet River (US) superfund site, NP sediment levels are lower than the lowest NOEC for sediment organisms but above the PNEC proposed by Environment Canada;
4) In the 8 U.S. rivers study, all NPEC levels are lower than the PNECs proposed by Environment Canada;
5) In the Great Lakes and St. Lawrence River (Canada) study, all NP levels in water are lower than the PNEC but 3 of 38 NPE1 levels and 1 of 38 NPE2 levels are above the PNEC; in sediments, 3 of 9 NP levels are above the PNEC while 1 of 9 NPE1 and 1of 9 NPE2 levels are above the PNEC;
6) In the study of Canadian rivers, lakes and freshwater harbors, NP levels in water at 1 of 42 sites exceeded the PNEC; for NPE1 4 of 28 sites exceeded the PNEC; for NPE2, 1 of 28 sites exceeded the PNEC; for NPE9, 0 of 3 exceeded the PNEC; for NP1EC and NP2EC, the one site tested did not exceed the PNEC (Priority Substance List Assessment Report, Nonylphenol and Its Ethoxylates, Draft for Public Comment, Environmental Canada, Health Canada, March 2000, Table 12, page 124); and
7) In this same study in sediments, NP levels in 5 of 58 samples from 24 sites exceeded the PNEC and for NPE1 and NPE2, 1 of 14 samples from 6 sites exceeded the PNEC (Ibid., Table 11, pages 122-3).

[14] C.A. Staples *et al*., "Evaluation of aquatic toxicity and bioaccumulation of C8- and C9-alkylphenol ethoxylates," *Environmental Toxicology and Chemistry*, vol. 17, pages 2470-80, 1998; M.R. Servos, "Review of the aquatic toxicity, estrogenic responses and bioaccumulation of alkylphenols and alkylphenol polyethoxylates," *Water Quality Research Journal of Canada*, vol. 34, pages 123-177, 1999; Priority Substance List Assessment Report, Nonylphenol and Its Ethoxylates, Draft for Public Comment, Environmental Canada, Health Canada, March 2000, page 43.

[15] 0.1 to 1.7% of the influent NP + NPEs was found in the digested sludge of two U.S. treatment plants (C.G. Naylor, "Environmental Fate and Safety of Nonylphenol Ethoxylates," *Textile Chemists and Colorists*, volume 27, pages 29-33, 1995). However, residual levels in sludge may be appreciable, typically a few hundred micrograms per gram and possibly as high as 1000 micrograms per gram, and consisting primarily of NP (Priority Substance List Assessment Report, Nonylphenol and Its Ethoxylates, Draft for Public Comment, Environmental Canada, Health Canada, March 2000, pages 26-28).

[16] 57% mineralization of NPE9 (240 microgram NPE per gram soil) was observed after 64 days of incubation at 72 F; the aromatic ring of NPE was not detected by HPLC after 63 days confirming extensive biodegradation (ring opening) had occurred (A.J. Hughes *et al*., "Biodegradation of NPE in soil," *Proceedings, 4th World Surfactants Congress, Barcelona, 3-7 VI 1996*, CED, Barcelona, volume 4, pages 364-372, 1996).
Priority Substance List Assessment Report, Nonylphenol and Its Ethoxylates, Draft for Public Comment, Environmental Canada, Health Canada, March 2000, page 29:
*Studies on the persistence of NP in soils indicate that NP can be rapidly degraded to carbon dioxide by soil microorganisms (Topp, 1999). NP at concentrations as high as 250 mg/kg was rapidly mineralized by soil organisms in cultivated agricultural soils at 4 C, temperate, non-cultivated soils and arctic soils. The lack of a lag phase in the mineralization indicated that the soil contained active microflora, conditioned to mineralize other natural phenols in soils. A study conducted at the Guelph Turfgrass Instittue by Bennie et al (1998) demonstrated a rapid disappearance of initial concentrations of 5.5 mg NP/kg soil in sludge treated soil plots. NP concentrations were undetectable after 90 days.*
E. Topp and A. Starratt, "Rapid mineralization of the endocrine-disrupting chemical 4–nonylphenol in soil," *Environmental toxicology and Chemistry*, vol. 19, pages 313-8, 2000.

[17] Soil eco-toxicity data is available only for NP. The lowest NOEC for NP is from a 1996 Danish report (Krogh *et al*.) of a 10% effect concentration ($EC_{10}$) of 3.4 micrograms NP per gram soil (Priority Substance List Assessment Report, Nonylphenol and Its Ethoxylates, Draft for Public Comment, Environmental Canada, Health Canada, March 2000, page 41). A higher $EC_{10}$ value, 48.7 micrograms NP per gram soil for another soil invertebrate (springtails, *Folsomia fimetaria*), was reported in a later presentation by the same authors (J. Jensen and P.H. Krogh, "Ecotoxicological assessment of sewage sludge application," presentation, Specialty Conference, Management and Fate of Toxic Organics in sludge Applied to Land," Copenhagen, Denmark, April 30 – May2, 1997). In a conservative approach, Environment Canada divided the lowest NOEC by a 10-fold uncertainty factor to give a PNEC of 0.34 micrograms NP per gram soil (Priority Substance List Assessment Report, pages 68-69).

Based on Canadian monitoring studies, NP levels in biosolids range from 0.74 to 1260 micrograms per gram (Ibid., Table 5, page 111). Based on application of the maximal amount of sludge to soil recommended (8 tons per hectare over a five year period), plowing to a depth of 15 centimeters and the density of soil, initial NP concentrations in soil can be calculated to range from 0.0003 to 5.04 micrograms per gram soil (Ibid., pages 68-9). Based on this data, 18 of 30 of the sludges are predicted to give initial NP concentrations in soil greater than the PNEC. However, "the predicted concentrations in soil are higher than the ENEV [PNEC] by less than a factor of 2 and are rarely in exceedance by a factor of 10."

Since the NOEC is 10-fold higher than the PNEC, these initial NP values rarely exceed the NOEC for earthworms or springtails. Since the NOEC values are based on long term exposure (21 days in the earthworm test) and NP rapidly and extensively degrades in soil (none detectable after 30 to 90 days, see note 16 above), it is highly unlikely that NP levels exceed the PNEC for any extended periods. This has been confirmed by field experiments in Denmark "which showed no negative effects of sewage sludge [containing either 35 or 140 micrograms NP per gram] on soil microorganisms or fauna up to one year after application [of 3.5, 7 or 21 tons dry matter per hectare]" (Jensen and Krogh, op. cit.).

[18] In this study, two different sewage sludges were amended on typical Brandenburg (Germany) sandy soils; the sludges contained either 28 milligrams NPE and 23 milligrams NP per kilogram or 428 milligrams NPE and 93 milligrams NP per kilogram (M. Kujawa *et al*., "Occurrence of organic pollutants in sewage sludge and influence of surfactants on their mobility in amended soils," presentation, Specialty Conference, Management and Fate of Toxic Organics in sludge Applied to Land," Copenhagen, Denmark, April 30 – May2, 1997). With both sludges NPE was not detectable after 14-18 days and NP was not detected after about 30 days. NP and NPE were detected only in the initial 0-10 centimeters of soil and not in the 10-20 or 20-30 centimeter depths.

[19] Priority Substance List Assessment Report, Nonylphenol and Its Ethoxylates, Draft for Public Comment, Environmental Canada, Health Canada, March 2000, pages 41,42 and 69:

*The uptake of NP from soil was slow, and NP was quickly mineralized by soil microorganisms.*

*NP accumulation in several species of plants was minimal, and NP was metabolized to hydroxylated and conjugated derivatives.*

*NP is not expected to persist in soils for extended periods of time (<90 days) and sludge applications are normally followed by a period of fallow.*

[20] The environmental safety of NP, including estrogenic effects, is discussed under point number 3 in the text.

[21] J. Odum *et al*., "The rodent uterotrophic assay: Critical protocol features, studies with nonylphenols, and comparison with a yeast estrogenicity assay," *Regulatory Toxicology and Pharmacology*, vol. 25, pages 176-88, 1997; Priority Substance List Assessment Report, Nonylphenol and Its Ethoxylates, Draft for Public Comment, Environmental Canada, Health Canada, March 2000, page 45.

[22] D.R. Cerven, "Uterine weight assay of p-nonylphenol (NP) and p-octylphenol ethoxylate-5 (OPE-5) administered orally to ovariectomized Sprague-Dawley rats," Amended Report, MB Research Labs, Spinnerstown, Pennsylvania, May 30, 1997, available from the APE Research Council, Washington, DC; J. Williams, A.M. Brady, R.W. Lewis and L. Hughes, "Assessment of alkyl phenol derivatives for estrogenic activity in a rat uterotrophic model," *Proceedings, 4th World Surfactants Congress, Barcelona, 3-7 VI 1996*, CED, Barcelona, volume 3, pages 34-41, 1996.

[23] S. Muller *et al*., "Evaluation of the estrogenic potency of nonylphenol in non-occupationally exposed humans," *Environmental Toxicology and Pharmacology*, vol. 6, pages 27-33, 1998:

*The results of this study show that the non-occupational exposure to NP does not pose an estrogenic health risk to humans.*

[24] Priority Substance List Assessment Report, Nonylphenol and Its Ethoxylates, Draft for Public Comment, Environmental Canada, Health Canada, March 2000, page 10:

*The estimated worst-case intake of NP/NPEs in food, the likely principal medium of exposure, is considerably less than the lowest effect level identified, for histopathological effects on the kidneys of male rats exposed to NP in the diet over three generations…The margin between this effect and estimated dermal intakes from some consumer products is relatively small; however, this comparison is based on the assumption that the NP/NPEs are absorbed through the skin to the same extent as via the gastrointestinal tract, whereas available data, although inadequate, indicate that dermal absorption is likely lower.*

The APE Research Council is providing new research that confirms substantially lower dermal absorption.

[25] "NPE Environmental Management Program," Media Advisory, APE Research Council, Washington, DC, March 2000, 2 pages.

[26] Letter to the Honorable Mel Lastman, Mayor of the City of Toronto, Canada, from Robert J. Fensterheim, Executive Director of the APE Research Council, Washington, DC, May 30, 2000, 2 pages. The final discharge limits approved by the Toronto City Council were 0.001 mg/L for nonylphenol and 0.01 mg/L for NPEs (See note 2 above).

[27] Municipal wastewater treatment plants in Canada or the U.S. using secondary or tertiary treatment are generally quite effective in removing nonylphenol and NPEs to levels that are not harmful to aquatic organisms. See the draft

PSL assessment report Nonylphenol and Its Ethoxylates referenced above, pages 56-67 and C.G. Naylor, 1995, also referenced above.

[28] Costs of the regulation include, for all Toronto businesses with ten or more employees, preparation of a pollution prevention plan and verification, by analytical chemistry testing, of compliance with the discharge limits. These costs are in addition to business costs to identify alternative or replacement products for the many consumer, institutional and industrial products using nonylphenol, NPEs and the other substances regulated and the cost to manufacturers and suppliers through Canada and beyond to reformulate or supply alternative products for customers in Toronto.