Comments on the Design for the Environment (DfE) Program Alternatives Assessment Criteria for Nonylphenol Ethoxylates

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Alkylphenols & Ethoxylates Research Council
Comments on
EPA Design for Environment Program
Alternatives Assessment for Nonylphenol Ethoxylate Surfactants
(September 26, 2011)

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For more than twenty years the Alkylphenols & Ethoxylates Research Council (APERC) and its member companies have been actively engaged in toxicological, environmental fate and ecotoxicity research on nonylphenol (NP), nonylphenol ethoxylates (NPE), octylphenol (OP) and octylphenol ethoxylates (OPE) as well as other alkylphenols and derivative compounds.[1] Consequently, APERC can contribute considerable information and expertise on the uses, toxicological data and risk assessments available for these compounds. Since NPEs and their environmental degradation intermediates have not been shown to present a risk to either human health or the environment, APERC questions both the need and basis for the recently released EPA Design for Environment (DfE) Alternatives Assessment for Nonylphenol Ethoxylate (NPE) surfactants. [2]

The NPE Alternatives Assessment was an outgrowth of the Agency's "action plan" for NPE, which APERC has previously stated is lacking in scientific rigor and includes oversights, inaccuracies and inconsistencies in the characterization of the hazards of NP and NPE.[3] In APERC's view, EPA's characterization of NPE and NP as "compounds of concern" in the NP/NPE action plan and in the NPE Alternatives Assessment is not justified. Therefore, the need to conduct an alternatives assessment on NPE is questionable, particularly since governmental assessments have not found human safety to be a concern. [4] [5] [6] In addition, a peer-reviewed assessment of the environmental

[1] Current members of the Alkylphenols & Ethoxylates Research Council include: Dover Chemical Corporation; SI Group; TPC Group; and The Dow Chemical Company.
[2] U.S. Environmental Protection Agency Design for Environment Program (U.S. EPA, DfE). (2011a, September 26). DfE Alternatives Assessment for NPE.
[3] Alkylphenols & Ethoxylates Research Council (2011, October 31). Comments on U.S. EPA Action Plan for Nonylphenol (NP) and Nonylphenol Ethoxylates (NPEs) (August 18, 2010, RIN 2070-ZA09)Docket No. EPA-HQ-OPPT-2010-0571-0001. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2010-0571-0040
[4] Environment Canada and Health Canada (EC and HC). (2001). Priority substances list assessment report for nonylphenol and its ethoxylates. ISBN: 0-662-29248-0. http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/psl2-lsp2/nonylphenol/index-eng.php.
[5] European Chemicals Bureau (ECB). (2002). European Union Risk Assessment Report: 4-nonylphenol (branched) and nonylphenol: Final report. http://ecb.jrc.it/DOCUMENTS/Existing-

occurrence of NPE and its biodegradation intermediates in U.S. surface waters found that the likelihood that these compounds will exceed the U.S. EPA ambient Water Quality Criteria (WQC) for NP is low, even when considered in aggregate.[7]

Assuming the NPE Alternatives Assessment moves forward, it should be noted that the criteria focus on biodegradation and acute toxicity of the parent surfactant compounds and are therefore inadequate to ensure a lesser hazard to human health and the environment since the human safety of the parent surfactants are not considered and the hazards of the degradation products of the alternative surfactants are not addressed. The criteria also rely on DfE criteria for "Safer Surfactants" that have not been sufficiently subject to public.[8] In addition, DfE circumvented its own process for stakeholder engagement[9]; included data sources that are not sufficiently transparent; and relied on selected data sources that are dated while ignoring many newer more reliable studies.

The following comments address APERC's concerns in more detail.

1.0 Hazard-based assessments are inadequate to determine the safety of NPEs or any alternative surfactants and are inconsistent with EPA's statutory responsibility to consider risk under the Toxic Substances Control Act (TSCA); consideration of use patterns, exposure and risk related to specific products, applications and/or uses must be incorporated in the assessment to achieve the DfE goal of provide a basis for informed decision-making to choose safer chemicals.

1.1 Hazard assessment is not a measure of safety and incorrectly assumes drop-in replacement with alternatives; additional factors must be considered as a basis for choosing safer surfactants.

The NPE Alternatives Assessment states "DfE's Alternatives Assessment Program helps industries choose safer chemicals and provides a basis for informed decision-making by developing a detailed comparison of potential human health and environmental effects of chemical alternatives" (emphasis added). However, the Alternatives Assessment for NPE relies disproportionately on a limited number of environmental hazard-based criteria (i.e., acute ecotoxicity and biodegradation) to evaluate and identify so-called "safer" alternative surfactants**.** This approach does not assess the safety of surfactants at all; it

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Chemicals/RISK_ASSESSMENT/REPORT.

[6] Wagner, P. (Chief, Inert Ingredient Assessment Branch, US EPA). (2006, July 31). Action memo: Inert reassessments: Four exemptions from the requirement of a tolerance for nonylphenol ethoxylates. US Environmental Protection Agency, Washington, DC, USA.

[7] Klecka, G., Zabik, J., Woodburn, K., Naylor, C., Staples, C., & Huntsman, B. (2007). Exposure analysis of C8- and C9-alkylphenols, alkylphenol ethoxylates, and their metabolites in surface water systems within the United States. Human and Ecological Risk Assessment, 13 (4), 792-822.

[8] U.S. EPA Design for the Environment Program (US EPA DfE). (2011b). Criteria for Safer Surfactants .Available for download at: http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm#Surfactants.

[9] U.S. EPA Design for Environment Program (Accessed November 22, 2011). Alternatives Assessment Methodology: What are the key steps to conducting an alternatives assessment? http://epa.gov/dfe/alternative_assessments.html

merely compares a limited number of hazard characteristics. Hazard assessment is not a measure of safety. Risk assessment, which considers both hazard and exposure, is a measure of safety.

The hazard-based NPE Alternatives Assessment relies on the assumption that alternative surfactants are "drop-in" substitutes and that use levels of the surfactant in products and human and environmental exposures will be comparable. In the case of NPE surfactants, this is not a valid assumption. Reformulation to replace NPEs in products often requires that an alternative surfactant be used at a higher concentration and/or that multiple chemicals are necessary to achieve levels of technical efficacy in use that are comparable to NPEs.

In addition, informed substitution requires that potential alternatives should be assessed to determine whether they are technically feasible and deliver the same or better value in cost and performance while at the same time providing an improved profile for human health and the environment. As discussed further in these comments below, the current draft of the NPE Alternatives Assessment is overly focused on only two environmental hazard characteristic and ignores these and other important factors.

1.2 Hazard-based assessment is inconsistent with EPA's statutory responsibility to consider risk under the TSCA as well as the risk-based principles supported by the Agency for modernization of TSCA; therefore the NPE Alternatives Assessment should be expanded to consider exposure and risk or alternately should clearly state the limits of hazard-based assessment in the document.

Hazard assessment is only one component of an assessment to determine the safety of a chemical or product. Considering that a hazard-based approach is inconsistent with EPA's statutory responsibility to consider risk under the TSCA, as well as the risk-based principles supported by the Agency for modernization of the Act [10], it is important that DfE either expand the assessment in the NPE Alternatives Assessment to additionally consider exposure and risk or clearly qualify the limits of hazard-based assessment in the document. Without further clarification of the limits to this approach, the NPE Alternative Assessment may be interpreted to suggest that EPA supports hazard-based decision-making as a basis for selecting a safer surfactant. Considering that the NPE Alternatives Assessment is being conducted specifically as part of the action plan for NPEs, this approach undermines the risk basis for decision-making under TSCA. Clarification of the limits of a hazard-based assessment is also important since the NPE Alternative Assessment will likely be referenced or used by other governmental authorities, industry, and non-governmental organizations.

[10] U.S. EPA, Essential Principles for Reform of Chemicals Management Legislation (2009, September). Available at http://www.epa.gov/oppt/existingchemicals/pubs/principles.html. EPA's first principle indicates that "[c]**hemicals should be reviewed against safety standards that are based on sound science and reflect risk-based criteria protective of human health and the environment." DfE's Alternatives Assessment for should be held to this same principle. .**

DfE should not rely on the "voluntary" nature of the DfE Alternatives Assessment to circumvent the requirement to consider risk under TSCA and to provide adequate opportunity for public input under the Administrative Procedures Act (including notice and comment) since in the marketplace the NPE Alternatives Assessment will represent a determination by U.S. EPA that alternatives identified in the NPE Alternatives Assessment are "safer".

2.0. Available assessments have found that NPEs and/or their degradant NP do not pose a risk to human health or the environment in their current uses in the United States raising questions about the need to conduct an alternatives assessment on these compounds; robust risk and safety assessments should be provided to support the human and environmental safety of the alternative surfactants in the NPE Alternatives Assessment.

The NPE Alternatives Assessment states "the methodology in this Alternatives Assessment is tailored to the unique toxicological profile of surfactants and thus addresses a limited set of hazard endpoints" and " focuses on the evaluation of NPE and its alternatives from an environmental health perspective, since the potential for toxicity to aquatic organisms—from the parent surfactant and its degradation byproducts—and environmental persistence have been important areas of toxicological research that have documented effects of concern". However, DfE provides no basis to support a conclusion that NPEs and/or their degradation products are posing either a concern or a risk to the aquatic environment in the United States. Nor does the NPE Alternatives Assessment provide reasonable rationale to disregard consideration of the hazards of alternative surfactants and their degradants to humans or to aquatic species due to chronic exposures.

2.1 Governmental and other valid scientific assessments have found that NPE surfactants and their degradation intermediate NP do not present a risk to human health; similar assessments should be provided in the NPE Alternatives Assessment to support the human safety of the alternative surfactants.

The weight-of-the-scientific evidence for NPE and NP continues to support their human safety. It is not just APERC that has come to this conclusion; governmental risk assessments conducted by the European Union (EU), Canada and United States Environmental Protection Agency (U.S. EPA) have come to the same conclusion.[11] [12] In fact, U.S. EPA conducted a children's health risk assessment on NPE under the Food Quality Protection Act (FQPA) in 2006 that approved NPE for use as an inert ingredient on food crops and concluded "no concern for increased sensitivity to infants and children from NPE."[13]

[11] Environment Canada and Health Canada (EC and HC)..
[12] European Chemicals Bureau (ECB). (2002)..
[13] Wagner, P. (Chief, Inert Ingredient Assessment Branch, US EPA). (2006, July 31).

Numerous chronic and multi-generational mammalian toxicity studies are available for NP and/or NPEs; results do not suggest concern for reproductive or developmental effects from *in utero* and\or early life stage exposures. Traditional toxicological studies in rats that measure chronic effects and/or monitor effects in parents and offspring over multiple generations often include an evaluation of reproductive and developmental effects that are indicative of an endocrine mode of action. Numerous studies – some conducted over two or three generations – have evaluated whether the alleged weak estrogenic activity of NP affected reproductive or developmental end points in rats.[14,15,16,17, 18,19] These studies uniformly concluded that there are no effects on reproductive function or performance from NP at any of the doses tested. These findings are consistent with and support the results of a five-generation rat study conducted by the US National Institute of Environmental Health Sciences, which concluded that "NP was not a selective reproductive or developmental toxicant."[20] Another study by Tyl et al (2006) determined that there were no adverse effects on sperm following three generations of exposure in rats.[21]

Research has also confirmed that ingested NP is rapidly broken down into compounds that are not estrogenic and are eliminated within 24 hours. [22] This study, conducted on rats, also confirmed that no significant accumulation of NP occurs in any body organ or tissues following dosing at levels exceeding real-world exposure estimates.

While ample evidence is available to support the human safety of NPEs in their current uses, it is not clear from the NPE Alternatives Assessment that similar data exist to support the safety of the alternative surfactants. Since the primary uses addressed in the NPE Alternatives Assessment relate to cleaning products and detergents, which are used by workers and consumers, a comprehensive assessment of the mammalian and human health hazards and risks of the alternatives is necessary to provide a robust and meaningful assessment of viable alternatives to NPEs.

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[14] Latendresse, J.R., Weis, C.C., Mellick, P.W., Newbold, R.R., & Delclos, K.B. (2004). A five generation reproductive toxicity assessment of p-nonylphenol (NP) in CD Sprague-Dawley rats. The Toxicologist, 78, 219.

[15] Nagao, T., Wada, K., Marumo, H., Yoshimura, S., & Ono, H. (2001). Reproductive effects of nonylphenol in rats after gavage administration: A two-generation study. Reproductive Toxicology, 15 (3), 293-315.

[16] Odum, J. and Ashby, J. (2000). Neonatal Exposure of Male Rats to Nonylphenol Has No Effect on the Reproductive Tract. Toxicological Sciences, 56, 400-404.

[17] Odum, J., et al. (1999). Effects of p-nonylphenol (NP) and diethylstilboestrol (DES) on the Alderley Park (Alpk) Rat: Comparison of mammary gland and uterus sensitivity following oral gavage or implanted mini-pumps. Journal of Applied Toxicology 19, 367-378

[18] Cunny, H.C., et al. (1997). Subchronic Toxicity (90-Day) Study with para-Nonylphenol in Rats. Regulatory Toxicology and Pharmacology, 26, 172-178.

[19] Tyl, R.W., Myers, C.B., Marr, M.C., Castillo, N.P., Seely, J.C., Sloan, C.S., Veselica, M.M., Joiner, R.L., Van Miller, J.P., & Simon, G.S. (2006). Three-generation evaluation of dietary para-nonylphenol in CD (Sprague-Dawley) rats. Toxicological Sciences, 92, 295-310

[20]. Latendresse. (2004).

[21] Tyl. (2006).

[22] Green, T. *et al.* (2003) Absorption, bioavailability, and metabolism of para-nonylphenol in the rat. Regulatory Toxicology and Pharmacology. 38: 43-51.

2.2 Environmental assessments of the acute and chronic effects of NPE and its degradation intermediates, including NP, in U.S. surface waters do not raise concern, particularly when considered relative to the U.S. EPA Water Quality Criteria (WQC) for NP; similar assessments should be provided in the NPE Alternatives Assessment to support the environmental safety of the alternative surfactants and their degradants.

While the U.S. EPA action plan for NP/NPEs and the DfE NPE Alternative Assessment each acknowledge that U.S. EPA's finalized WQC for NP in 2006 neither considers whether concentrations in U.S. waters represent a risk relative to those WQC. The NP WQC are concentrations in surface water that are protective of acute and chronic effects in fresh and salt water fish and other aquatic species.

Numerous studies and extensive environmental monitoring data on NPE and their degradants in U.S. surface waters have been published by the U.S. Geological Survey (USGS), U.S. EPA as well as academic researchers. In an extensive assessment of the available literature by Klecka et al. (2007), the authors found that the probability that concentrations of NPE and its metabolites in US surface waters exceed the chronic NP WQC is low, even when considered in aggregate.[23] These findings contradict the concern expressed in the NPE Alternatives Assessment "over potential ecological and other effects from the manufacturing, processing, distribution in commerce, and uses of NP and NPEs".

While ample evidence is available to support the environmental safety of NP and NPEs in their current uses, it is not clear from the NPE Alternatives Assessment that similar data exist to support the safety of the alternative surfactants and their environmental degradants. The primary uses addressed in the NPE Alternatives Assessment relate to cleaning products and detergents, which are used and discharged continuously into the aquatic environment after treatment in wastewater treatment plants resulting in chronic exposure of aquatic species to their degradants. Therefore a comprehensive assessment of environmental hazards, exposures and risks of the alternatives and their degradants is necessary to provide a robust and meaningful assessment of the safety of alternatives to NPEs.

2.3 The NPE Alternative Assessment should consider the current environmental impact of the alternatives as well as the projected environmental impact based on their increase market volume if they replace the use of NPEs.

The NPE Alternatives Assessment document states that concern for NPEs is derived in part because "NP and NPEs are produced in large volumes, with uses that lead to widespread release to the aquatic environment' noting that "U.S. and Canadian consumption of NPEs has been estimated between 300 and 400 million pounds per year". This equates to a range of 136,078 and 181,437 metric tons. APERC generally concurs with this range for the North American market of NPE and estimates that the market for

[23] Klecka., (2007).

all alkylphenol ethoxylates in 2010 in North America was approximately 157,000 metric tons. Market studies indicate that market volumes for some of the alternative surfactants are already in the same range and in some cases are between two and three times greater than APEs. For example, in 2010 the North American market for alkyl ether sulfates (AES) and alcohol ethoxylates (AE) were estimated to be 434,000 and 305,000 metric tons respectively, while sodium lauryl sulfate or alkyl sulfates (AS) were estimated at 148,000 metric tons.[24]

The NPE Alternative Assessment should consider the current environmental impact of the alternatives as well as the projected environmental impact if the alternatives increase in use to replace the use of NPEs.

3.0 The NPE Alternatives Assessment does not provide an adequate basis for the biodegradation criteria and classifications.

DfE diverges from their existing DfE Alternatives Assessment Criteria for Hazard Evaluation [25] and relies on hazard assessment criteria that have not been adequately subject to public review and comment, as discussed below in Section 5.0 of these comments. Specifically on page 7 and in Table 2-1 of the NPE Alternative Assessment the DfE Criteria for Safer Surfactants are described. [26]

The NPE Alternative Assessment states:

> "The Criteria for Safer Surfactants (U.S. EPA, 2011a) use the following hazard characteristics to distinguish surfactants for cleaning products: the rate of aerobic biodegradation, hazard profiles of the degradation products, and degree of aquatic toxicity of the parent compound and degradation products. Since the surface active nature of surfactants causes toxicity to aquatic organisms, the criteria weigh these characteristics holistically and require that surfactants with higher aquatic toxicity demonstrate a faster rate of biodegradation without degradation to products of concern." (emphasis added)

However, the Criteria for Safer Surfactants does not provide any justification for the assumption that "surfactants with higher aquatic toxicity" that demonstrate a "faster rate of biodegradation without degradation to products of concern" are actually "safer". As discussed above, safety is a reflection of both hazard and exposure (i.e., risk) so it is necessary to understand the risk of the alternatives within the context of relevant use

[24] Colin A. Houston. (2010, December). Surfactant Developments Newsletter. Published by Colin A. Houston & Associates, Aiken, SC USA

[25] U.S. Environmental Protection Agency Design for Environment Program (U.S. EPA, DfE). 2011c. Design for the Environment Program Alternatives Assessment Criteria for Hazard Evaluation, Version 2.0, August 2011, Office of Pollution Prevention & Toxics, U.S. Environmental Protection Agency, Washington, DC, USA.

[26] U.S. EPA DfE. (2011b)..

patterns and exposures. Surfactants used in cleaning and laundry products are continuously discharged down-the-drain to wastewater treatment plants where they are degraded before discharge to the environment. Regardless of biodegradation profile, environmental exposure to the degradants may be continuous; therefore DfE should require chronic ecotoxicity assessments for the degradants of all the alternative surfactants.

3.2 The biodegradation criteria in the NPE Alternative Assessment have not been subject to adequate public review and comment; alternatively the biodegradation criteria in the more general DfE Alternatives Assessment Criteria for Hazard Evaluation, which have been subject to some public comment, can be used.

In the DfE Criteria for Safer Surfactants a criterion of "a slow rate of biodegradation (greater than 28 days)" is introduced. This criterion is inconsistent with established criteria for persistence including those in the DfE Alternatives Assessment Criteria for Hazard Evaluation, which was published in August. As discussed below, based on these latter criteria, NPE and NP should be classified as having a "low" to "moderate" potential for persistence.

The biodegradation criteria in the DfE Alternatives Assessment Criteria for Hazard Evaluation states that compounds with half-lives of less than 16 days based on biodegradation simulation tests, or passing the 60% degradation threshold for a ready biodegradation test, are designated as "low" or "very low" for potential to be persistent. Half-lives of 16 to 60 days from simulation tests indicate a "moderate" potential for persistence.

As the data in Table 1 attached to these comments shows, NPE, OPE and their degradation intermediates all fit into the environmental persistence categories of "Very Low to Moderate" according to the criteria in the recently published DfE Alternatives Assessment Criteria for Hazard Evaluation.

In addition, DfE defines "degradates of concern" in the Criteria for Safer Surfactants as meeting both specific acute toxicity thresholds and "slow" biodegradation. The data in the attached Table 1 clearly show that the NPE and OPE commercial products and their degradation intermediates are properly designated as "Low" for persistence according to the DfE Alternatives Assessment Criteria for Hazard Evaluation. Most studies for these compounds have results that conform to "Low" persistence. While two studies show "Very Low" persistence and two studies suggest "Moderate" persistence. So, NPE and OPE have acute aquatic toxicity that is similar to the alternative surfactants and therefore meets the aquatic toxicity thresholds in the "Safer Surfactants" criteria. However, based on the high quality studies for NPE, OPE, NP and OP shown in attached Table 1 their biodegradation profile should not be considered to support a designation as surfactants with "degradates of concern".

Regardless of the classification for degradates of NPE and OPE surfactants, similar data should be required for the degradates of the alternative surfactants in the NPE Alternatives Assessment document since their use will likely result in chronic exposure of aquatic species to their degradants. More rapid biodegradation of the alternative surfactants is not an adequate reason to disregard the chronic ecotoxicity of the degradates since the use and disposal patterns for the primary uses under discussion (i.e., cleaning, detergent and other consumer products) result in ongoing chronic exposure of aquatic species to the degradates due to their constant use, disposal treatment and reintroduction into the environment

3.3 The NPE Alternative Assessment should also address the toxicity of complete alternative surfactant packages, including other co-ingredients that are commonly used in alternative formulations in an attempt to match the performance of NPEs.

The NPE Alternatives Assessment acknowledges that "formulators will replace an NPE surfactant with a blend of two or more surfactants (e.g., a linear alcohol ethoxylate plus an alkyl glycoside)" and "depending on product type, a change in surfactant may also prompt other ingredient or formulary adjustments". However, the document does not require a hazard assessment of the alternative surfactant packages. To provide useful guidance in the selection of alternative surfactants, DfE should view the surfactant replacement package as the alternative, not just the surfactant, and should assess the hazards and risks of the all the ingredients in the package to the same degree that NPEs have been assessed.

4.0 The NPE Alternatives Assessment relies on data that are of variable quality and utility and in the case of NPE, OPE and their degradants more reliable studies should be used to assess their persistence.

The data presented in the NPE Alternatives Assessment was of variable quality and utility. The use of modeled data and professional judgment can be appropriate in some cases, but the assessment is only as good as the model used, or the amount of knowledge or expertise governing the professional judgment. In addition, alternative surfactants with less data, and therefore subject to modeling and expert judgment, should not be viewed as being assessed in a manner that is either comparable to NPEs or adequate for determining their relative hazards.

The NPE Alternatives Assessment relied primarily on Talmage (1994) [27] as the basis of most of the biodegradation data for NPE, OPE and their degradation intermediates and ignored many newer, more reliable studies that should be used to assess the persistence of these compounds.

Talmage (1994) is a compilation of data that summarizes studies mainly from the 1960s, 1970s, and 1980s. Many of the old studies, which were conducted to assess treatability in

[27] Talmage S.S. (1994). Environmental and Human Safety of Major Surfactants—Alcohol and Alkylphenol Ethoxylates. Lewis Publishers, Boca Raton, FL, USA.

wastewater treatment plants, relied on indirect measures of quantification of NPE (e.g., colorimetric methods). Considerable work has since been conducted that used radiolabeled test material, measures of oxygen demand, carbon dioxide production, and direct measurement of test material using chromatographic methods.

DfE selected only one study out of many listed in Talmadge (1994) to reflect the biodegradation of NPEs (Kravetz et al. 1978, which showed 10 to 53% degradation of NPE in 28 days). DfE should have also included three river die-away studies that showed OPE10 degrading 78 to 95% in 11 days, 94 to 95% in 5 days, and NPE9 degrading 75 to 95% in 10 to 20 days, respectively. [28] [29] [30] From all these data, the weight of evidence for the commercial products NPE9 and OPE10 supports the conclusion that they have a "Low" potential for persistence.

Some of the studies conducted since Talmage (1994) that used more modern methods of analysis and include the degradation intermediates are shown in the Table 1, which is attached to these comments. These newer studies should be relied on to assess the biodegradability of NPE, OPE, and their degradation intermediates.

5.0 The process by which DfE developed the NPE Alternatives Assessment circumvented the DfE process for stakeholder engagement, included data sources that are not sufficiently transparent and cited DfE criteria that have not been sufficiently subject to public comments.

5.1 U.S. EPA circumvented its own stakeholder process for the development of the NPE Alternatives Assessment.

With regard to the Alternatives Assessment process for NPE, it is of great concern to the members of APERC that DfE has circumvented its own process requirement to convene stakeholders in the development of the alternative criteria and assessment. Offering a draft assessment document does not offer the same opportunity for stakeholders to review, discuss and provide data that an open public stakeholder process would offer. Notwithstanding the voluntary nature of the DfE Alternatives Assessments Program, the product recommendations that arise from this program will ultimately influence the purchasing preferences in the market. Therefore it is APERC's view that the Agency should provide all members of the public with the opportunity to provide input on all aspects of the development of a specific alternative assessment, not just those parties most likely to benefit from the outcome (i.e., companies seeking DfE recognition for their products).

[28] Ruiz Cruz J, Dobarganes Garcia MC. 1976. Pollution of natural waters by synthetic detergents. X. Biodegradation of nonionic surfactants in river water Grasas y Aceitas 27: 309-322.
[29] Dobarganes Garcia MC, Ruiz Cruz J. 1977. Pollution of natural waters by synthetic detergents. XI. Influence of experimental variables in the biodegradation of nonionic surfactants in river water Grasas y Aceitas 28: 161-172.
[30] Ruiz Cruz J, Dobarganes Garcia MC. 1977. Pollution of natural waters by synthetic detergents. XII. Relation between structure and biodegradation of nonionic surfactants in river water Grasas y Aceitas 28: 325-331

5.2 The NPE Alternatives Assessment included data sources that are not sufficiently transparent

DfE's NPE Alternative Assessment relies on some data that are not sufficiently transparent for public review and comment on a document that is intended to influence product preferences in the market. The chemical assessments in Table 2-3 of the NPE Alternatives Assessment included measured data from U.S. EPA confidential databases and confidential studies submitted by chemical manufacturers as well as the CleanGredients® database. Data from confidential databases and studies are clearly not available for public review and comment. Also, since the CleanGredients® database is a fee-based subscription tool it is also not sufficiently transparent for public review and comment. The DfE Alternatives Assessment should be revised to remove all reference to data that are confidential or otherwise not sufficiently transparent and available for public comment.

5.3 The NPE Alternatives Assessment relies on DfE criteria that have not been sufficiently subject to public comment.

The NPE Alternatives Assessment states:

> "Over the years, DfE and other parts of EPA have conducted research to characterize NPEs and safer alternative surfactants. As a result, most of the information gathering, chemical profiling, and stakeholder interactions typical of an alternatives assessment have already taken place and serve as foundation and reference material for this document. To identify safer surfactants, DfE has worked in collaboration with diverse stakeholder groups, during both the development of the DfE Criteria for Safer Surfactants[31] and SDSI, which was launched at an EPA public meeting in June 2006."

It is clear U.S. EPA considers the chemical alternatives assessment process to be a critical component of its TSCA program for the risk management of chemicals with action plans. Thus, the criteria that are being developed in the NPE Alternatives Assessment may have the effect of providing a basis for Agency decisions to regulate or restrict the use of chemicals in the marketplace. Notwithstanding the "voluntary" nature of the DfE Alternatives Assessments Program, it is reasonable to foresee that the recommendations about the relative "safety" of certain alternative surfactants will be used within other EPA programs and potentially by the states and localities wishing to articulate standards and requirements for the use of certain chemicals by the regulated community. Consequently, in developing procedures and standards for the review of chemical substances, EPA should provide all members of the public with adequate notice and opportunity to provide comment on all aspects of both the development of the criteria and the application of the criteria within the DfE's Alternatives Assessments Program. This is particularly true for compounds with TSCA action plans, like NPE, for which U.S. EPA is clearly utilizing the DfE Alternatives Assessment Program as a risk-management tool.

[31] U.S. DfE (2011b).

The NPE Alternatives Assessment relies on the DfE Criteria for Safer Surfactants.[32] These criteria have not been subject to adequate public review and comment. There should, at a minimum, be an official notice in the Federal Register to convene interested stakeholders for a meeting or meetings to discuss appropriate criteria for surfactants and to solicit appropriate data. In addition, the availability of any draft documents should be published in the Federal Register along with appropriate public comment periods. Finally DfE should provide a summary of the Program's consideration and response to public comments that are received.

In the case of the DfE Criteria for Safer Surfactants no such efforts to solicit and respond to public comment are apparent. These criteria are simply posted on the DfE website with no explanation of their basis or derivation. It seems the DfE Criteria for Safer Surfactants were developed based on DfE interaction behind the scenes with companies seeking recognition for their products under the DfE program; thereby precluding dialogue with other stakeholders.

6.0 Summary

NPEs are cost- effective surfactants that provide high technical performance in a broad array of applications. Considering that the weight of the scientific evidence for NPEs and NP continues to support their human and environmental safety when used as intended and disposed of responsibly, there is no need for an alternatives assessment for this surfactant

APERC believes that the NPE Alternatives Assessment represents at best a simplistic hazard-based assessment that will not ensure that products formulated with the alternatives identified as preferable to NPEs will pose a lesser hazard or risk to human health or the environment. APERC also believes that the NPE Alternatives Assessment is negligent in not requiring a broader assessment of the human health, chronic ecotoxicity, exposures and risks of the alternative surfactants. In fact, granting "preferred" status to the alternative surfactants based solely on acute aquatic toxicity and biodegradation potential of the parent compounds may result in the promotion of products that have limited health and environmental effects data while promoting market deselection of NPEs, which have been extensively-studied, subject to comprehensive risk assessments and shown not to pose a risk to human health or the environment in their current uses.

While ample evidence is available to assess and support the human and environmental safety of NPEs in their current uses, it is not clear from the NPE Alternatives Assessment that similar data exist to support the safety of the alternative surfactants; therefore a comprehensive assessment of the human health and environmental hazards and risks of the alternatives and their degradates should be required in the Alternatives Assessment to provide a robust and meaningful assessment of viable alternatives to NPEs

[32] US EPA DfE. (2011b).

Table 1. Biodegradation Data for NPE, OPE and their Biodegradation Intermediates. (All studies reviewed in Klecka et al., 2008)					
Commercial APE	**Test**	**Extent of Degradation**	**Comment[1]**	**DfE Persistence Classification**	**Reference**
NPE7	Closed bottle	60% ThOD, 28-d	10-d window not applicable[2]	Low	Markarian et al. (1989)
NPE9	OECD 301B	80% ThCO2, 28-d	10-d window not applicable[2]	Low	Staples et al. (1999, 2001)
	ISO 14593	70% ThCO2, 28-d	10-d window not applicable[2]	Low	Staples et al. (1999, 2001)
OPE9	OECD 301B	83% ThCO2, 28-d	10-d window not applicable[2]	Low	Staples et al. (1999, 2001)
NPE15	River die-away	85 to 90% primary degradation, 17-d	T1/2 << 17 d	Low	Quiroga et al. (1996)
NPE15	River die-away	85% primary degradation, 5-d	T1/2 << 5 d	Very Low to Low	Manzano et al. (1998)
NPE15	River die-away	68% (7°C), 30-d 96% (25°C), 30-d	T1/2 < 30-d T1/2 << 30-d	Low	Manzano et al. (1999)
NPE8	Lake water die-away	Up to ~100% loss, 33-d	T1/2 < 33-d	Low	Mann & Boddy (2000)
NPE10	Estuarine die-away		T1/2 2.5 to 35-d (22.5°C)	Low	Kvestak & Ahel (1995)
NPE18	Estuarine die-away	~100% primary degradation, 16-d	T1/2 << 16-d	Very Low to Low	Potter et al. (1999)
Degradation Intermediates					
NP	OECD 301B OECD 301F	48% ThCO2 62% ThCO2	10-d window not applicable[2]	Moderate Low	Staples et al. (1999, 2001)
NPE1.5	OECD 301B	59% ThCO2	10-d window not applicable[2]	Moderate to Low	Staples et al. (1999, 2001)
NPEC1,2	OECD 301B	63 to 65% ThCO2	10-d window not applicable[2]	Low	Staples et al. (1999, 2001)
OP	OECD 301B	70% ThCO2	10-d window not applicable[2]	Low	Staples et al. (1999, 2001)
OPE1.5	OECD 301B	65% ThCO2	10-d window not applicable[2]	Low	Staples et al. (1999, 2001)
OPEC1,2	OECD 301B	69 to 80% ThCO2	10-d window met, but not applicable[2]	Very Low	Staples et al. (1999, 2001)
NPE1-3	River die-away		T1/2 2 to 4-d	Very Low to Low	Ahel et al. (1994a)

[1] From U.S.EPA (2011c), at p. 40, "If the compound degrades by more than 40% in 28 days during one of the Ready Biodegradability tests specified above…then the half-life of a chemical is likely to be less than 60 days…", citing to Aronson et al. (2006)

[2] Recent guidance according to the EU Detergent Directive indicates that the 10-day window is inappropriate for assessing the biodegradability of surfactant mixtures (CSTEE 1999; Richterich and Steber 2001).

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The Bullen Companies Inc.
September 29, 2011

From: Tim Morris
To: David DiFiore

Re: Request for Comments on the Draft DfE Alternatives Assessment for NPEs

Hi David,

I just did a quick review of the draft and I have some initial comments.

Since you are including Octylphenol EO surfactants as well as NPEs, you may want to refer to the program as APE replacements (Alkyl Phenol Ethoxylates) which is all inclusive of this class of surfactant; i.e. OPEs, NPEs. Small point but it may avoid confusion to formulators like me. Another observation is that most of the alternatives are geared towards laundry/manual dishwash formulations. Hard surface cleaners are a big application for APEs in the I&I market. We use them and are phasing them out over the next 18 months...we already started the process 2 years ago.

I have over 20 years of experience with surfactant technology, so if you ever want to discuss specific topics on this subject, feel free to contact me.

Best regards,
Tim

Tim Morris
Technical Director
Product Formulations and Regulatory
The Bullen Companies Inc.
(610) 534-8900

Clean Control Corporation
September 29, 2011

From: Cory Hammock
To: David DiFiore

Re: Request for Comments on the Draft DfE Alternatives Assessment for NPEs

David,

From my perspective, the linear alcohol ethoxylates (particularly alcohols in the C12-C15 range) are the only acceptable alternatives to NPE. The ethoxylated/propoxylated alcohols have similar application potential in environments that require lower foam; however surfactant properties are adversely affected compared to LAE and NPE.

Although suitable for many applications, the remaining alternatives listed do not exhibit surfactant properties similar to NPE. The fate and aquatic toxicity information is useful for comparison purposes only.

Please let me know if you would like to discuss these comments.

Sincerely,

Cory S. Hammock
Vice President of Research & Development Clean Control Corporation
1040 Booth Road
PO Box 7444
Warner Robins GA 31095-7444
Office: 478-922-5340
Direct: 478-752-6618

Clean Production Action
October 22, 2011

From: Lauren Heine
To: David DiFiore

Subject: Comments on the Draft DfE Alternatives Assessment for NPEs

Dear David:

Congratulations on the DfE Alternatives Assessment for Nonylphenol Ethoxylates. Please accept the following comments.

I really like the overall comprehensive approach that EPA is taking by combining both voluntary and potential regulatory approaches. I think it is fair that DfE is NOT pulling together a Partnership as DfE is doing with the other EPA chemicals of concern given all the work that DfE and EPA have already done on surfactants.

I like the use of the DfE Criteria for Safer Surfactants which is a set of criteria specifically tailored for surfactants and thus provides a focus on those attributes that are most discriminating and also helps manufacturers or users know where it is most important to test.

I like the use of the DfE criteria for safer surfactants. It may be helpful (but may also confuse things) if you explain why you are using the DfE Criteria for Safer Surfactants rather than the recently published CAA criteria- or at least a bit more detail on how they are the same or different. I think there is a little confusion here because in the chemical profiles you rank the persistence of some of the safer alternatives as "very low" but in the hazard table based on the DfE Criteria for Safer Surfactants, they are listed as low. Maybe only a geek like me would notice that but if the criteria are a little different between the systems, it might be good to flag that they are very low according to the DfE CAA criteria and just "low" according to the DfE Criteria for Safer Surfactants (if that is indeed the case).

I think the overall approach is really helpful and I like that you point out safer alternatives from a range of classes. I also think it is helpful that you point to CleanGredients as a source of over 300 surfactants. Clearly safer alternatives are available.

A question:

You lay out a powerful and useful method for evaluating surfactants. What is the best way for a manufacturer to have a new or previously unassessed surfactant assessed to determine if it is indeed a safer surfactant? Would they apply to have their surfactant evaluated for listing in CleanGredients? Are there other approaches?

Is it possible to have a safer alternative that does not meet the DFE Criteria for Safer Surfactants?

Thank you for your good work and good luck with this program.
--
Lauren Heine, Ph.D.
Principal, Lauren Heine Group LLC
Consulting Co-Director, Science and Applications Clean Production Action Juneau, AK
Tel: 360-220-2069
lauren@lheinegroup.com

GEMTEK
September 28, 2011

From: Kim C. Kristoff
To: David DiFiore

RE: Request for Comments on the Draft DfE Alternatives Assessment for NPEs

David,

Thank you for sending this to stakeholders. After having read both the original public comments and the EPA responses it is evident that there still remains some question about the appropriate treatment of NP and NPE.

These ancient chemicals should have been banned from production more than twenty years ago. The fact that they proliferate still is not surprising at nearly half the cost of more recent APG and alcohol ethoxylates. Still, for those manufacturers who continue to use them, the game is changed and their time is over...good riddance. Through CleanGredients and the DfE there are over 3,000 viable, affordable and readily available functional alternatives with no remaining excuse for continuing to use NP or NPE.

Regards,
GEMTEK
Kim C. Kristoff
President
3808 N. 28th Avenue
Phoenix, Arizona 85017
Ph: 602-265-8586

November 30, 2011

USEPA Design for the Environment Program (DfE)
Attn: David DiFiore (via e-mail: difiore.david@epa.gov)

Dear David:

Huntsman Petrochemicals LLC ("Huntsman") has recently been made aware of the "DfE Alternatives Assessment for Nonylphenol Ethoxylates" (the "Alternatives Assessment") that was published on the USEPA DfE website. Huntsman is a manufacturer of a wide variety of surfactant products, including nonylphenol ethoxylates (SURFONIC® N-series products), linear alcohol ethoxylates (SURFONIC L-series products), and our novel methyl ester ethoxylates (SURFONIC ME-series products), offering a diverse portfolio of surfactant products to our customers. We have received CleanGredients® and DfE certification for several of our SURFONIC L-series and SURFONIC ME-series products.

Huntsman has reviewed the Alternatives Assessment, and have discussed our concerns with the Alkylphenols & Ethoxylates Research Council (APERC). While Huntsman is not a member of the APERC, we have reviewed the comments recently submitted to the USEPA DfE by APERC, and Huntsman is in agreement with APERC's comments on the Alternatives Assessment document.

Huntsman agrees with APERC's conclusion that "*EPA's characterization of NPE and NP as "compounds of concern" in the NP/NPE action plan and in the NPE Alternatives Assessment is not justified. Therefore, the need to conduct an alternatives assessment is questionable, particularly since governmental assessment have not found human safety to be a concern.*" Huntsman believes that the Alternatives Assessment document should have been more robust as to the following points:

- While the document is clearly focused on the environmental aspects of the alternatives (biodegradation, bioaccumulation and toxicity to aquatic organisms), the report did not address other human health endpoints of the alternatives or their degradates. The document should also have included an overview of other toxicological endpoints, both acute and chronic mammalian tox, genetic tox, reproductive and developmental tox, and carcinogenicity.
- In addition to the hazard information outlined above, the Alternatives Assessment should have included use and potential exposure information necessary to provide an in-depth assessment of risks to human health and the environment, not only from the alkylphenols and alkylphenol ethoxylates, but also from the alternative surfactants included in the report.

- It is premature to discuss an endocrine disruption classification until EPA fully defines the classification scheme (beyond the Tier 1 screening studies) used in the identification of an endocrine disrupting compound.
- Finally, there is much information presented on the degradates of NPE's and OPE's, yet there is no information on the degradates (identified, potential, or otherwise) of the other alternative surfactants to determine if there are any potential issues with the biodegradation of the alternative chemicals, along with the toxicity of the degradates.

Huntsman appreciates the opportunity to provide comment on this important topic. If I can provide any further information or assistance, please contact me.

Regards,

Ray Papciak
Manager, Product Safety

8600 Gosling Road
The Woodlands, TX 77381
281-719-7400

Refrigeration Technologies
October 24, 2011

From: John Pastorello
To: David DiFiore

Re: Alternatives Assessment for Nonylphenol Ethoxylates

I concur with the assessments. It is time to consider grounding the phosphates and glycol ethers.

Regards,

John Pastorello
Refrigeration Technologies
1111 N. Armando St
Anaheim, CA 92806

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714-238-9207
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Staples, Inc.
October 24, 2011

From: Roger McFadden
To: David DiFiore

Subject: EPA DfE Alternatives Assessment for Nonyl Phenol Ethoxylates

David,

We were delighted to receive the latest draft copy of the EPA DfE Alternatives Assessment for Nonyl Phenol Ethoxylates dated September 26, 2011. This type of information is very useful to our company. It provides credible, comprehensive and science based information to help us make informed decisions about how to meet a growing demand by our customers for safer product alternatives while avoiding regrettable substitutions. The detailed comparison of potential human health and environmental effects of chemical alternatives is very useful to us.

Thanks again for all the great information that you and the DfE make publicly available. It helps to inform both the supply-side and the demand-side of the supply chain.

Best Regards,
Roger

Roger McFadden
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TD Research Ltd.
November 17, 2011

From: Bernard Tangelder
To: David DiFiore

Subject: Request for Comments on the Draft DfE Alternatives Assessment for NPEs

Hi David:

I know we have not spoken in a while, but hope you are doing well. We have a client in California who asked us to review the DfE Alternative Assessment for NPEs.

It is our understanding from the cover email that accompanied this document that the Alternatives Assessment Plan is to help industries choose safer chemicals and provide a basis for informed decision making. The concern with the draft alternative assessment is the proposal for differentiating hazard levels for the Persistence criteria. The Persistence criteria for the Low and Very Low Criteria references the 10-day window as a point of differentiation between the two hazard levels. It has been established by the OECD and CSTEE that the 10-day window is not a requirement for surfactants and therefore it is not purposeful or practical to use this as a point of differentiation.[1] This is best summarized from the summary below from the Human and Environmental Risk Assessment on Alcohol Ethoxylates:

> The 10-day window criterion in a ready test formerly applied to all substances but does not now apply to technical mixtures such as commercial surfactants (OECD 2006). It requires that, after initial evidence of biodegradation has been demonstrated by 10% substance removal, further biodegradation leading to the pass level 6 must be completed within 10 days. This procedure was introduced to increase the stringency of the ready test procedures, and is usually successfully applied to standard testing on individual substances. However, the CSTEE has decided that the 10-day window criterion is not a requirement for surfactants (CSTEE 1999). The CSTEE give several conceptual and technical reasons that the application of the 10-day window does not improve the stringency of ready tests on surfactant materials. The main reason given is that, as surfactant degradation is generally characterised by multiphase kinetics that may be inevitable with a mixed microflora and possibly a multi-component substrate, the 10-day window is not appropriate, as it might interfere with the aim of the ultimate biodegradability test, which is to assess the capability (of a percentage) of a product to be fully degraded in simple compounds during a 28-day period. The OECD has now taken the same position, stating that the 10-day window is not appropriate for technical

[1] Human & Environmental Risk Assessment on ingredients of European household cleaning (HERA). (2009). Alcohol Ethoxylates. p. 27. Accessed at http://www.heraproject.com/files/34-F-09%20HERA%20AE%20Report%20Version%202%20-%203%20Sept%2009.pdf.

> mixtures containing several components such as surfactants (OECD 2006). Thus, in general, the 10-day window criterion is not considered in establishing the ultimate ready biodegradability of the AEs covered in this HERA risk assessment.[2]

Therefore, surfactants that meet the proposed Low or Very Low Hazard Persistence criteria should be considered as the same level of hazard and therefore surfactants rating from very high to low for aquatic toxicity should be acceptable for use in DfE labeled products if they rate Low or Very Low Hazard Persistence Criteria.

I am not completely sure from reading the draft if the intent of the Alternative assessment Criteria is to change the current DFE Criteria for Safer Surfactants, but from what is proposed in the Alternative Assessment Criteria, the current Criteria/attributes for Safer Surfactants already addresses. The formulator community is pleased with the DfE program that allows them to use safer surfactants and the adoption of the draft has the potential to unnecessarily limit the number of surfactants if the hazard Level of Low and Very Low for the Persistence Criteria are not merged together.

It is good to see that the EPA will continue to allow the sources of Information outlined under 2, b. on page 8 to complete the chemical assessments of toxicological and environmental endpoints.

We trust that these comments are of value and please feel free to let me know if you have any questions or comments or need additional information.

Best regards,

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[2] *Id.* at p. 27-28