

A P E R E S E A R C H C O U N C I L

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EPA Chemical Action Plan for NP/NPE Lacks Scientific Rigor

August 19, 2010 - EPA's characterization of nonylphenol (NP) and nonylphenol ethoxylates (NPEs) as "compounds of concern" in the Agency's recently released action plan for these compounds is not justified and does not reflect the weight-of-evidence for the extensive data available for these compounds. The Alkylphenols & Ethoxylates Research Council (APERC) looks forward to the opportunity to discuss the science related to these compounds with the Agency.

The Agency's categorization of the NP/NPE action plan document as a "screening level review," along with the caveat that it is based on "EPA's initial review of readily available use, exposure, and hazard information" does not adequately excuse the lack of rigor in its development. Nor does the Action Plan provide an adequate basis for the expansive regulatory actions that it proposes.

There are numerous oversights and inaccuracies in the NP/NPE action plan; however, the following are of particular concern to APERC:

- The NP/NPE action plan document characterizes these compounds as "persistent"; this is particularly troubling since robust governmental assessments conducted by the European Union, Environment Canada, Washington State and the state of Oregon are overlooked. These assessments, which were specific to the properties of persistence and bioaccumulation, concluded NP and NPE are not persistent or bioaccumulative.^{i,ii,iii,iv} EPA should rely on the clear definitions for "persistence" and "bioaccumulative" recognized by international organizations – as well as the Agency's own programs under the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Toxics Substances Control Act^{v,vi} – along with the scientific weight-of-evidence for chemicals being addressed under Chemical Action Plans.
- Also troubling is that EPA's "concern about potential risk to human health" from NP/NPE is based on information contained in a screening level Hazard Characterization document on alkylphenols. This Hazard Characterization document was developed as part of EPA's High Production Volume (HPV) Challenge Program^{vii}, which was conceived as a voluntary initiative aimed at developing and making publicly available screening level data for high volume chemicals. Each submission contains data on a checklist of 18 specific tests. The Alkylphenols Category document does not reflect the abundant data for NP and does not address NPE.
- EPA's focus on the Alkylphenols Hazard Category document ignores governmental assessments that support the human safety of current uses of NP and

NPE. Most notable, is EPA's own 2006 assessment on the use of NPEs as inert ingredients in pesticide products. This assessment, which also considered data on NP, was conducted as part of a reassessment of all inert ingredients as mandated by Food Quality Protection Act (FQPA).^{viii} It concluded there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to NPEs when used as an inert ingredient considering dietary and non-occupational exposures. This EPA assessment also found no concern for increased sensitivity to infants and children from NPEs. It also concluded NP and NPE are not carcinogenic. In addition, governmental risk assessments conducted in Canada^{ix} and the European Union^x concluded that current uses of NP/NPEs pose no concern for the safety of humans.

These governmental assessments are consistent with and supported by the results of a five-generation rat study sponsored by the US National Institute of Environmental Health Sciences (NIEHS) and conducted by the National Center for Toxicological Research (NCTR), which concluded that "NP was not a selective reproductive or developmental toxicant."^{xi}

- On the environmental side, the NP/NPE action plan does acknowledge that EPA finalized Water Quality Criteria (WQC) for NP.^{xii} However, it does not consider whether concentrations in US waters represent a risk relative to those WQC. In an extensive assessment of surface water and/or sediment monitoring studies available in the published or publicly available literature, Klecka et al. (2007) found that the likelihood that concentrations of NPE, NP and other metabolites in US surface waters exceed the chronic NP WQC is low – even when considered in aggregate.^{xiii}
- EPA's proposal to issue a Significant New Use Rule (SNUR) under Section 5 of TSCA for the use of NPEs in industrial detergent and cleaning products is not supported by a finding of risk to either laundry workers or the environment. This plan, which is contingent on a phase out by an industrial laundry association, sidesteps the Agency's responsibility to consider whether there is risk associated with these uses.

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- ⁱ European Chemicals Bureau (ECB). (2003). PBT Working Group Substance Information Sheets for Nonylphenol (CAS 25154-52-3) and Phenol, 4-Nonyl, branched (CAS 84852-15-3).
- ⁱⁱ Environment Canada (EC). (2006). Ecological categorization of substances on the Domestic Substance List; Categorization Decisions. (Completed in September 2006). http://www.ec.gc.ca/substances/ese/eng/dsl/cat_index.cfm.
- ⁱⁱⁱ Washington State Department of Ecology (2006a, January) Rule Adoption Notice: Persistent Bioaccumulative Toxins Chapter 173-333 WAC. <http://www.ecy.wa.gov/biblio/0607007.html>
- ^{iv} Oregon Department of Environmental Quality (OR DEQ). (2009, October). Final Report: Senate Bill 737: Development of a Priority Persistent Pollutant (P3) List for Oregon. No. 09-WQ-013. <http://www.deq.state.or.us/wq/SB737/docs/P3LReportFinal.pdf>.
- ^v US EPA (1999, October 29). Persistent Bioaccumulative Toxic (PBT) Chemicals; Lowering of Reporting Thresholds for Certain PBT Chemicals; Addition of Certain PBT Chemicals; Community Right-to-Know Toxic Chemical Reporting. Final Rule, Federal Register: Volume 64, Number 209, pages 58666-58753.
- ^{vi} US EPA (1999, November 4). Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances, Federal Register: Volume 64, Number 213, pages 60194-60204
- ^{vii} US Environmental Protection Agency (EPA). High Production Volume Challenge. <http://www.epa.gov/chemrtk/index.htm>
- ^{viii} 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.
- ^{ix} Environment Canada and Health Canada. (2001, April). Priority Substances List Assessment Report - Nonylphenol and its Ethoxylates. <http://www.ec.gc.ca/substances/ese/eng/psap/final/npe.cfm>.
- ^x European Chemicals Bureau (ECB). (2002). European Union risk assessment report: 4-nonylphenol (branched) and nonylphenol: Final report. http://ecb.jrc.it/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT.
- ^{xi} 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.
- ^{xii} US Environmental Protection Agency (US EPA). (2006, February 23). Notice of availability of final aquatic life ambient water quality criteria for nonylphenol. Federal Register, 71 (36), 9337-9339. <http://www.epa.gov/EPA-WATER/2006/February/Day-23/w2558.htm>.
- ^{xiii} Klecka, G., Zabik, J., Woodburn, K., Naylor, C., Staples, C., and 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, 792-822.