Public Comment
U.S. EPA Science Advisory Board
Drinking Water Committee
April 29-30, 2015

My name is Barbara Losey and I am here today on behalf of the Alkylphenols & Ethoxylates Research Council (APERC) to comment on US EPA's Draft CCL4.

APERC is a North American organization whose mission is to promote the safe use of alkylphenols, alkylphenol ethoxylates, including nonylphenol, octylphenol and their ethoxylates through science-based research, product stewardship and outreach efforts, within the framework of responsible chemical management.

APERC submitted extensive written comments in response to EPA's specific request for information and comment on nonylphenol as a candidate for the CCL4. The comments also provide information regarding nonylphenol ethoxylate, octylphenol and octylphenol ethoxylate, which were nominated for consideration to be added to the CCL4. These comments have also been provided to the SAB.

In short, EPA's assessment of NP for CCL4 was based on an erroneous Lowest Observed Adverse Effect Level (LOAEL) value of 2 mg/kg-bw/day and therefore an incorrect potency or Toxicity Category was derived. This, along with single out-of-date and worst-case surface water monitoring data point of 40 µg/L, which is not relevant to current drinking water levels of this compound, led EPA to propose moving NP forward to the CCL4. When accurate and relevant toxicity data are considered, including four multi-generational studies with rats–two conducted by the US government at NTP and NCTR – that cover all sensitive life stages as well as reproductive or developmental effects, NP does not meet the "potency" and "occurrence" thresholds to move to the CCL4. Nor do NPE, OP and OPE.

The case of NP provides a good example of issues with transparency related to the data used in the CCL4 selection process. It also demonstrates limitations related to reliance on the RTECS® database as a data source for the CCL process. EPA should not simply rely on values in the RTECS® database. A review of the primary source material is necessary to confirm or clarify

values in the database. Actually, a more robust review of the available literature on CCL candidate chemicals would be preferable.

Also, EPA should utilize a hierarchy when selecting occurrence data to prioritize compounds under the CCL process. Use of exposure data that are most relevant to drinking water should be used (i.e., finished drinking water data should have greater relevance than source water, which should have greater relevance than wastewater effluent data). In the case of NP, EPA selected a single historical worst-case surface water value to justify prioritizing it for the CCL4, which was unfortunate since monitoring data in drinking water is available.

Also, I would like to point out that the estrogenic activity of NP noted by EPA does not preclude the risk-based assessment of this compound for CCL4 screening purposes. While NP and OP have weak estrogenic-like activity, their potencies generally range from 1,000 to 1,000,000-fold weaker than the endogenous estrogen, estradiol. In addition, the non-endocrine toxicity of NP and OP occurs at doses that are either lower than or within the same range the doses that affect endpoints that may be linked to estrogenic activity (i.e., reproductive and developmental). Therefore, in higher-tier multi-generational mammalian studies, the relatively weak estrogenic activity of NP and OP is not the most sensitive or critical effect.

Perhaps more relevant than the CCL4 screening criteria, assessments of the risk to humans from NP and OP in drinking water have been conducted and indicate high Margins of Exposure (MOEs) and therefore a high margin of safety (i.e, 10^5) for this exposure source. Also, there are human biomonitoring data available for NP and OP, which can be used to characterize human risk for each of these compounds from all sources, not just drinking water, which indicate similarly high Margins of Exposure and safety for these compounds.

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