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Oral Comments
of the
Alkylphenols & Ethoxylates Research Council
to the Chartered Science Advisory Board
Regarding the Science Advisory Board Drinking Water Committee
Report (September 3, 2015) on the
U.S EPA Draft Fourth Candidate Contaminant List
Public Teleconference, September 24, 2015

I am Barbara Losey, Deputy Director of the Alkylphenols & Ethoxylates Research Council (APERC).¹ Thank you for this opportunity to provide comments for your consideration related to the Science Advisory Board Drinking Water Committee (SAB DWC) report on EPA's Draft Fourth Candidate Contaminant List (CCL4).^{2, 3} The Chartered SAB's review is an important step in Science Advisory Board (SAB) process as it will function to ensure that all charge questions assigned to the SAB Drinking Water Committee (SAB DWC) are adequately addressed, as well as to make sure that scientifically valid information about contaminants and/or process issues presented by the public are considered.

As noted below, it appears that the SAB DWC has not adequately responded to the charge question related to recommending chemicals for removal from the draft CCL4. In the process of reviewing its first draft report (dated June 30, 2015), the SAB DWC removed - without adequate basis - their recommendation to EPA regarding nonylphenol (NP).^{4, 5}

¹ The Alkylphenols & Ethoxylates Research Council (APERC) is a North American organization whose mission is to promote the safe use of alkylphenols (APs) and alkylphenol ethoxylates (APEs), including NP through science-based research, product stewardship and outreach efforts, within the framework of responsible chemical management. www.aperc.org.

² Science Advisory Board Drinking Water Committee (SAB DWC). (2015, September 4). Draft Report for Quality Review: Review of EPA's Draft Fourth Contaminant Candidate List (CCL4). <http://yosemite.epa.gov/sab/sabproduct.nsf/ea5d9a9b55cc319285256cbd005a472e/b4af29cc838f2c6085257eb60070020a!OpenDocument>

³ U.S. EPA (2014, February 4) Notice: Fourth Drinking Water Candidate Chemical List - Draft [Federal Register](#) Vol. 80 No. 23 pp 6076 -6084.

⁴ Science Advisory Board Drinking Water Committee (SAB DWC). (2015, June 30). Draft Report on the EPA Draft Fourth Candidate Contaminant List (CCL4). <http://yosemite.epa.gov/sab/SABPRODUCT.NSF/ea5d9a9b55cc319285256cbd005a472e/e569f409bd01a2bd85257e750065db47!OpenDocument>

⁵ SAB DWC. (2015, September 4).

APERC submitted extensive written comments in response to EPA's Draft CCL4.⁶ These written comments were provided in support of a public statement that I made on behalf of APERC at the public meeting of SAB DWC on April 29, 2015.⁷ In short, my statement to the SAB DWC pointed out that EPA's assessment of NP for the draft CCL4 was based on an erroneous Lowest Observed Adverse Effect Level (LOAEL) value of 2 mg/kg-bw/day due to the fact that EPA had not investigated whether this value was in fact a true LOAEL by reviewing the primary source related to this value. As a result, an incorrect toxicity category was derived for NP.

In addition to explaining why NP does not meet the criteria for inclusion on the draft CCL4, this error with NP was provided to the SAB DWC as an example of transparency and process issues related to the data used in the CCL4 selection process. It also served to demonstrate limitations related to reliance on the RTECS[®] database as a data source for the CCL process. The NP example highlighted issues that the RTECS[®] database has with transcription of data from primary sources. At the April 29, 2015 public meeting of the SAB DWC, APERC recommended that the SAB DWC consider that review of the primary source material is necessary to confirm or clarify values used in the development of the CCL4 and further suggested that a more robust review of the available literature on CCL candidate chemicals would be preferable.⁸ In the case of NP, review of the primary source for the data cited in the RTECS database would have changed its toxicity categorization and it would not have met the thresholds for listing in the draft CCL4.

Following its April 29, 2015 public meeting, the SAB DWC released a Draft Report on the EPA's Draft CCL4 dated June 30, 2015, which acknowledged and supported APERC's recommendation with the following passage on page 15 lines 12-16.

*"There are two chemical contaminants that the SAB recommends for reconsideration. The first is nonylphenol. At the meeting a public commenter noted that there was an editorial error in the data that were used in the determination of whether nonylphenol should be included on the CCL. The SAB recommends that the agency assess the primary sources of the nonylphenol data to confirm or refute this claim and update the assessment for this contaminant accordingly."*⁹

⁶ Alkylphenols & Ethoxylates Research Council (APERC). (2015, February 4). Comments on US EPA Draft Drinking Water Contaminant Candidate List 4.

⁷ Losey, Barbara, Deputy Director, Alkylphenols & Ethoxylates Research Council. (2015, April 29) Statement at the Public Meeting of the US EPA Science Advisory Board Drinking Water Committee.

⁸ Losey, B. (2015, April 29).

⁹ SAB DWC. (2015, June 30). Draft Report on the EPA Draft Fourth Candidate Contaminant List (CCL4). <http://yosemite.epa.gov/sab/SABPRODUCT.NSF/ea5d9a9b55cc319285256cbd005a472e/e569f409bd01a2bd85257e750065db47!OpenDocument>

This passage, and any reference to NP, are missing from the revised Draft SAB DWC Report on EPA's Draft CCL4 dated September 3, 2015.¹⁰ There is no suggestion or explanation for the removal of this recommendation in the "Summary of Comments from Drinking Water Committee Members on the June 30, 2015 Draft Report on CCL4 for Discussion on the August 3, 2015 DWC Teleconference" or elsewhere.¹¹ Removal of this recommendation for NP was related to a discussion on the August 3, 2015 call of the SAB DWC related primarily to public comments received on Toluene Diisocyanate (TDI), which concluded with the SAB DWC deciding not to make recommendations in their report to EPA about any chemicals that should be removed or added to the draft CCL4. The SAB DWC's rationale was that they lacked full knowledge of the scientific literature on all the chemicals in the draft CCL4 to make specific chemical recommendations. Consequently, it was also decided that the SAB DWC's prior recommendation (June 30, 2015) on NP should be removed from the next draft of the report.

APERC views this reasoning by the SAB DWC as contrary to their mandate to respond to the charge questions posed to them and inconsistent with other recommendations made in the September 3, 2015 version of their report for the following reasons:

1. The SAB does not need have to have full knowledge of all the available literature on specific chemicals in order to make recommendations in response to specific public comments directed at them during a public meeting.

In the case of comments provided by APERC at the Drinking Water SAB public meeting on April (i.e., EPA should check primary sources and not just lift data from RTECs), the recommendation was process related and required no further knowledge of the compound in question. It is reasonable to expect that the SAB DWC could form an opinion at least about that process issue. In fact, the SAB DWC recommendation in the June 30th version of the report primarily addressed this process issue and recommended that EPA check the primary source for the LOEC selected for NP in order to confirm or refute the public comments.

2. SAB DWC members are selected with the expectation that they will bring some expertise related to the relevance of contaminants, including chemicals, to drinking water; in the case of NP, at least one member of the SAB DWC co-authored a published report that addressed the occurrence and toxicological relevance of NP in drinking

¹⁰ SAB DWC. (2015, September 3).

¹¹ SAB Drinking Water Committee (SAB DWC). (2015, August 3) Summary of Comments from DWC Members on the June 30, 2015 Committee Draft Report on CCL4.
[http://yosemite.epa.gov/sab/SABPRODUCT.NSF/29A4492543050FBC85257E92005C7EA2/\\$File/Discussion+Topics+for+Aug+3+call.pdf](http://yosemite.epa.gov/sab/SABPRODUCT.NSF/29A4492543050FBC85257E92005C7EA2/$File/Discussion+Topics+for+Aug+3+call.pdf)

water, confirming there was sufficient expertise on this chemical represented on the SAB DWC.¹²

3. Despite their intention not to make recommendations about chemicals, the SAB DWC does in fact make recommendations about chemicals that should be removed or added to the draft CCL4 in the September 3rd version of their report, indicating that they do have the ability to make specific recommendations about specific contaminants without having to have full knowledge of any or all chemicals listed in the draft CCL4 report.

For example, the SAB DWC used their knowledge about the occurrence of estrogen hormones from data collected to date under the Third Unregulated Contaminant Monitoring Rule (UCMR3) as well as specific knowledge about rodent studies on these hormones to suggest that they be deprioritized in the public meeting and as below in the Sept. 4th version of their report.

"An example in which UCMR data can inform the CCL 4 is for estrogen hormones. For instance, for the 24 estrogen steroid hormones equilin and estrone, not one sample in the 7,169 evaluated in UCMR3 had a 25 positive detection at 4 and 2 ng/L, respectively. Estradiol, ethynylestradiol, and estriol all had sub-ng/L 26 method reporting levels, yet were only detected in 3, 3, and 1, respectively, out of 7,169 tests conducted. 27 Only one hit for estradiol appears to exceed the health reference level; however, this HRL is taken from studies in rodents (Highman et al. 1980) in which dose response is not clear and the shorter term study was used to calculate the cancer risk despite the availability of longer term exposure studies. Thus, prudent use of UCMR data could potentially eliminate these estrogen hormones from the CCL, or tag 31 them as low priority for listing."¹³

Also, the SAB DWC recommended "the agency should consider adding more disinfection byproducts to the CCL, considering their potential human toxicity and frequency of occurrence in public drinking water systems."¹⁴

Considering that the SAB DWC has, or should have, sufficient knowledge to make recommendations about chemicals that should be removed or added to the CCL4, APERC urges the Chartered SAB to send the September 4th report back to the SAB DWC with a request that they properly address the charge questions related to listed candidate chemicals that do not

¹² Snyder, S.A., Trenholm, R.A., Snyder, E. M., Bruce, G.M., Bennett, E., Pleus, R.C., Hemming, J.D.C. (2008). Toxicological Relevance of EDCs and Pharmaceuticals in Drinking Water. Awwa Research Foundation, Denver, CO.

¹³ SAB DWC. (2015, September 3).

¹⁴ SAB DWC. (2015, September 3).

merit listing and chemicals that should be considered for listing. APERC also specifically requests that the SAB DWC recommendation regarding NP in the June 30th report be reinserted into the report. Finally, APERC requests that the Chartered SAB request that the SAB DWC consider the data transparency issue raised by the example of NP. The addition of a process step requiring review of primary data sources cited by EPA to justify listing a chemical on the CCL does not add a significant burden to the agency and a process that ensures the use of scientifically valid information is warranted, particularly in light of the significance of a CCL listing.

Thank you again for your time and consideration of these comments.