Re: Request for Correction: “Drinking Water: Regulatory Determination on Perchlorate”

The U.S. Chamber of Commerce (Chamber) submits this request for correction (RFC) of information developed and relied upon by the Environmental Protection Agency (EPA or Agency) to support its determination to regulate perchlorate under the Safe Drinking Water Act (SDWA). 76 Fed. Reg. 7762. As described by this RFC, EPA’s determination to regulate perchlorate improperly relied upon data that is not objective. The Chamber seeks correction of this information, as it complies with neither the Information Quality Act (IQA) as implemented under Office of Management and Budget (OMB) guidelines nor EPA guidelines. Treasury & General Governmental Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554 § 515(a); 44 U.S.C. § 3516 (notes).

EPA’s reliance on flawed, non-objective data sunders the factual foundation of its determination to regulate perchlorate.

To regulate a drinking water contaminant under the SDWA, EPA must find that the contaminant occurs with a frequency and at levels of public health concern in public water systems. 42 U.S.C. § 300g-1(b)(1)(A)(i). Had EPA relied upon objective occurrence data available at the time of the regulatory determination, it is likely that EPA would not have been able to make the required finding, and thus would not have made a corresponding decision to regulate perchlorate.
1. **Requester Identity and Information**

   The Chamber is the world’s largest business federation, representing the interests of more than three million businesses and organizations of every size, sector, and region. The Chamber’s broad membership base includes large and small companies—more than 96 percent of Chamber members are small businesses with 100 employees or fewer—trade associations, and chambers of commerce.

   The Chamber includes member companies engaged in the use, manufacture and sale of products containing perchlorate. Other Chamber members rely on water supplies delivered by public water systems of all sizes. A number of these companies will be directly affected by EPA’s regulatory determination, guidance and other actions that utilize the erroneous information this RFC seeks to correct. And nearly every Chamber member would be subject to higher costs for core business activities, necessitated by the imposition of costs resulting from unnecessarily expensive perchlorate regulations.

   Pursuant to the IQA, the Chamber is an affected person that seeks to obtain correction of information maintained and disseminated by EPA that does not comply with OMB and EPA Guidelines. The Chamber’s main point of contact for this RFC is:

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2. **Description of the Information**

EPA made the following findings based on the UCMR 1 data:

- “EPA found that 160 (approximately 4.1 percent) of the 3,865 PWSs that sampled and reported had at least 1 analytical detection of perchlorate (in at least 1 sampling point) at levels greater than or equal to the MRL [method reporting level] of 4 ug/L.” 76 Fed. Reg 7764-65 & Table 1.

- EPA estimated the number of people exposed to perchlorate above various concentrations levels. For example, EPA estimated that 5.1 million people (central value estimate) were served by a public water system that had a least one detection of perchlorate above 4 ug/L, and that 3.0 million people (central value estimate) were served by a public water system that had at least one detection above 6 ug/L. 76 Fed. Reg. 7765 & Table 2. EPA provided similar estimates at concentration levels of 9, 14, 19 and 23 ug/L.

- “Based on the data in Table 1 and the range of HRLs [health risk levels], EPA has determined that perchlorate is known to occur or there is a substantial likelihood that it will occur with a frequency and at levels of public health concern.” 76 Fed. Reg. 7765.

The information contained in the regulatory determination for perchlorate, described above, meets the OMB definition of “information.” “‘Information’ means any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic . . . .” OMB Guidelines § V.5; 67 Fed. Reg. 8460. The UCMR 1 data contained in the regulatory determination was presented in textual, tabular and numerical form.

The information at issue also meets the OMB definition of “influential” information. “Influential” means: “that the agency can reasonably determine that the dissemination of the information will have or does have a clear and substantial impact on important public policies . . . .” OMB Guidelines § V.9; 67 Fed. Reg. 8460. EPA directly relied upon the UCMR 1 data in making findings regarding the occurrence of perchlorate in public water systems and in determining to regulate perchlorate under the SDWA. OMB has stated that “influential information” should be held to a heightened standard of quality. 67 Fed. Reg. 8452.
3. **How the Information Does Not Comply**


The OMB Guidelines also state that in “a scientific, financial or statistical context, the original and supporting data shall be developed using sound statistical and research methods.” *Id.* With respect to the use of data, the preamble to the final OMB Guidelines states that:

We note, in the scientific context, that in 1996 the Congress, for health decisions under the Safe Drinking Water Act, adopted a basic standard of quality for the use of science in agency decision making. Under 42 U.S.C. 300g-1(b)(3)(A), an agency is directed, “to the degree that an Agency action is based on science,” to use “(i) the best available peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).” 67 Fed. Reg. 8457 (emphasis added). OMB included these congressional standards in its Guidance by reference and made them applicable to all agencies subject to the OMB Guidelines. 67 Fed. Reg. 8557. *See also,* OMB Guidelines § V.3.b.ii.C; 67 Fed. Reg. 8560. As a result, the data used in making the regulatory determination for perchlorate was required to be collected by accepted methods or, in certain circumstances, by best available methods.

As discussed in more detail below, a substantial portion (31 percent) of the UCMR 1 data, which EPA relied upon in deciding to regulate perchlorate, was not collected by the accepted method, as described in the UCMR regulations. Data that is not collected in conformance with accepted methods is not reliable. In addition, recent, comprehensive data collected from public water systems in California (which was available at the time the regulatory
determination was made) demonstrates that the occurrence of perchlorate in public water systems is very much lower than the UCMR 1 data set indicates. This more recent data demonstrates that the UCMR 1 perchlorate data is inaccurate and biased.

A. The UCMR 1 Data Does Not Comply with Data Quality Guidelines Because it was Not Collected By Accepted Methods

The regulatory determination for perchlorate was based on the UCMR 1 data set. However, as shown below, the UCMR 1 data for perchlorate was unreliable, because a significant portion of it was collected contrary to the methodology required by the UCMR regulations. Because the UCMR 1 data was unreliable, it should not have formed the basis for the perchlorate regulatory determination. Instead, EPA should have conducted the necessary research to locate or develop a reliable set of data upon which to base the regulatory determination.

The UCMR regulations prescribe the accepted method of collecting occurrence data—the data must be collected at the point the water enters the distribution system—i.e., after the water has passed through any treatment or blending facilities operated by the relevant water system.

According to the UCMR regulations, samples for perchlorate were to be collected at the entry point to the distribution system after treatment, representing each non-emergency water source in routine use during the twelve-month period of monitoring.  The sampling location for chemical contaminants must be the entry point to the distribution system or the compliance monitoring point specified by the State or EPA under 40 CFR 141.24(f)(1), (2), and (3). If the compliance monitoring point as specified by the State is for source (raw) water and any of the contaminants in paragraph (a)(3) of this section [the twelve UCMR 1 listed contaminants, which includes perchlorate] are

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1 According to the UCMR 1 regulations, assessment monitoring was to be conducted for twelve contaminants, including perchlorate, by all 2,774 PWSs serving more than 10,000 persons, and by a representative sample of approximately 800 small PWSs serving 10,000 or fewer persons. 64 Fed. Reg. 50612, 50614. More specifically:

- The sampling location for chemical contaminants must be the entry point to the distribution system or the compliance monitoring point specified by the State or EPA under 40 CFR 141.24(f)(1), (2), and (3). If the compliance monitoring point as specified by the State is for source (raw) water and any of the contaminants in paragraph (a)(3) of this section [the twelve UCMR 1 listed contaminants, which includes perchlorate] are
detected, then you [the public water system] must also sample at the entry point to the distribution system at the frequency indicated in paragraph (a)(5)(ii)(B) of this section with the following exception: If the State or EPA determines that sampling at the entry point to the distribution system is unnecessary because no treatment was instituted between source water and the distribution system that would affect the measurement of the contaminants listed in paragraph (a)(3) of this section, then you do not have to sample at the entry point to the distribution system.

40 CFR § 141.40(a)(5)(ii)(C); 64 Fed. Reg. 50617 (emphasis added). In other words, at locations where contaminants are present, sampling must be conducted at the point of entry to the distribution system. The only exception is where EPA or the State determines that there is a “pass-through” situation—where the contaminant concentration would be the same at the sample collection point and at the entry point into the water distribution system.

In contrast to these requirements, 31 percent of UCMR 1 samples were not collected at the entry point into the distribution system. Instead, they were collected from untreated source water. Brandhuber et al., *A review of perchlorate occurrence in public drinking water systems*, AWWA Journal (Nov. 2009) at 67 (Exhibit A). The review conducted by Brandhuber et al. demonstrates that the UCMR 1 data was not collected by “accepted methods,” “best available methods,” or “sound research methods.”

Data that is not collected in accordance with accepted methods is not reliable. The purpose of a sampling methodology is to control data collection so results are reproducible and reflect actual conditions. In the preamble to the final UCMR 1 regulation, EPA stated that specifying a sampling point “will ensure a nationally consistent data set and will provide consistent data for exposure assessment.” 64 Fed. Reg. 50571. In the case of perchlorate, 31 percent of the samples were collected from the incorrect location and are thus not consistent with the remainder of the data. This does not “provide consistent data for exposure assessment.”

As one might expect, perchlorate was detected with greater frequency in samples collected from untreated source water than it was in water collected at the entry point to the distribution systems. In fact, perchlorate was detected in 2.7 percent of samples collected from untreated source water, while perchlorate was detected in only 1.5 percent of samples collected from the entry point to the distribution system.
Intertox, Inc., *Comments in Response to EPA Notice* (Oct. 8, 2009) at 24 (Exhibit B). In other words, perchlorate was detected almost twice as often in untreated source water than it was at the point of entry into the water distribution systems. **This is a strong indication that the collection of a significant portion of the UCMR 1 samples from raw, untreated water sources rendered the UCMR 1 data set unreliable.**

**B. The UCMR 1 Data Does Not Comply with Data Quality Guidelines Because it is not Representative of Current Conditions**

More accurate and reliable data on perchlorate occurrence is available—and was available at the time of the regulatory determination—from public water systems in California than what EPA used to make its determination.

Most of the water sources that the UCMR 1 data indicated were impacted by perchlorate are located in California. More recent data from California public water systems demonstrates that the actual occurrence of perchlorate at the time of the regulatory determination is very much lower than indicated by the UCMR 1 data.

In its regulatory determination for perchlorate EPA stated that, based on UCMR 1 data, 16.6 million people (high end estimate) were served by public water systems with at least one detection of perchlorate above 4 ug/L and that 11.8 million people (high end estimate) were served by systems with at least one detection above 6 ug/L. 76 Fed. Reg. 7765. (The central value estimates of the population served by water above 4 ug/L was 5.1 million; and the central value estimate served by water above 6 ug/L was 3.0 million).\(^2\) *Id.*

Malcolm Pirnie, Inc. consolidated the UCMR 1 data upon which EPA relied in making its regulatory determination. Malcolm Pirnie, *National Cost Implications of a Potential Perchlorate Regulation* (AWWA July 2008) at Appendix A (Exhibit C). According to Malcolm Pirnie, a total of 189 water sources had at least one sample of perchlorate above 6 ug/L. *Id.* Of these, 112 were located in California and 77 were located in other states. *Id.* Using EPA’s methodology for calculating high end estimates, along with population data from EPA’s Safe Drinking Water Information System (SDWIS) and EPA’s UCMR 1 database, it can be determined that of the 11.8

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\(^2\) The high end estimate was derived by adding the entire population served by all public water systems in which at least one sample was found to contain perchlorate above the threshold. 76 Fed. Reg. 7765. The central value estimate was developed by assuming that the population served by the public water system was equally distributed among all entry points to the distribution system, and adding together only that proportion of the population served by those entry points that had at least one perchlorate sample above the threshold. *Id.*
million people served by public water systems with at least one detection above 6 ug/L, at least 4.2 million resided in California. See, Worksheet (Exhibit D).

Recent perchlorate occurrence data is available for all public water systems in California. Each quarter, the California Department of Public Health (CDPH) submits data to EPA’s Safe Drinking Water Information System (SDWIS). CDPH, Annual Compliance Report (2009) (Exhibit E). The data submitted includes data regarding violations of maximum contaminant levels (MCLs). In California, a state MCL of 6 ug/L has been adopted for perchlorate. Public water systems in California are required to report perchlorate MCL violations to CDPH and, in turn, CDPH provides EPA with its annual compliance report, which includes data on MCL violations. Id. The 2009 Annual Compliance Report is the most recent annual report that has been made publicly available by CDPH. The perchlorate data collected by public water systems in California provides a more recent, accurate, reliable and complete data set for assessing perchlorate occurrence in California than the UCMR 1 dataset.3

CDPH’s 2009 Annual Compliance Report shows that only nine public water systems in California exceed the state MCL of 6 ug/L for perchlorate. CDPH, Annual Compliance Report (2009) at Appendix C (Exhibit E). All of these systems were very small systems, and the total population served by these systems is 776 people. Id. Thus, the actual population in California that is served by public water systems with at least one detection of perchlorate above 6 ug/L, according to the most recently available CDPH data, is 776 people. This contrasts sharply with the estimate, based on UCMR 1 data, that 4.2 million people (high end estimate) in California are served by water systems with at least one detection above 6 ug/L. The UCMR 1 data, which EPA published in its regulatory determination and upon which EPA relied in making its determination to regulate perchlorate, therefore does not satisfy the definition of “objectivity” set forth in the OMB Guidelines.

The OMB Guidelines state that “objectivity” involves a focus on ensuring accurate, reliable, and unbiased information. OMB Guidelines § V.3.b; 67 Fed. Reg. 8459. The estimate that 4.2 million people in California are served by water systems with at least one detection above 6 ug/L—an estimate that overstates the actual

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3 Because most of the California data is provided in relation to the state’s 6 ug/L MCL, the best point of comparison between current California occurrence data and the old UCMR 1 data is at the 6 ug/L level. Nonetheless, helpful comparisons can also be made at most of the other levels EPA has referenced (e.g., 9, 14, 19 and 23 ug/L).
number of persons exposed to perchlorate by a factor of more than 5,000—is clearly inaccurate and biased. The actual number of people in California served water containing perchlorate above 6 ug/L was readily ascertainable at the time the regulatory determination for perchlorate was published in the Federal Register.

Thus, while it is clear the UCMR 1 occurrence data upon which EPA relied does not meet the requirements of the OMB Guidelines, what is not clear is why EPA elected to rely upon the UCMR 1 data instead of more recent readily available data.

Several events transpired since the collection of UCMR 1 data that also should have put EPA on notice that the occurrence of perchlorate was significantly less at the time it issued its regulatory determination than it was at the time of the UCMR 1 sampling. These events included:

- Several states adopted advisory or regulatory levels for perchlorate before the regulatory determination was made, including Arizona, California, Maryland, Massachusetts, Nevada, New Mexico, New York and Texas. EPA, *State Perchlorate Advisory Levels* (Apr. 20, 2005) (Exhibit F).

- Levels of perchlorate in the Colorado River, which is the source of water for approximately 20 million people in the southwest, declined significantly in the interim due to remediation efforts in Nevada. According to the Nevada Division of Environmental Protection, perchlorate concentrations declined from 9.7 ppb in June 1999 to 1.8 ppb in May 2008 (Exhibit G). Nevada DEP, *Southern Nevada Perchlorate Cleanup Project*

These events, which were well known, should have alerted EPA to the fact that the UCMR 1 perchlorate occurrence data collected between 2001 and 2003 was no longer an accurate measure of perchlorate occurrence at the time the regulatory determination was made in 2011. The systemic problem with the California occurrence data undermines the validity of the entire UCMR 1 data set because there were more detections of perchlorate in the UCMR 1 data set in California than in all other states combined.

Moreover, the problems with the UCMR 1 data set are not limited to California—there are data quality problems outside of California as well:

- During UCMR 1 sampling, the Manatee County, Florida water system had one sample that reported a concentration of 21.0 ug/L. Malcolm Pirnie, *National Cost*
Implications of a Potential Perchlorate Regulation, at 28 & Appendix A (Exhibit C). Manatee County reported that this one sample was attributable to analytical errors. Id. No perchlorate has been detected in water delivered by Manatee County outside of this one false positive. Id. The Manatee County water system serves 447,382 people, according to EPA’s SDWIS database. It thus appears that 447,000 people that were counted as being exposed to perchlorate at levels above 4, 6, 9, 14 and 19 ug/L in the regulatory determination actually were not exposed above those levels.

- The UCMR 1 data indicates the City of Henderson, Nevada delivered water with concentrations of perchlorate up to 20 ug/L. Malcolm Pirnie at Appendix A. However, in its most recent publicly available consumer confidence report, the City of Henderson reports that it does not deliver water above 5.9 ug/L. City of Henderson, Water Quality Report (2008) (Exhibit H). This decline is undoubtedly due to the declining concentrations of perchlorate in the Colorado River, which is the source of Henderson’s drinking water. The City of Henderson water system serves 246,000 people, according to EPA’s SDWIS database. It thus appears that an additional 246,000 people that were counted as being exposed to perchlorate at levels above 6, 9, 14 and 19 ug/L in the regulatory determination actually were not exposed above those levels.

- The UCMR 1 data indicates the City of Midland, Texas delivered water with concentrations of perchlorate up to 7.9 ug/L. Malcolm Pirnie at 29 & Appendix A (Exhibit C). At the time the UCMR 1 data was collected, Midland was recharging a largely dry well field with water from a more distant source during the winter, and then pumping the well field to satisfy peak summer demand. Id. That practice, which caused perchlorate to enter the City’s water supply, has since been discontinued and there is currently no detectible perchlorate in the Midland system. Id. The City of Midland water system serves 111,147 people, according to EPA. It thus appears that 111,000 people that were counted as being exposed to perchlorate at levels above 4 and 6 ug/L in the regulatory determination actually were not exposed above those levels.

- The UCMR 1 data indicates the City of High Point, North Carolina delivered water with concentrations up to 13.8 ug/L, based on one sample result; all other samples collected in the High Point system did not detect perchlorate. Malcolm Pirnie at 28 & Appendix A (Exhibit C). The laboratory that analyzed this sample has since confirmed the detection was a false positive. Id. Thus, there is and was no detectible perchlorate in the City of High Point water system. The City of High Point water
system serves 104,000 people, according to EPA. It thus appears that an additional 104,000 people that were counted as being exposed to perchlorate at levels above 4, 6, and 9 ug/L in the UCMR 1 dataset actually were not exposed above those levels.

These four drinking water systems, which are discussed in the Malcolm Pirnie report, serve approximately 900,000 people. The UCMR 1 database reports that all four of these systems served water containing perchlorate at concentrations above 6 ug/L. However, the investigations conducted by Malcolm Pirnie establish that none of the 900,000 people served by these four systems are being provided water containing perchlorate above 6 ug/L.

Malcolm Pirnie did not conduct a comprehensive analysis of which public water systems that the UCMR 1 database reported as purveying water containing perchlorate currently purvey lower concentrations of perchlorate—or no perchlorate at all. Malcolm Pirnie only examined a very small number of large water systems to better estimate the nationwide costs of complying with a perchlorate drinking water regulation. Malcolm Pirnie at 26-29. Just in the course of its cost estimating work, Malcolm Pirnie uncovered these substantial inaccuracies in the UCMR 1 database. It is unknown what would be revealed by a more thorough review of the 160 public water systems that the UCMR 1 data set purports to show contain perchlorate.

Brandhuber et al. attempted to contact all 160 public water systems the UCMR 1 data set indicated purveyed drinking water containing detectable levels of perchlorate. Brandhuber et al. at 69-70. Key findings of this brief telephone survey were as follows: (a) 70 of the 160 system operators responded to the survey; (b) 12 systems reported that their drinking water did not contain perchlorate; (c) 13 systems have taken a total of 32 contaminated sources off-line; and (d) 9 systems were blending contaminated sources with other water. These actions would have decreased or eliminated perchlorate contamination in a significant fraction of the 160 affected public water systems.

Based on the above, it is likely that the perchlorate occurrence numbers that EPA published for other exposure levels (i.e., 4, 9, 14, 19, and 23 ug/L) are also inaccurate and biased. This conclusion is supported by the following:

- As mentioned above, several states adopted advisory or regulatory levels for perchlorate, including Arizona, California, Maryland, Massachusetts, Nevada, New Mexico, New York and Texas. EPA, *State Perchlorate Advisory Levels* (Apr. 20, 2005)
(Exhibit E). The adoptions of these levels would have reduced perchlorate concentrations in public water systems.

- Levels of perchlorate in the Colorado River, which is the source of water for approximately 20 million people in the southwest, have been declining for over a decade. Nevada DEP, *Southern Nevada Perchlorate Cleanup Project* (Exhibit F). The declining concentrations in the Colorado River also would have tended to reduce perchlorate concentrations in the many public water systems that use water from the Colorado River.

- In its regulatory determination, EPA stated 1.6 million people (high end estimate) were exposed to drinking water above 19 ug/L. Data from UCMR 1 purports to show that the following six California cities purveyed drinking water above 19 ug/L: Chino, La Verne, Pasadena, Redlands, Rialto and Riverside. The combined total population served by these water systems is 683,782, according to EPA’s Safe Drinking Water Information System (SDWIS). Malcolm Pirnie shows UCMR 1 also included Manatee County and High Point as water systems purveying water above 19 ug/L, even though those systems did not actually purvey water containing perchlorate. The combined population served by these two water systems is 693,382, according to EPA’s SDWIS database. CDPH and Malcolm Pirnie have shown that none of these water systems is actually purveying water above 19 ug/L. Combined, these eight water systems serve 1.38 million people.

Assuming no other errors, a more accurate high end estimate of the number of people exposed to perchlorate above 19 ug/L would be 220,000 (1.6 million minus 1.38 million). This contrasts sharply with the 1.6 million figure published by EPA in the Federal Register and relied upon in making the regulatory determination.

In sum, the UCMR 1 dataset is outdated, inaccurate, unreliable and very significantly biased (to the high side). As a result, the data set does not qualify as objective data as mandated by the IQA. Because the UCMR 1 data was not objective, it should not have formed the basis for the perchlorate regulatory determination. EPA should instead have researched and collected accurate, reliable and unbiased data. Failing that, EPA's regulatory determination on perchlorate cannot stand.

4. **Recommendation of Corrective Action**
The Chamber recommends the following corrective actions:

- Due to the very serious data quality errors in the UCMR 1 data set, EPA should publish in the Federal Register a notice retracting the data that appears in the perchlorate regulatory determination at 76 Fed. Reg. 7764-65;

- EPA should withdraw the regulatory determination itself, as there are no accurate, reliable or unbiased data to support it; and

- EPA should re-analyze the number of persons exposed to perchlorate in public water systems with: (1) data collected more recently than the UCMR 1 data; (2) data collected in accordance with accepted methods; and (3) data that is accurate, reliable and unbiased.

5. **Effect of the Error**

In order for EPA to regulate any substance under the SDWA, the Administrator must make three basic determinations. One of those determinations is that “the contamination is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern.”

The principal effect of the errors in the UCMR 1 data set, with respect to perchlorate, is that EPA—relying on the UCMR 1 data set—made a determination to regulate perchlorate. It is clear, based on the most recent data from California public water systems, and the information brought forward by Malcolm Pirnie, that perchlorate likely does not occur with a frequency and at levels of public health concern in public water systems. It appears that current, reliable, accurate and unbiased data was available to EPA at the time it made its regulatory determination for perchlorate. If EPA had relied on that data, EPA would likely have made a determination not to regulate perchlorate.
Because EPA’s determination to regulate perchlorate in drinking water is not based on current, accurate, complete, reliable and unbiased data, the Chamber is entitled to submit this stand-alone RFC. Pursuant to EPA Guidelines, the Chamber requests within 90 days the correction sought by this RFC. If EPA requires more than 90 calendar days, please provide the Chamber notice that more time is required, an explanation, and an estimated decision date. You may reach me at (202) 463-5457 or wkovacs@uschamber.com.

Sincerely,

William L. Kovacs