

CHAMBER OF COMMERCE  
OF THE  
UNITED STATES OF AMERICA

WILLIAM L. KOVACS  
SENIOR VICE PRESIDENT  
ENVIRONMENT, TECHNOLOGY &  
REGULATORY AFFAIRS

1615 H STREET, N.W.  
WASHINGTON, D.C. 20062  
(202) 463-5457

September 18, 2012

Information Quality Guidelines Staff (Mail Code 2811R)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
[quality@epa.gov](mailto:quality@epa.gov)

**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)(ii). 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:

William L. Kovacs  
Senior Vice President, Environment, Technology & Regulatory Affairs  
U.S. Chamber of Commerce  
1615 H Street, NW  
Washington, DC 20062  
(202) 463-5457  
[wkovacs@uschamber.com](mailto:wkovacs@uschamber.com)

## **2. Description of the Information**

EPA published its regulatory determination for perchlorate on February 11, 2011. 76 Fed. Reg. 7762. EPA relied on data collected during the first Unregulated Contaminant Monitoring Rule (UCMR 1) in making its regulatory determination. EPA stated that it “collected and analyzed drinking water occurrence data for perchlorate from 3,865 PWSs [public water systems] between 2001 and 2005 under UCMR 1.” 76 Fed. Reg. 7764.

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

In order for data to have the requisite quality, it must be accurate, reliable and unbiased. According to the OMB Guidelines: “Quality’ is an encompassing term comprising utility, objectivity, and integrity.” OMB Guidelines § V.1; 67 Fed. Reg. 8459. Further: “Objectivity’ involves two distinct elements, presentation and substance.” OMB Guidelines § V.3; 67 Fed. Reg. 8459. With regard to substantive objectivity: “objectivity’ involves a focus on ensuring accurate, reliable, and unbiased information.” OMB Guidelines § V.3.b; 67 Fed. Reg. 8459.

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.<sup>1</sup> 40 CFR § 141.40(a) & Table 1; 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

---

<sup>1</sup> 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. 50561. Assessment monitoring was to be conducted by each PWS over a 12-month period between 2001 and 2003. *Id.* As it turned out, some sampling was conducted after 2003, and the number of systems sampled differed slightly from that set forth in the regulations. 76 Fed. Reg. 7764.

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).<sup>2</sup> *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

---

<sup>2</sup> 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.<sup>3</sup>

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

---

<sup>3</sup> 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 detectible 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.

-----

Information Quality Guidelines Staff

September 18, 2012

Page 14 of 14

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](mailto:wkovacs@uschamber.com).

Sincerely,

A handwritten signature in black ink, appearing to read "William L. Kovacs". The signature is written in a cursive style with a large initial "W".

William L. Kovacs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

FEB 28 2013

OFFICE OF WATER

William L. Kovacs  
Senior Vice President, Environment, Technology & Regulatory Affairs  
U.S. Chamber of Commerce  
1615 H Street, NW  
Washington, DC 20062

Dear Mr. Kovacs:

This is the response to your September 18, 2012, Information Quality Guidelines (IQG) Request for Correction (RFC 12004)<sup>1</sup>. In this letter, you requested correction of information developed and relied upon by the Environmental Protection Agency to support its determination to regulate perchlorate under the Safe Drinking Water Act (SDWA) and that the EPA withdraws the regulatory determination. The EPA's determination to regulate perchlorate is an interim step in the process that leads towards a final drinking water standard. Because the regulatory determination is not the end of a decision process and because the issues you raised with regard to the occurrence data also are integral to the development of the proposed drinking water standard for perchlorate, the EPA has chosen to use a parallel process to address several of the data issues that you have raised<sup>2</sup>. Specifically, the EPA will further evaluate available information on the occurrence of perchlorate in public water systems, including data provided in your RfC, to inform the Agency's Health Risk Reduction and Cost Analysis (HRRCA) for the proposed rule. We will reassess the first Unregulated Contaminant Monitoring Rule (UCMR1) data and more recent perchlorate occurrence studies (such as those from California Department of Public Health to which you refer) as part of this analysis. In that context, the EPA will carefully consider your comments and will provide an explanation of how we addressed these issues as a part of the proposed rule. The EPA will make this evaluation of the occurrence of perchlorate in public water systems available for review and comment at the time we propose the National Primary Drinking Water Regulation for perchlorate. You will have an opportunity to review and comment upon the EPA's updated analysis at that time.

The EPA is, however, responding to one aspect of the RfC here. Specifically, your letter suggests that source water monitoring data under the UCMR 1 do not comply with data quality guidelines because they were not collected by accepted methods. UCMR1 allows alternative source water sampling points if the State uses source water monitoring as a more stringent monitoring requirement (64 FR 50570). Notwithstanding the fact that some public water systems with source-water positives did not also collect samples at the entry point to the distribution system, as provided for in UCMR1, the EPA believes that

---

<sup>1</sup> RFC 12004, September 2012 <<http://epa.gov/quality/informationguidelines/documents/12004.pdf>>

<sup>2</sup> *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (October 2002); Section 8.5 (page 32) <[http://epa.gov/quality/informationguidelines/documents/EPA\\_InfoQualityGuidelines.pdf](http://epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf)>

the source water results serve as an indicator of likely perchlorate occurrence in drinking water. Furthermore, the OMB's Government Wide Information Quality Guidelines emphasize that the quality of information should be commensurate with the use to which the information will be put<sup>3</sup>. The EPA continues to conclude that the data were appropriate for use in the context of the regulatory determination for perchlorate. If you are not satisfied with this response relating to the appropriateness of the quality of the UCMR 1 data addressed in the prior paragraph, you may submit a Request for Reconsideration (RFR). The EPA requests that any such RFR be submitted within 90 days of the date of the EPA's response. If you choose to submit an RFR, please send a written request to the EPA Information Quality Guidelines Processing Staff via mail (Information Quality Guidelines Processing Staff, Mail Code 2811R, U.S. EPA, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460); electronic mail, [quality@epa.gov](mailto:quality@epa.gov); or fax, (202) 565-2441. Additional information about how to submit a RFR can be found on the EPA IQG website ([www.epa.gov/quality/informationguidelines](http://www.epa.gov/quality/informationguidelines)).

Sincerely,



Nancy K. Stoner  
Acting Assistant Administrator

cc: Malcolm D. Jackson, Assistant Administrator and Chief Information Officer,  
Office of Environmental Information

---

<sup>3</sup>*Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (October 2002); Section 1 (page 3) <  
[http://epa.gov/quality/informationguidelines/documents/EPA\\_InfoQualityGuidelines.pdf](http://epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf)>

**CHAMBER OF COMMERCE  
OF THE  
UNITED STATES OF AMERICA**

**WILLIAM L. KOVACS**  
SENIOR VICE PRESIDENT  
ENVIRONMENT, TECHNOLOGY &  
REGULATORY AFFAIRS

1615 H STREET, N.W.  
WASHINGTON, D.C. 20062  
(202) 463-5457

May 28, 2013

**VIA ELECTRONIC FILING**

Information Quality Guidelines Staff (Mail Code 2811R)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
[quality@epa.gov](mailto:quality@epa.gov)

**Re: Request for Reconsideration of Information Quality Act Request  
for Correction Regarding “Drinking Water: Regulatory  
Determination on Perchlorate” (RFC 12004)**

On September 18, 2012, the U.S. Chamber of Commerce (“Chamber”) submitted a Request for Correction (“RFC”) under the Information Quality Act (“IQA”), asking EPA to correct information it published in the Federal Register regarding perchlorate occurrence in drinking water. 76 Fed. Reg. 7762 (Feb. 11, 2011). The information was not objective, within the meaning of the IQA, because it contained: (1) outdated information when more recent information was readily available; (2) information collected in violation of the directly applicable regulations; and (3) numerous outright data errors. EPA relied upon this information in making its determination to regulate perchlorate under the Safe Drinking Water Act.

On February 28, 2013, EPA responded to the Chamber’s RFC by denying the RFC (in part) and stating that EPA would address other issues raised in the RFC when it publishes its proposed perchlorate drinking water rule. The RFC was assigned RFC #12004 and is attached as Exhibit 1. EPA’s response to the RFC is attached as Exhibit 2.

As further discussed below, the information EPA published regarding perchlorate occurrence was based on an approximately ten-year old data set. More recent—and much more accurate—data was readily available at the time EPA published its information regarding perchlorate occurrence in the Federal Register. Further, 31 percent of the data in the data set was collected in violation of the regulations established for the collection of occurrence data under the Safe Drinking Water Act (i.e., the regulations governing collection of the specific data in question). Finally, the data has been found to contain numerous additional errors, including the reporting of false positive detections of perchlorate.

EPA did not substantively respond to the majority of the issues raised in the Chamber's RFC, stating that it would instead "use a parallel process to address several of the data issues." It violates the letter and the spirit of the IQA to use data that is not objective to initiate a significant regulatory process—a process that likely would not have been initiated in the first place if objective data had been used. The IQA requires that EPA correct the information it disseminated rather than continue using it.

EPA denied the Chamber's request that EPA correct information based on a data set collected in violation of its own regulations. EPA's regulations governing collection of contaminant occurrence data identify the specific location from which that data must be collected. EPA acknowledged that the data was not collected from the required location, but claimed that its violation of its own regulations is permissible under general guidelines issued by the Office of Management and Budget ("OMB"). This "close enough for horseshoes" response is lacking. EPA is required by law to follow its own regulations, and it cannot point to guidelines on a general topic from a different agency to justify violation of its own regulations that are directly applicable.

The Chamber seeks reconsideration of EPA's refusal to correct the information it published in the Federal Register and upon which it relied in making its determination to regulate perchlorate. The published information does not comply with the IQA<sup>1</sup> as implemented under OMB guidelines<sup>2</sup> and EPA guidelines.<sup>3</sup> EPA

---

<sup>1</sup> Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, P.L. 106-554; 44 U.S.C. §3516 (notes).

<sup>2</sup> Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452 (Feb. 22, 2002) ("OMB Guidelines").

<sup>3</sup> Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the Environmental Protection Agency, EPA/260R-02-2008 (October 2002) ("EPA Guidelines").

must correct the deficient information. Correction of the deficient information may result in reconsideration of the regulatory determination on perchlorate. However, that is the entire purpose of the IQA—to correct erroneous information so that regulatory decisions are based upon a sound scientific foundation. Any other outcome would result in an inefficient use of time and resources by EPA and all other stakeholders involved in the perchlorate rulemaking. Rather than spending resources on a regulatory process that is founded upon data that is not objective, EPA should correct the data.

## **I. Requester Identity and Information**

The United States Chamber of Commerce 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 state and local chambers of commerce. The Chamber has member companies engaged in the use and manufacture of products containing perchlorate. Other Chamber members depend on water supplies delivered by water supply systems of all sizes. Many of these companies will be directly affected by EPA's regulatory determination, guidance, and other actions that utilize the erroneous information the RFC seeks to correct. And virtually every Chamber member would be subject to increased costs if higher prices resulted from unnecessary new rules.

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

William L. Kovacs  
Senior Vice President, Environment, Technology & Regulatory Affairs  
U.S. Chamber of Commerce  
1615 H Street, NW  
Washington, DC 20062  
(202) 463-5457  
wkovacs@uschamber.com

## II. Background

### A. History of EPA's Decision

On February 11, 2011, EPA published information regarding the occurrence of perchlorate in public water systems in the Federal Register. 76 Fed. Reg. 7762. Based on that information, EPA made a determination to regulate perchlorate under the Safe Drinking Water Act. *Id.* In making its determination, EPA found that perchlorate was present in public water systems at a frequency and at levels of public health concern. The information EPA relied upon was based on data collected under the first Unregulated Contaminant Monitoring Rule (UCMR 1). The UCMR 1 data provided information from 3,865 public water systems during the 2001 to 2005 time period. 76 Fed. Reg. 7764. According to EPA, the UCMR 1 data showed that as many as 11.8 million people were served by a public water system that had at least one sample with perchlorate at or above the detection limit of 4 ug/l (parts per billion). On that basis, EPA found that there was a “substantial likelihood” that “perchlorate will occur with a frequency and at levels of public health concern.” 76 Fed. Reg. 7765.

### B. The Chamber's RFC

The Chamber identified significant data quality issues in the perchlorate occurrence information EPA published in the Federal Register and which formed the basis for EPA's regulatory decision. On September 18, 2012, the Chamber lodged a Request for Correction with EPA (RFC #12004). The Chamber's RFC, attached as Exhibit 1, raised three basic issues:

- (1) Nearly one-third of the UCMR 1 data, upon which the information published in the Federal Register was based, was not collected in conformance with EPA regulations governing the collection of perchlorate occurrence data. Instead of being collected at the point of entry into water distribution system piping, and after any pre-existing blending or treatment (thus reflecting water actually served to customers), 31 percent of the data was collected from raw water supplies.
- (2) The UCMR 1 data was approximately ten years old and was significantly out-of-date. More recent data was readily available at the time EPA made its regulatory determination on perchlorate but, for reasons unknown, EPA did not evaluate this more recent data, which showed significantly less perchlorate occurrence in public water systems. Had EPA examined the more recent data, it would have discovered, for example, that only about

776 residents of California were served by water systems with perchlorate detections above the state MCL of 6 ug/l and not the 3 million to 11.8 million indicated by the obsolete data set upon which EPA did rely. *See* 76 Fed. Reg. 7765 & Table 2.

- (3) The UCMR 1 data set included data based on erroneous laboratory reports and discontinued local water purveying practices. For example, Manatee County, Florida, and High Point, North Carolina reported one-time detections of perchlorate that were later determined to be the result of laboratory errors. In addition, Midland, Texas, and Henderson, Nevada, changed water purveying practices, substantially reducing or eliminating the presence of perchlorate in their drinking water systems. The information EPA published in the Federal Register incorporated uncorrected data based on these false positives and obsolete water purveying practices.

In brief, EPA disseminated information based on data that was out-of-date, improperly collected, and compromised by errors. EPA relied on this same information in deciding to regulate perchlorate. The Chamber requested that EPA publish a notice in the Federal Register retracting the erroneous information, and re-assess whether, based on the actual occurrence of perchlorate in public water supplies, regulation of perchlorate would be mandated by the Safe Drinking Water Act.

### C. EPA's Response to the RFC

On February 28, 2013, EPA responded to the Chamber's RFC. EPA did not directly address the Chamber's three recommendations for corrective action: (1) that EPA publish a notice retracting the information on perchlorate occurrence published in the Federal Register; (2) that EPA withdraw the regulatory determination for perchlorate because there is no objective information to support it; and (3) that EPA analyze and publish objective information on the occurrence of perchlorate in public water systems.

However, it is clear from context that EPA does not intend to publish a notice retracting the information on perchlorate occurrence it published in the Federal Register or withdraw the regulatory determination for perchlorate. Instead, EPA stated that it would "use a parallel process to address several of the data issues that [the Chamber] raised." EPA stated that it would further evaluate information on the occurrence of perchlorate to inform its health risk reduction and cost analysis ("HRRCA"). EPA also stated that it would reassess data from the UCMR 1 data set and more recent perchlorate occurrence data as part of that analysis. Finally, EPA

stated that it would make its evaluation of perchlorate occurrence in public water systems available for review and comment at the time it proposes its drinking water rule for perchlorate.

In its February 28, 2013 response EPA did respond “to one aspect of the RFC.” In particular, EPA responded to the Chamber’s position that occurrence data collected in violation of the UCMR 1 regulations cannot be considered to have been collected by “accepted methods” and is therefore not objective. In its response, EPA stated that notwithstanding that “some public water systems” did not collect samples “at the entry point to the distribution system, as provided for in UCMR1,” data collected from raw water “serve as an indicator of likely perchlorate occurrence in drinking water.” EPA referenced the OMB Guidelines for the proposition that “the quality of the data should be commensurate with the use to which the data will be put.” EPA then concluded that data collected in raw water “were appropriate for use in the context of the regulatory determination.”

### **III. Explanation of Disagreement with EPA’s Response to RFC**

#### **A. EPA Must Comply With Its Own Specific Regulations Governing Data Collection**

As pointed out in the Chamber’s RFC, EPA’s own regulations specifically require that UCMR monitoring data must measure what is actually entering the drinking water distribution system. That is, the data must reflect the water that is actually being sent to customers rather than the raw water received before blending or treatment. As the RFC explained, the UCMR clearly stated that the “sampling location **must be** the entry point to the distribution system,” subject only to certain exceptions not applicable here. *See* 40 C.F.R. § 141.40(a)(5)(ii)(C); 64 Fed. Reg. 50617 (emphasis added).

EPA does not contest this point or suggest that the data was collected in conformance with these regulatory requirements. Rather, EPA points to general OMB guidance to excuse its failure to comply with its own regulations and urges that the OMB guidance allows EPA to rely on lower quality information. This represents a fundamental misunderstanding of both the OMB guidelines and the relevant administrative law. First, the OMB guidelines “recognize that some government information may need to meet higher or more specific information quality standards,” and expressly identify “influential scientific, financial, or statistical information” as

information requiring such treatment.<sup>4</sup> *Id.* at 8452-53. UCMR 1 data constitutes “influential scientific information” within the meaning of the OMB guidelines. Each agency is required to “adopt specific standards of quality that are appropriate for the various categories of information they disseminate.” *Id.* at 8458-59.

Here, EPA adopted specific standards of quality for UCMR 1 data. As noted above, EPA’s regulations state that UCMR 1 data “**must be**” collected at the “entry point to the distribution system.” 40 C.F.R. § 141.40(a)(5)(ii)(C). The regulations even list two exceptions—neither of which is applicable here. Under established interpretive rules, the expression of specific exceptions means that they are the **only** exceptions.<sup>5</sup>

EPA’s choice of the entry point as the sampling location is specified in regulations promulgated following notice and comment and carries the force and effect of law. EPA’s technical guidance explaining the UCMR states that the entry point to the distribution system is “the preferred sampling location for a program such as the UCMR that needs to assess human exposure through drinking water.” *Technical Background Information for the Unregulated Contaminant Monitoring Regulation*, § 5.1.11 (1999). EPA’s technical guidance goes on to explain that “[c]oncentrations in the raw source water may change through treatment, [and] thus sampling at the source would not necessarily provide an accurate measure.” *Id.* Indeed, the technical guidance goes on to state that relying on information from the raw water source—as EPA did here—“could confound the analysis.” *Id.* Further, “sampling at entry points to the distribution system after any treatment follows the existing regulatory approach for currently regulated contaminants.” 64 Fed. Reg. 50571.

EPA cannot ignore its own regulations. While EPA has discretion to establish procedures and weigh evidence, it is bound by and must follow its own regulations. *See, e.g., Nader v. Bork*, 366 F. Supp. 104, 108-109 (D.D.C. 1973) (“An agency regulation has the force and effect of law, and it is binding upon the body that issues it.”) As the Circuit Court for the District of Columbia has explained, an agency has

---

<sup>4</sup> There is no doubt that the sampling data from UCMR 1 is “influential scientific, financial, or statistical information.” The OMB guideline defines that term to mean that “the information will have or does have a clear and substantial impact on important public policies or important private sector decisions.” *Id.* at 8460. As the very purpose of the UCMR 1 data is to determine whether certain constituents should be regulated under the Safe Drinking Water Act, it is clear that this standard is met here.

<sup>5</sup> *See, e.g., Ethyl Corp. v. EPA*, 51 F.3d 1053, 1061 (D.C. Cir. 1995) (“mention of one thing implies the exclusion of another thing.”) The specific UCMR 1 regulations are controlling over a general data quality act guideline from OMB. *See, e.g., United States v. Lara*, 181 F.3d 183, 198 (1st Cir. 1999); *see also Diaz v. Cobb*, 435 F. Supp. 2d 1206, 1213 n.7 (S.D. Fla. 2006). It is no answer to say that the regulations and OMB guideline are not in conflict; applying a general provision in this circumstance “undermines limitations created by a more specific provision.” *Varity Corp. v. Howe*, 516 U.S. 489, 511 (1996).

substantial discretion to make a given policy decision. On its way to decision, however, the agency must follow its own regulations; “it is a ‘well-settled rule that an agency's failure to follow its own regulations is fatal to the deviant action.’” *Mine Reclamation Corp. v. F.E.R.C.*, 30 F.3d 1519, 1524 (D.C. Cir. 1994).

Here, it is clear that EPA did not follow its own regulations—even EPA does not dispute that nearly one-third of the data on which it relied was not collected in compliance with UCMR 1 regulations. Pointing to general OMB guidelines does not cure this flaw, both because EPA must follow its own regulations and because the specific UCMR 1 regulations constitute the “specific standards of quality” that are called for in the OMB guidelines. This deviation is not a technicality. As the Chamber’s RFC pointed out, perchlorate was detected approximately twice as often in samples collected in raw water as in samples collected at the required location. The Chamber understands that sampling raw water is not unusual, and that raw water samples can perform a valuable screening function. But as set forth in the UCMR 1 regulations, sampling the raw water is *not* a substitute for evaluating the water after treatment. Rather, a detection of constituents in the raw water merely indicates the need to test the finished water to determine whether the constituent is actually present in the water served to the public. That, after all, is the purpose of the program—not to examine source water, but to determine if the public is being exposed to constituents at levels which may lead to adverse health effects. Raw water samples do not support conclusions about the quality and healthfulness of water served to the public; at most, raw water detections may point to the need for data from finished water.

The Chamber again requests that EPA correct the perchlorate occurrence data set, re-analyze whether perchlorate occurs with the required frequency in public water systems, and come to a scientifically and legally defensible conclusion. Continuing with a regulatory process founded upon a data set that was not collected in compliance with applicable regulations and that does not satisfy data quality requirements is not an efficient use of EPA’s resources or the resources of the other stakeholders in the regulatory process. As the Acting Administrator recently explained to the GAO, EPA has limited resources and must deploy them wisely to best protect the public.<sup>6</sup>

---

<sup>6</sup> See July 11 2011, letter from Bob Perciasepe to David C. Trimble, Acting Director, Natural Resources and the Environment, U.S. Government Accountability Office, as reprinted in GAO-11-347, “Environmental Protection Agency: To Better Fulfill Its Mission, EPA Needs a More Coordinated Approach to Managing Its Laboratories” (August 24, 2011).

B. EPA May Not Resolve Questions About the Data Supporting Its Decision to Set an MCL for Perchlorate In the Process of Setting the MCL.

EPA deferred comment on the remaining two issues raised by the Chamber's RFC: (1) the significant data errors discovered by an independent review of that data, and (2) the fact that EPA relied on decade-old data when more recent data was readily available. Instead of responding to the issues raised in the RFC, EPA's response indicates that it will address the remaining problems with the data as part of a "parallel process" as EPA goes about setting the MCL for perchlorate.

In its guidelines, EPA describes the situations in which it intends to respond to requests for correction by using a "parallel process." The guidelines state that:

When EPA provides opportunities for public participation by seeking comments on information, the public comment process should address concerns about EPA's information. For example, when EPA issues a notice of proposed rulemaking supported by studies and other information described in the proposal or included in the rulemaking docket, it disseminates this information within the meaning of the Guidelines. The public may then raise issues in comments regarding the information. If a group or an individual raises a question regarding information supporting a proposed rule, EPA generally expects to treat it procedurally like a comment to the rulemaking, addressing it in the response to comments rather than through a separate response mechanism." EPA Guidelines at 32.

Here, EPA did not provide an opportunity for public participation by seeking comments on the regulatory determination for perchlorate or the perchlorate occurrence information disseminated in the Federal Register. As a result, the public did not have the opportunity to raise issues in comments regarding the perchlorate occurrence information. It is worth noting that the Safe Drinking Water Act requires that regulatory determinations and their supporting documents be made available for public comment at the time the regulatory determination is published. 42 U.S.C. § 300g-1(b)(1)(B)(iii). Notwithstanding the statutory requirement, neither the regulatory determination nor the supporting information was made available for public comment.

The information for which the Chamber seeks correction was not published in a proposed rule and was not published in a manner that allowed for public comment. *See* EPA Guidelines at 32. Quite the contrary. The information on perchlorate occurrence that was published in the Federal Register was published in a notice that did **not** seek or allow public comment. The Chamber and other stakeholders did not

have the opportunity to comment on the information. Under its own guidelines, EPA cannot address the Chamber's RFC in a "parallel process" as if it were a public comment. The "parallel process" mechanism provided for in EPA's guidelines is inapplicable to a situation where public comment was not sought. EPA must address the Chamber's RFC by responding to it directly. This situation is made all the worse because EPA was required by law to seek public comment on the regulatory determination and its supporting information. EPA did not do so. EPA cannot avoid commentary on its regulatory determination and its supporting information by deciding to not seek public comment and then avoid an IQA petition on the information supporting its regulatory determination by suggesting that the petition is somehow akin to public comment in an on-going rulemaking.

As pointed out in the Chamber's RFC, EPA's regulatory decision was based on data that both contains documented errors and is out of date. EPA does not challenge the conclusion that there are serious problems with the data, but rather says it will address them as part of a parallel process. This puts the cart before the horse. EPA should retract the information it published in the Federal Register, which does not comport with the IQA; identify and collect information of the requisite quality; and re-visit its regulatory determination.

The perchlorate occurrence data was used to determine whether an MCL was necessary at all. It is problematic to suggest that the answer to *whether* to set an MCL for perchlorate can be answered in the context of deciding *what* the MCL should be. EPA's response appears to assume a conclusion. The Chamber has proffered evidence that: (1) less than 1,000 people in California were being exposed to perchlorate above the current California regulatory level at the time of regulatory determination instead of over 4 million indicated in the information disseminated in the Federal Register; and (2) a peer-reviewed publication that surveyed water purveyors found another 1 million false positives in the underlying data.

The agency cannot meaningfully address whether to go somewhere in the process of deciding the best route to get there. Courts have repeatedly rejected such *post hoc* rationalizations for agency action. *Southwest Airlines Co. v. Transportation Sec. Admin.*, 650 F.3d 752, 761 (D.C. Cir. 2011). EPA concedes that it may not set an MCL for perchlorate without finding that perchlorate is both frequently present in public drinking water systems and that regulation is likely to eliminate health risks. The data that it relied upon to reach those conclusions here is fundamentally flawed, and EPA must correct it.

Rather than continue down its current path, EPA should first correct the data it published in the Federal Register. Continuing down the current path in reliance on a deeply flawed data set is neither an efficient use of the agency's resources or the resources of the participating stakeholders. Proceeding with a rulemaking that is founded upon information fraught with such serious data quality problems violates the letter and spirit of the IQA. The Chamber urges EPA to formally retract the perchlorate occurrence information it published in the Federal Register.

#### **IV. Specific Recommendation for Corrective Action**

As set forth in the RFC, EPA should: (1) publish in the Federal Register a notice retracting the perchlorate occurrence information that appears in the perchlorate regulatory determination at 76 Federal Register, pages 7764-65; (2) withdraw the regulatory determination itself, as there are no accurate, reliable, or unbiased data to support it; and (3) re-analyze the number of persons exposed to perchlorate in public water systems with data of the requisite quality.

#### **V. Conclusion**

EPA's decisions gain acceptance from the public and the regulated community if they are driven by science. In adopting the Information Quality Act, Congress imposed basic data quality standards to further this end. EPA should gather reliable, accurate, and objective data, and follow that data to whatever conclusions it demands. Anything less than that violates the IQA, Safe Drinking Water Act, and established agency policy.

If EPA requires more than 90 calendar days to make a decision on this Request for Reconsideration, 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](mailto:wkovacs@uschamber.com).

Sincerely,



William L. Kovacs