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The Authoritative Resource on Safe Water [SM]

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U.S. Environmental Protection Agency
Office of Water Docket (Mailcode 2822T)
1200 Pennsylvania Ave. NW
Washington, DC 20460

RE: Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List—Preliminary Determinations Docket EPA-HQ-OW-2007-0068

Dear Docket:

The American Water Works Association appreciates the opportunity to comment on the preliminary regulatory determinations from the second Contaminant Candidate List (CCL2) as detailed in the May 1st *Federal Register* notice (72 FR 24016). AWWA is an international, nonprofit, scientific and educational society dedicated to the improvement of drinking water quality and supply. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our 60,000 plus members represent the full spectrum of the drinking water community: treatment plant operators and managers, environmental advocates, engineers, scientists, academicians, and others who hold a genuine interest in water supply and public health. Our membership includes more than 4,700 utilities that supply roughly 80 percent of the nation's drinking water. Based on this broad membership base, these comments should be considered as representative of the drinking water community in general. These comments are divided into two major sections, starting with general comments, and then followed by comments on specific contaminants discussed in the May 1st *Federal Register* notice.

General Comments

As previously mentioned, AWWA appreciates the opportunity to comment on the above referenced preliminary regulatory determinations. The Contaminant Candidate List (CCL) and subsequent regulatory determinations are the foundation for the standard-setting process resulting from the 1996 Safe Drinking Water Act (SDWA) Amendments. These two components are among the most important changes in EPA's approach for developing national drinking water regulations since the SDWA was initially passed in 1974. Ensuring that the appropriate contaminant is selected for regulation is the critical first step in the development of national drinking water regulation that should subsequently be followed by setting the standard at the appropriate level for that contaminant.

The May 1st *Federal Register* address the preliminary regulatory determinations from CCL2 and the CCL process and the subsequent regulatory determinations are intertwined. AWWA has significant concerns with the parallel ongoing process for the third Contaminant Candidate List (CCL3) and those concerns will be sent in a separate letter to Cynthia Dougherty upon submission of these comments.

Section 1412(b)(1)(A) of the 1996 SDWA Amendments details the criteria for identification of contaminants for potential regulation:

i. *the contaminant may have an adverse effect on the health of persons;*

ii. the contaminant 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; and

iii. in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

Another reform that is particularly applicable to this notice is found in Section 1412(b)(3)(A):

> *In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall 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).*

EPA's preliminary regulatory determinations for eleven contaminants on the second Contaminant Candidate List (CCL2) as published in the May 1st *Federal Register* complies with these two sections of the SDWA. AWWA commends EPA for not regulating contaminants purely for the sake of regulation, as was the case for some of the 83 contaminants listed in the 1986 SDWA Amendments. AWWA also commends EPA for using the best-available, peer-reviewed science in these preliminary determinations.

AWWA agrees with EPA's decision not to regulate these eleven contaminants. The occurrence levels are generally low based on national surveys such as the Unregulated Contaminant Monitoring Rule (UCMR), and regulation does not present an opportunity for significant risk reduction as mandated by the 1996 SDWA Amendments. These preliminary determinations follow the logic previously used in July 2003 for the first round of regulatory determinations and for the first six-year review (Roberson, 2005). AWWA believes that use of consistent logic in these two parallel regulatory efforts is important, contributing to a more transparent process, and commends EPA for proceeding in this manner. Based on the first round of regulatory determinations, a range of 0.02%-3.2% for national occurrence could be considered as the minimum threshold for development of a new regulation. National occurrence estimates for these eleven contaminants are well below this threshold, with boron having the highest prevalence of occurrence, at 1.7% of systems sampled in the National Inorganics and Radionuclides Survey (NIRS). Based on the first six-year review, a range of 0.53%-9.28% for national occurrence could be considered as the minimum threshold for revising an existing regulation.

Some might consider the lack of new contaminant regulations since the 1996 SDWA Amendments as an indication that this new regulatory development process is not working. AWWA disagrees with that viewpoint and believes, rather, that not regulating trivial contaminants is a positive development for EPA. Thirteen previously regulated contaminants had zero violations according to SDWIS data. Despite the lack of contaminant occurrence at levels of health concern, as inferred from the absence of violations for these contaminants, their regulation was nevertheless mandated by 1986 SDWA listing (Roberson, 2003).

A further indication that the new regulatory development process is working properly is the successful collection of occurrence data, through the Unregulated Contaminant Monitoring Rule (UCMR), to support regulatory determinations. Four of the contaminants (2,6-Dinitrotoluene, EPTC, Fonofos, Terbacil) in the current notice have zero occurrence based on the monitoring results from the first UCMR (UCRM1). These four contaminants were considered to be of potential concern based on the best information at the time back in 1998 when the first Contaminant Candidate List (CCL1) was published. UCMR1 monitoring results showed that these four contaminants were never detected in any of the more than 3,800 monitored systems.

AWWA recommends that EPA expand its discussion of the logic underlying the determinations for these eleven contaminants. The logic provided in the May 1st notice is not entirely clear. Generally, EPA needs to raise the level of transparency in its decision logic so that stakeholders can understand how data and information translate to determinations and to ensure consistency across the two parallel regulatory efforts (regulatory determinations and six-year review). For example, in the current notice there is no discussion about the remaining 40 CCL2 contaminants, what data are needed to make regulatory determinations, and what is being done to collect those data. Stakeholders have no way of knowing if more information on health effects or occurrence is required, or whether analytical methods research is needed before health effects and/or occurrence data can be reliably obtained.

The integration of EPA's overall drinking water research agenda with the overall regulatory development process is not sufficiently explained in this notice. The research being done on the balance of the contaminants from the second Contaminant Candidate List (CCL2) is not discussed. The process for conducting the appropriate research and then making the appropriate regulatory decision for the 40 remaining contaminants needs to be clearly communicated to the drinking water community. For example, although national occurrence data from over 3,800 systems exists for acetochlor, molinate, and nitrobenzene, which were included in UCRM1 List 1, these three contaminants are not discussed at all in the May 1st *Federal Register*. It is unclear how the regulatory development process is driving EPA's research agenda.

AWWA recommends that, in the final notice, EPA develop a table on the information gaps for chemical contaminants similar to the table of pg. 24052 of the May 1st *Federal Register* for microbial contaminants. The limited research information in the current notice gives the appearance that little progress has been made since our 2002 comments on the first round of regulatory determinations. There is a strong need for appropriately communicating the body of research on CCL contaminants to the water sector.

AWWA wants to reiterate its concern that the 60-day comment period is not sufficient for adequately analyzing the complex issues surrounding perchlorate and for review, in general, of the associated background documentation. On May 22nd, AWWA requested an extension of the public comment period to 120 days and this extension was not granted. Not granting the requested extension is unfortunate, as the short comment period does not allow for adequate review by the drinking water community of the background documentation and for adequate debate on the complex policy issues. Perchlorate has been on EPA's regulatory agenda since its inclusion on the draft of the first CCL in 1997. While EPA has had over a decade to work through the complex policy issues surrounding perchlorate, the drinking water community had only 60 days to sift through these issues and make the appropriate policy decision.

Perchlorate

Perchlorate is a very important issue for the drinking water community, and the perchlorate options detailed in the May 1st *Federal Register* notice raise many complex issues. Perchlorate provides EPA with a critical opportunity to appropriately implement the standard setting provisions of the 1996 SDWA amendments and the CCL/UCMR process. Additionally, there has been significant public interest generated by press coverage and subsequent interest by legislative bodies in certain states and at the federal level.

Building upon our position previously communicated to EPA in letters on February 2, 2005 and May 27, 2005, we recommend that EPA now make the decision to regulate perchlorate. AWWA believes that EPA has enough information to make a positive regulatory determination, and then to move forward with a proposed perchlorate regulation consistent with the requirements of the Safe Drinking Water Act.

We make this recommendation for the following reasons, absent any one of which we might make a different recommendation:

1. The National Research Council (NRC) and the Centers for Disease Control and Prevention (CDC) have found that perchlorate may have an adverse impact on the health of persons.
2. Perchlorate is known to occur in public water supplies in a number of states.
3. While occurrence data does not suggest that perchlorate occurs at levels of public health concern in the vast majority of public drinking water supplies and the

population at risk appears to be small, that group does include a sensitive subpopulation (pregnant women and developing fetuses) of significant concern.
4. The Greer data and the Reference Dose (RfD) recommended by the National Research Council (NRC) now make it possible for EPA to determine a protective level for perchlorate with a degree of confidence appropriate to a national primary drinking water regulation.
5. There are appropriate and reliable analytical methods for utilities and others to measure perchlorate concentrations in public water supplies, as documented by UCMR sampling, and laboratory capacity is not an issue.
6. A number of states are moving to regulate perchlorate and a patchwork of different regulations will confuse the public and the regulated community. And
7. Strong anecdotal data suggests that the lack of a perchlorate MCL has impeded a number of cleanups at hazardous waste sites. Cleanup at these sites could benefit public water suppliers, among others.

In developing a drinking water regulation for perchlorate, EPA needs to address the Relative Source Contribution (RSC) for perchlorate in food and water. The proposal in the May 1st *Federal Register* notice is a starting point for making an appropriate RSC decision. AWWA recommends that EPA not adjust for RSC, since the subjects in the Greer study were exposed to background levels of perchlorate in addition to an experimental dose, as discussed on pg. 24046 of the May 1st *Federal Register* notice.

Alternatively, if EPA doesn't accept the above recommendation, then EPA should derive the value of average daily rate of intake from background sources ($ADRI_B$) from the mean (preferred approach) or upper tail (less preferred approach) of the NHANES data specific either to the entire sampled population or to individuals using bottled water. This background value should then be subtracted from the Reference Dose (RfD) and that result used to calculate the Drinking Water Equivalent Level (DWEL). This Modified ADRI approach better approximates the target average daily rate of intake (ADRI) that must be reached to ensure the RfD is not exceeded when water is added to the perchlorate contribution from all other sources combined ($ADRI_T$).

From a technical perspective, some of the options presentation in the May 1st *Federal Register* simply do not make sense. For example, the EPA option of a regression of the NHANES urinary data versus UCMR is not feasible and should not be considered. It would result in only a couple of dozen data points, an insufficient number to allow a meaningful regression.

Appendix A to these comments is a report by Dr. Douglas Crawford-Brown of the University of North Carolina-Chapel Hill that was prepared on behalf of AWWA. Dr. Crawford-Brown's report explains the above recommendations in greater detail, comparing and contrasting alternative approaches to selecting a valid RSC value. We ask that his report be considered to be part of these comments.

Metolachlor
AWWA does not have any additional occurrence data on metolachlor or its degradates, but believes that more research is needed on the occurrence and health effects of many herbicides and pesticides and their degradates. The results of this research then need to be appropriately included in regulatory decisions by the Office of Pesticide Programs (OPP) and the Office of Groundwater and Drinking Water (OGWDW).

For example, metolachlor was not included in OPP's Cumulative Risk Assessment (CRA) for the chloroacetanilides because it was not apparent from currently available data that it shares the same target site in the nasal tissue as acetochlor, alachlor and butachlor, even though it does distribute to the nasal turbinates and "might" metabolize to quinoneimine, the active agent (as do acetochlor, alachlor and butachlor). Propachlor was also excluded from the Cumulative Risk Assessment for similar reasons. EPA should promote further research to definitively determine whether or not metolachlor , a very widely used pesticide, is carcinogenic, as acetochlor, alachlor and metolachlor have very similar chemical structures.

The triazine herbicides are another example of the need to obtain the appropriate occurrence and health effects data of herbicides and pesticides and their degradates. AWWA has commented extensively in the past to OPP on the atrazine reregistration process. AWWA, through the Water Industry Technical Action Fund (WITAF) and a partnership with the Awwa Research Foundation (AwwaRF), has conducted extensive research on atrazine and its chlorinated metabolites. A listing of the published papers resulting from this research is enclosed as Appendix B.

The need for more occurrence and health effects data increases with the growing concern about potential reproductive and developmental effects from many herbicides and pesticides and their degradates. These new health endpoints will create monitoring and compliance challenges for water utilities, as the typical quarterly compliance monitoring is likely not appropriate for these new health endpoints. Both metolachlor and atrazine are on EPA's recently released draft list of 73 pesticides for Initial Tier 1 Screening as a potential endocrine disruptor under the Federal Food, Drug, and Cosmetic Act.

Methyl tertiary-butyl ether (MTBE)
AWWA supports EPA's decision not to make a regulatory determination for methyl tertiary-butyl ether (MTBE) at this time as the risk assessment is currently being revised. AWWA does not have any additional MTBE data to add to the topics listed in the May 1st *Federal Register* notice.

Microbial Contaminants
An information summary describing the state of the knowledge on the prevention, treatment, and health effects of cyanobacteria and its toxins would be useful for utilities and for state primacy agencies. The information should be concise and practical to ensure the document will be useful to water utility personnel. The summary should also include information on occurrence and conditions that might favor growth of algae and production of toxins. A strategy for communicating this information to utility customers

should also be addressed. In addition to resources generated by EPA, the summary should include information of research funded by other organizations, particularly Awwa Research Foundation (AwwaRF).

Again, AWWA appreciates the opportunity to comment on these important drinking water issues. If you have any questions about these comments, please feel to call Alan Roberson or me in our Washington Office at 202-628-8303.

Yours Sincerely,

Thomas W. Curtis
Deputy Executive Director

cc: Ben Grumbles—USEPA OW
Cynthia Dougherty—USEPA OGWDW
Audrey Levine—USEPA ORD
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APPENDIX A

OPTIONS ANALYSIS BY
DR. DOUGLAS CRAWFORD-BROWN
UNIVERSITY OF NORTH CAROLINA-CHAPEL HILL

Review and Analysis of RegDet2 Perchlorate Issues

A report to the American Water Works Association

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5-16-07

1. Introduction

This review covers the material presented by the EPA in Chapter 12 of Regulatory Determinations Support Document for Selected Contaminants from the Second Drinking Water Contaminant Candidate List (CCL2), EPA Report 815-D-06-007. While that document does not develop or propose regulatory limits for control of perchlorate in water, it considers several options for treatment of the fact that perchlorate exposures occur not only through water but through a variety of foods and other liquids. This issue is central to the establishment of a regulatory limit on allowed drinking water concentrations since the allowed concentration calculated assuming drinking water is the only route of exposure would be multiplied by a Relative Source Contribution (RSC) for drinking water to establish a final allowed concentration. The RSC in turn is the fraction of total perchlorate entering the body daily due solely to drinking water ingestion, and is calculated from:

(1) $RSC = ADRI_{DW} / ADRI_{T}$

Where $ADRI_{DW}$ is the average daily rate of intake from drinking water alone and $ADRI_{T}$ is the average daily rate of intake from all sources combined. The lower the value of the RSC, the more stringent the allowed concentration in drinking water is likely to be.

2. Obtaining the RSC

The EPA then considers a variety of ways to obtain the RSC. The present analysis reviews these approaches and assesses their strengths and weaknesses with respect to public health protection, scientific validity and transparency. In addition, at least one other approach is considered here based on the unique nature of the clinical studies on which the health effects conclusions are based.

2.1. Await further studies of the RSC.

The EPA notes in the current document that "the currently available food data…are inadequate to develop a better informed RSC (and HRL)". This might suggest that both the RSC and the HRL cannot be developed with reasonable confidence through the existing base of data, and that further collection of data from non-drinking-water pathways must be developed before this confidence can be increased above some threshold needed to establish an HRL with reasonable confidence. The authors of the document are correct that important food categories, which account for a significant fraction of food intake, are absent in the database on perchlorate concentrations. The result could be an underestimation of the contribution from non-drinking-water pathways by as much as a factor of 2 or more, which would result in an RSC that is too high and an HRL that is too high to be protective of public health as defined by current EPA practice. However, as discussed below, this limitation in the database could in part by corrected by using averages of the concentration in the food categories that HAVE been measured (perchlorate per unit food mass) as approximations to the concentration in the unmeasured food categories.

The first option, therefore, is to postpone development of an RSC and an HRL until the database on the RSC is better established. This is essentially Section 12.5.1 of the EPA document. This approach has the merit that it satisfies the criterion of minimal epistemic status, which states that no step of an assessment should proceed until it can be accomplished with reasonable confidence (Crawford-Brown, 2005). This first option requires that the various options described below each are judged to be below this minimal required level of epistemic status (otherwise, those other options would become reasonable). The EPA has identified a reasonable approach to enhancing the existing database through the inclusion of perchlorate measurements in the FDA's Total Diet Study, now underway. These data should become available by perhaps mid 2008. The weakness of the approach is that it delays regulatory determination for perchlorate while the enhanced database is being developed. However, this should not be considered a weakness if it is determined that a value of the RSC other than 1 must be applied (see Section 2.2) and the EPA judges that the current ability to establish an RSC value by all of the options in Sections 2.2 through 2.4 falls below the epistemic threshold.

2.2. Do not correct for an RSC.

This approach, discussed briefly (although not as an explicit option) in the EPA report, is based on the manner in which the RfD for ingestion of perchlorate might be developed from the existing clinical studies. The EPA cites the Greer et al (2002) study as the basis for discussions to date. It also was the body of data on which the National Research Council based their conclusions in their report Health Implications of Perchlorate Ingestion (NRC, 2005). That study produced a No Observed Effects Level (not considered a No Observed Adverse Effects Level because the biochemical changes measured were not consider adverse in and of themselves) of 0.007 mg/kg-day. The NRC further recommended a total uncertainty factor of 10 for intraspecies extrapolation (the data were from humans), resulting in a potential RfD of:

(2) $$\text{RFD} = 0.007 / 10 = 0.0007 \text{ mg/kg-day}$$

In normal EPA practice, this RfD would be multiplied by the RSC for ingestion of drinking water to obtain a limit on exposure. However, this practice arose from the common use of clinical, epidemiological or experimental animal studies in which individuals were exposed solely through the route of interest (e.g. ingestion of water). Given this sole route of exposure in determining the NOAEL or LOAEL, it was necessary to correct for the fact that individuals in the general population might be exposed to the compound through multiple routes. As a result, the application of an RSC in the regulatory process was based on the (often unstated, but nonetheless implicit) assumption that the study population was NOT exposed through routes other than the one of interest, while the general population was exposed through ALL routes.

This assumption is not fully warranted in the case of perchlorate because the individuals in the Greer et al (2002) studies maintained a normal diet during the period of the study. Therefore, they should have been exposed to perchlorate from non-drinking-water routes at an ADRI value roughly equivalent to that of the general population that is the target of regulatory determinations. If this is the case, application of a further RSC would in effect "double count" the influence of the non-drinking-water exposures, because the NOEL from the Greer et al (2002) study already reflected these background exposures (absent these background exposures, the NOEL would be expected to be higher than 0.007 mg/kg-day from drinking water alone).

The second option, therefore, is to not apply a further RSC in developing an allowed concentration in drinking water. This approach assumes that the ADRI from exposure pathways other than drinking water was approximately the same in the study and target population (which is women of reproductive age). The weaknesses of the approach are that (i) the actual ADRI value for non-drinking-water pathways was not measured in the Greer et al (2002) study and so it cannot be demonstrated that they are the same as in the population of interest, and (ii) this option differs from the typical EPA practice with respect to application of an RSC. However, as described above, the typical EPA practice arose from use of clinical, epidemiological or animal studies in which background exposures could be ignored, which is not the case for the study of perchlorate.

2.3. Use Urinary Excretion Data to Estimate an RSC.

This third approach relies on the assumption that the rate of excretion of perchlorate in urine is essentially equivalent to the rate of ingestion from all pathways combined. The authors of the document cite studies by Valentin-Blasini et al (2005), Tellez et al (2005) and Blount et al (2006) in support of this assumption, and these studies do indeed establish that excretion and intake are proportional. It also must be assumed that the fraction excreted does not depend on the vehicle of administration, but there is no reason to believe that this assumption is violated (especially since that fraction is so close to 1). As a result, it appears reasonable to assume that the daily rate of excretion of perchlorate equals approximately the daily rate of ingestion.

In the following discussion, the current author has modified, or at least clarified, the different approaches suggested in the EPA document and based on the urinary excretion data. The reason for doing this is that the EPA document as currently written is somewhat confusing on the differences between the approaches. The following options are the ones that are obtained when these confusions are removed.

2.3.1. Avoid an RSC, But Determine Whether Regulation is Effective.

This option focuses not on the RSC, but on whether regulation of perchlorate in drinking water is needed in the first place. The argument is as follows:

- Obtain the distribution of urinary daily excretion rates per unit body mass in the US population sampled in NHANES.
- Assume the urinary daily excretion rates per unit body mass equal the total intake rates per unit body mass (and hence ADRI) in that population.
- Compare some upper tail of the distribution of NHANES ADRI values against the RfD of 0.0007 mg/kg-day.
- If this upper tail ADRI value is significantly less than the RfD, there is no merit to establishing a regulatory control on exposures to total perchlorate intake.
- If there is no merit to controlling TOTAL perchlorate intake, there is also no merit to establishing control on intakes through drinking water.

As evidence for the possibility of this approach, the authors note that the current NHANES data show a median ADRI for perchlorate (all pathways combined) of 0.000066 mg/kg-day and a 95th percentile ADRI of 0.000234 mg/kg-day. Note that the median ADRI is a factor of 0.0007 / 0.000066 = 10.6 below an RfD of 0.0007 mg/kg-day; and the 95th percentile is a factor of 0.0007 / 0.000234 = 3 below an RfD of 0.0007 mg/kg-day. As a result, even the 95th percentile ADRI value is below the RfD. The same data show that even the 99th percentile ADRI is below an RfD of 0.0007 mg/kg-day. Since most EPA regulatory decisions use an upper-tail estimator at the 95th percentile or below, the above analysis suggests that environmental exposures to perchlorate from all routes combined (and hence by extension from drinking water alone) are below an RfD of 0.0007 mg/kg-day. This in turn suggests that reduction of the ADRI values in the population, through regulatory or other controls, would have no public health benefit for 99% or more of the population.

The third option, therefore, is to use the existing database on urinary excretion to justify dropping perchlorate from further regulatory consideration. The strength of this approach is that it is rooted in empirical data on actual ADRI values in the U.S. population, which reflect the actual exposures to those populations, rather than calculations of exposure based on models. It also is public health protective because it makes the decision on perchlorate in drinking water rest on the conservative assumption that ALL of the excreted perchlorate arose from intake through drinking water. A potential weakness is that the sample size at present causes the upper tails of the distribution to be uncertain, and larger sample size could cause a shift in the 95th and 99th percentiles. The sample size (slightly above 2800) makes it unlikely that the 95th percentile would shift upwards by more than a factor of 3, but the 99th percentile is particularly uncertain and could shift to well above 0.0007 mg/kg-day with a larger sample (or it could shift to well below this value). *If the larger sample did show an upward increase in the 95th and 99th percentiles to values above 0.0007 mg/kg-day, the* *need to develop an RSC would re-emerge and the other options explored here would need to be considered.*

In addition, the above analysis was completely conditional on 0.0007 mg/kg-day being the RfD. If the EPA were to decide that a lower RfD was justified, as has been happening in some states, the 95^{th} percentile of the ADRI would likely rise above the RfD. To explore this issue, I fit the NHANES data with a lognormal distribution (median of 0.000066 mg/kg-day and GSD of 2.2 as a best fit). More than 99% of the population would be below an RfD of 0.0007 mg/kg-day; 97% of the population would be below an RfD of 0.0003 mg/kg-day; 70% of the population would be below an RfD of 0.0001 mg/kg-day; and 55% of the population would be below an RfD of 0.00007 mg/kg-day. ***This indicates that the reasonableness of this approach to excluding the need for development of an RSC depends critically on the RfD selected***.

2.3.2. Use the NHANES Data to Estimate the RSC.

The NHANES data might also be used to estimate the RSC through some form of regression. The procedure would require linking the NHANES data to another database on drinking water exposures; the authors of the document suggest the UCMR 1 database. The NHANES data would then be stratified by exposures through drinking water; i.e. sub-populations in the NHANES database would be assigned to different categories of water-borne perchlorate exposures through the values in the UCMR 1 database. From such a regression of urinary excretion rate (the Y-axis) against water concentration (the X-axis), the contribution from non-water pathways would be obtained from the Y-axis intercept. Let this regression equation be:

(3) $ADRI_T = ADRI_B + m \times C_W$

where $ADRI_T$ is the total intake rate per unit body mass (water plus other pathways combined) as measured in NHANES; $ADRI_B$ is the background intake rate per unit body mass (pathways other than water); C_W is the concentration of perchlorate in the water; and m is the slope of the regression line. Clearly, the RSC then would depend on the water concentration. The RSC is then:

(4) $RSC = m \times C_W / (ADRI_B + m \times C_W)$

The fourth option, therefore, is to obtain the RSC from a regression of the NHANES data against water concentration data. The strength of this approach is that it provides an empirical basis for determining the RSC. A weakness is that it requires the assumption that $ADRI_B$ is constant for all water concentration categories, which may be particularly problematic in regions where water is used for irrigation and where this irrigation is the major source of contamination of food products by perchlorate. A further weakness is that the ability to link individuals in the NHANES database to specific water concentrations is compromised both by the lack of full representativeness of the UCMR 1 (or other) water database, and the fact that individuals obtain water from a variety of sources throughout the day and the seasons. A further weakness is that the water database contains a very high fraction of results below the detection limit, significantly reducing the ability to identify the Y-axis intercept (the uncertainty in this intercept will be large). The assumption also must be made that the regression equation for public and non-public water supplies is the same; there is no reason to suspect it is not, but this has not been established empirically to date.

The difficulties facing this approach can be seen in the analysis of the UCMR perchlorate data by Brandhuber and Clark (2005). They supplemented the UCMR dataset with monitoring data collected in Massachusetts by the state's Department of Environmental Protection (MDEP), in California by the Department of Health Services (CaDHS) and in Arizona and Texas. For the UCMR sampling, the percentages of Community Water Supplies exceeding 4, 6, 10 and 20 µg/L were 2.6%, 1.6%, 0.9% and 0.2%, respectively (the detection limit is approximately 4 µg/L). Although over 5% of large systems in the UCMR database had some detectable perchlorate in at least one of the finished water samples, the concentrations in the set of "detects" were generally quite low. More than two-thirds (68%) of the measurable perchlorate concentrations were in the 4 ppb to 8 ppb range, and 86% were below 12 ug/L. Only 2.6% of the detected samples had concentrations above 24 ug/L. The highest observed level in the UCMR data was 420 ug/L.

The UCMR data are insufficient at present, therefore, to develop a probabilistic population-weighted distribution of concentrations in even the sampled systems, much less for the United States. Fortunately, the fraction of the NHANES urinary data having reliable above-detection-limit results is quite large due to the much lower detection level for measurements. Still, there are few geographic areas in which the perchlorate concentration both the water concentration in both urine and drinking water have been measured simultaneously, and are above detection limits, severely limiting the sample size on which this option can be based. It is very likely, therefore, that a significantly enhanced sampling program will be required, targeting geographic areas where the water concentrations are highest, before the regression in Equation 4 can be performed reliably.

2.3.3. Use the NHANES Data to Estimate the RSC Using the Bottled Water Subpopulation.

The NHANES data contain a subset of data specific to individuals who consume drinking water primarily through bottled water. These individuals should have negligible contributions to their $ADRI_T$ from drinking water, and hence the mean excretion rate per unit body mass from the NHANES subpopulation (bottled water users) could be set equal to $ADRI_B$.

The fifth option is to obtain the RSC value from Equation 5 using the mean of the bottled water subpopulation of NHANES to estimate the mean of $ADRI_B$ and the mean value of the concentration in water in the U.S. to estimate mean $ADRI_{DW}$ in Equation 1. It is important that the means be used since $ADRI_B$ is also the mean for the population. The RSC would then be:

(5) $RSC = ADRI_{DW} / (ADRI_{DW} + ADRI_B)$

This approach assumes that $ADRI_B$ obtained from the bottled water subpopulation applies to the general U.S. population. This can be problematic if the dietary habits differ between these two groups, which is a possibility given that bottled water can be quite expensive and, hence, a significant fraction of a family's food budget. This suggests in turn that the bottled water subpopulation may be wealthier on average than the general U.S. population, which in turn can cause dietary differences that will not be accounted for in this approach.

While there are limited data on the concentration of perchlorate in bottled water, the data that do exist suggest quite low concentrations (values below 1 µg/L, and a mean significantly less than 0.5 µg/L). With an assumed mean intake rate for water of 0.6 L/day and a body mass of 70 kg, this yields a mean ADRI for bottled water of less than 0.004 µg/kg-day or 0.000004 mg/kg-day. From the analysis in Option 3, the mean value of $ADRI_T$ for the U.S. population (using the same lognormal distribution as in that option) is 0.000089 mg/kg-day. As a result, the bottled water contribution represents a fraction equal to 0.000004 / 0.000089 = 0.04 or 4% of the total intake rate for perchlorate by all pathways. This contribution can be ignored, especially since it is likely that the actual mean bottled water concentration is significantly below the value of 0.5 µg/L assumed above.

A rough estimate of the actual mean value for bottled water may be obtained by assuming the same lognormal distribution characteristics (GSD of 2.2) as for the NHANES dataset. With 2 of the 51 values in the FDA dataset at approximately 0.5 µg/L (the mean of these two samples), this suggests the 95^{th} percentile of the distribution is approximately 0.5 µg/L. With a lognormal distribution and GSD of 2.2, the mean value would be approximately 0.38 x 0.5 = 0.19 µg/L (the value of 0.38 is the ratio of the mean over the 95^{th} percentile for a lognormal distribution with a GSD of 2.2). This yields a bottled water contribution of 0.0000016 mg/kg-day, or a fraction equal to 0.0000016 / 0.000089 = 0.018 or 1.8%, which again can be neglected.

However, it must be noted that the current sample of measurements in bottled water is small (51 in the FDA sample cited in the EPA document), with the large majority of samples (49) being below the detection limit. In addition, the samples are not from a population of suppliers that is known to be representative of the bottled water supplied to the individuals in the NHANES study. As a result, there is large uncertainty in the estimate of the mean concentration of perchlorate in bottled water for the subpopulation of bottled water drinkers in the NHANES study. Still, it seems unlikely that the true mean is so much higher than 0.19 µg/L as to make the bottled water contribution to $ADRI_T$ significant.

The sixth option is to obtain the RSC value from Equation 1 using the mean value of $ADRI_T$ ***in the bottled water subpopulation of NHANES to estimate the mean of*** $ADRI_B$ ***and the difference between the mean value of*** $ADRI_T$ ***in the non-bottled water***

NHANES population and the mean value of $ADRI_T$ in the bottled water population as the estimate of the mean value of $ADRI_{DW}$. The RSC would then be:

(6) $$RSC = (ADRI_{TNB} – ADRI_{TB}) / ADRI_{TNB}$$

This approach assumes that the sole difference in the values of $ADRI_T$ in the two populations (with and without bottled water) is due to the substitution of low-perchlorate bottled water for tap water. This assumption has not been examined to date. And again, the problem remains that this assumes complete equality of the ADRI values for non-water pathways in the bottled water and general populations.

2.4. Use the Existing Food Data as a Surrogate for the Total Food Intake

The seventh option uses the limited data on perchlorate concentrations in food products to obtain an estimate of $ADRI_B$ needed in Equation 5. This option relies on the data contained in Exhibit 12-2 of the EPA document, or a similarly developed dataset (Exhibit 12-2 is, however, the most complete summary of data existing). Consider a foodstuff of type x (for example, x = 1 is iceberg lettuce in Exhibit 12-2). A mean value for the perchlorate concentration might be obtained; this is approximately a mean of 7.6 ppb or 0.0076 μg/g. The mean ingestion rate of lettuce in the U.S. is a function of age. Taking the values from the EPA Exposure Factors Handbook (Table 9-5 in U.S. EPA, 1999), the rate of intake for iceberg lettuce (assuming all lettuce consumed was iceberg) would be 0.211 g/kg-day (20-39 years). The mean ADRI from iceberg lettuce would then be 0.0076 x 0.211 = 0.0016 μg/kg-day or 0.0000016 mg/kg-day. This procedure would be followed for each food product x in Exhibit 12-2, using the population-averaged mean ingestion rate for each food product times the mean intake rate of the food product per unit body mass. The sum over all values of x of these individual ADRI values would then be the first approximation to $ADRI_B$.

As mentioned in the EPA document, however, the food products in Exhibit 12-2 constitute only about half of the total food intake in the population (in addition to other concerns mentioned below). If it were assumed that the concentration of perchlorate per unit food mass is approximately the same in the sampled and unsampled food products, the $ADRI_B$ value from the paragraph above could be multiplied by 2 as a first approximation to the total value of $ADRI_B$. This approach, however has several limitations that would cause the uncertainty in estimates of RSC to be high:

- The food data in Exhibit 12-2 are not completely geographically representative;
- The data are overly weighted towards food products that were expected *a priori* to contain perchlorate;
- Sample sizes for many of the products are small (often less than 10);
- It ignores correlations between intake rates for different food products;
- It ignores geographic differences that might cause concentrations to be related to dietary differences in different geographic regions (this could be dealt with by applying the procedure in different geographic regions separately, but the database is inadequate for such a stratification).

2.5. Replace Calculation of the RSC with a Background Subtraction Method

The eighth and final option replaces the RSC approach with one in which the value of $ADRI_B$ is determined (here, from the mean of the NHANES data as described previously) and then subtracted from the RfD in calculating something equivalent to a DWEL. The option would use either the mean of the complete NHANES dataset or the mean of the dataset restricted to bottled water intake. The former dataset is larger and more representative of a national average, but contains contributions from drinking water (and hence is not a completely justified estimate of background). The latter removes this problem of including drinking water contributions, but results in a significantly smaller and less representative dataset.

Such an approach differs from the classical application of an RSC. Specifically, it will result in a DWEL or equivalent concept that is higher than that produced by an approached rooted in an RSC calculation, with the two approaches converging onto each other as the RSC for drinking water gets closer to 1. This final approach, however, provides a more scientifically defensible means of determining the water concentration that will produce a target level of ADRI. As such, it is to be preferred to an option based on calculation and application of an RSC, however that RSC is calculated.

The use of a mean value for $ADRI_B$ from the NHANES data is preferable relative to some value in the tail unless the intakes from non-water sources are in some way positively correlated with the drinking water intakes (there is no evidence to suggest such a correlation). To the extent a non-mean value is used from the upper tail of the NHANES distribution, this will provide an additional degree of conservatism or margin of safety in the development of the DWEL or equivalent value.

3. Summary

Eight options are identified here for treatment of the RSC, taken from the EPA document under review. They are assigned here a purely subjective measure of desirability or feasibility (High, Medium, Low) based on the strengths and weaknesses of each option both internally and relative to each other.

1. Await further studies of the RSC before proceeding with regulatory determination or any other regulatory steps, based on the judgment that the existing database is inadequate for any attempt to estimate the RSC. (Medium desirability because it is fully feasible but (i) delays a decision and (ii) will still face the problem of correlations between diet and geographic area that may limit the interpretation of results).

2. Do not correct for the RSC at all, based on the argument that the NOEL and hence RfD from the Greer et al (2002) study already includes the effect of the RSC. (High desirability because it comports with the likely features of the study, although this would need to be better confirmed before proceeding with this option).

3. Use the existing NHANES database on urinary excretion rates as an approximation of the daily intake rate for perchlorate from all sources, and determine whether existing rates of intake are above or below the RfD. Only consider developing an RSC if they are above. (Medium desirability because it is conditional on the establishment of an RfD; but having established an RfD, this becomes highly feasible. The limitation is that the sample size of positive results in the NHANES dataset is small, resulting in significant uncertainty in the upper tails of the distribution of the urinary excretion rates. In addition, other options will be required if the calculated ADRI – at whatever percentile of the distribution is selected - ends up being above the established RfD).

4. Obtain the value of $ADRI_B$ via regression of the NHANES data against water concentration data, and then estimate $ADRID_W$ from the water concentration data. Use Equation 4 to estimate the value of RSC. (Low desirability because of the poor quality of the water concentration data and inability to reliably link the water and NHANES data spatially).

5. Obtain the value of $ADRI_B$ from the mean of the NHANES data specific to individuals using bottled water and then estimate $ADRID_W$ from the water concentration data. Use Equation 5 to estimate the value of RSC. (Medium desirability because the assumption that bottled water is only a slight contributor to $ADRI_B$ is good, but there is a chance that the resulting estimates are not representative of the exposures in the general population).

6. Obtain the value of $ADRI_B$ from the mean of the NHANES data specific to individuals using bottled water and then estimate $ADRID_W$ from the difference between ADRI in the general and bottled water populations. Use Equation 5 to estimate the value of RSC. (Medium desirability because the assumption that bottled water is only a slight contributor to $ADRI_B$ is good, but there is a chance that the resulting estimates are not representative of the exposures in the general population).

7. Obtain the estimate of $ADRI_B$ from the data in Exhibit 12-2 of the EPA document and multiply by a factor of approximately 2 to account for the missing food products. Then use Equation 5 to estimate RSC based on existing water concentration data. (Medium desirability because the approach follows standard EPA practice, but the database is poorly developed at present; desirability is low if the current database is used).

8. Obtain the value of $ADRI_B$ from the mean (preferred approach) or upper tail (less preferred approach) of the NHANES data specific either to the entire sampled population or to individuals using bottled water. Subtract this background value from the RfD and then develop a DWEL or equivalent concept. (High desirability because this option better approximates the target ADRI that must be reached to ensure the RfD is not exceeded when background is added to the water contribution to $ADRI_T$).

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APPENDIX B

WITAF/AwwaRF TRIAZAINE RESEARCH PUBLICATIONS

PUBLICATIONS RESULTING FROM TRIAZINE RESERACH PROJECTS

Adams, C., Jiang, H., McGuire, M., Graziano, M., Roberson, A and Frey, M. Accuracy and Interferences for Enzyme-Linked Immunoassay Tests for Atrazine. *Journal AWWA*, 96:12:126 (December, 2004).

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Jiang, H., and Adams, C. Determination of Chloro- and Hydroxy-s-triazines using Direct Injection Liquid Chromatography-Mass Spectrometry. *J. Chromatography-A*.

Jiang, H., and Adams, C. Treatability of Chloro-s-Triazines by Conventional Drinking Water Treatment Technologies. *Water Research* 40 (2006) 1657.

Adams, C., Jiang, H., Graziano, N., Roberson, A., McGuire, M., and Khiari, D. Occurrence and Removal of Chloro-s-triazines in Water Treatment Plants. *Environmental Science & Technology*, 40:11:3609.

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July 2, 2007

U.S. Environmental Protection Agency
Office of Water Docket (Mailcode 2822T)
1200 Pennsylvania Ave. NW
Washington, DC 20460

RE: Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List—Preliminary Determinations Docket EPA-HQ-OW-2007-0068

Dear Docket:

The American Water Works Association appreciates the opportunity to comment on the preliminary regulatory determinations from the second Contaminant Candidate List (CCL2) as detailed in the May 1st *Federal Register* notice (72 FR 24016). AWWA is an international, nonprofit, scientific and educational society dedicated to the improvement of drinking water quality and supply. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our 60,000 plus members represent the full spectrum of the drinking water community: treatment plant operators and managers, environmental advocates, engineers, scientists, academicians, and others who hold a genuine interest in water supply and public health. Our membership includes more than 4,700 utilities that supply roughly 80 percent of the nation's drinking water. Based on this broad membership base, these comments should be considered as representative of the drinking water community in general. These comments are divided into two major sections, starting with general comments, and then followed by comments on specific contaminants discussed in the May 1st *Federal Register* notice.

General Comments

As previously mentioned, AWWA appreciates the opportunity to comment on the above referenced preliminary regulatory determinations. The Contaminant Candidate List (CCL) and subsequent regulatory determinations are the foundation for the standard-setting process resulting from the 1996 Safe Drinking Water Act (SDWA) Amendments. These two components are among the most important changes in EPA's approach for developing national drinking water regulations since the SDWA was initially passed in 1974. Ensuring that the appropriate contaminant is selected for regulation is the critical first step in the development of national drinking water regulation that should subsequently be followed by setting the standard at the appropriate level for that contaminant.

The May 1st *Federal Register* address the preliminary regulatory determinations from CCL2 and the CCL process and the subsequent regulatory determinations are intertwined. AWWA has significant concerns with the parallel ongoing process for the third Contaminant Candidate List (CCL3) and those concerns will be sent in a separate letter to Cynthia Dougherty upon submission of these comments.

Section 1412(b)(1)(A) of the 1996 SDWA Amendments details the criteria for identification of contaminants for potential regulation:

i. *the contaminant may have an adverse effect on the health of persons;*

ii. the contaminant 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; and

iii. in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

Another reform that is particularly applicable to this notice is found in Section 1412(b)(3)(A):

> *In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall 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).*

EPA's preliminary regulatory determinations for eleven contaminants on the second Contaminant Candidate List (CCL2) as published in the May 1st *Federal Register* complies with these two sections of the SDWA. AWWA commends EPA for not regulating contaminants purely for the sake of regulation, as was the case for some of the 83 contaminants listed in the 1986 SDWA Amendments. AWWA also commends EPA for using the best-available, peer-reviewed science in these preliminary determinations.

AWWA agrees with EPA's decision not to regulate these eleven contaminants. The occurrence levels are generally low based on national surveys such as the Unregulated Contaminant Monitoring Rule (UCMR), and regulation does not present an opportunity for significant risk reduction as mandated by the 1996 SDWA Amendments. These preliminary determinations follow the logic previously used in July 2003 for the first round of regulatory determinations and for the first six-year review (Roberson, 2005). AWWA believes that use of consistent logic in these two parallel regulatory efforts is important, contributing to a more transparent process, and commends EPA for proceeding in this manner. Based on the first round of regulatory determinations, a range of 0.02%-3.2% for national occurrence could be considered as the minimum threshold for development of a new regulation. National occurrence estimates for these eleven contaminants are well below this threshold, with boron having the highest prevalence of occurrence, at 1.7% of systems sampled in the National Inorganics and Radionuclides Survey (NIRS). Based on the first six-year review, a range of 0.53%-9.28% for national occurrence could be considered as the minimum threshold for revising an existing regulation.

Some might consider the lack of new contaminant regulations since the 1996 SDWA Amendments as an indication that this new regulatory development process is not working. AWWA disagrees with that viewpoint and believes, rather, that not regulating trivial contaminants is a positive development for EPA. Thirteen previously regulated contaminants had zero violations according to SDWIS data. Despite the lack of contaminant occurrence at levels of health concern, as inferred from the absence of violations for these contaminants, their regulation was nevertheless mandated by 1986 SDWA listing (Roberson, 2003).

A further indication that the new regulatory development process is working properly is the successful collection of occurrence data, through the Unregulated Contaminant Monitoring Rule (UCMR), to support regulatory determinations. Four of the contaminants (2,6-Dinitrotoluene, EPTC, Fonofos, Terbacil) in the current notice have zero occurrence based on the monitoring results from the first UCMR (UCRM1). These four contaminants were considered to be of potential concern based on the best information at the time back in 1998 when the first Contaminant Candidate List (CCL1) was published. UCMR1 monitoring results showed that these four contaminants were never detected in any of the more than 3,800 monitored systems.

AWWA recommends that EPA expand its discussion of the logic underlying the determinations for these eleven contaminants. The logic provided in the May 1st notice is not entirely clear. Generally, EPA needs to raise the level of transparency in its decision logic so that stakeholders can understand how data and information translate to determinations and to ensure consistency across the two parallel regulatory efforts (regulatory determinations and six-year review). For example, in the current notice there is no discussion about the remaining 40 CCL2 contaminants, what data are needed to make regulatory determinations, and what is being done to collect those data. Stakeholders have no way of knowing if more information on health effects or occurrence is required, or whether analytical methods research is needed before health effects and/or occurrence data can be reliably obtained.

The integration of EPA's overall drinking water research agenda with the overall regulatory development process is not sufficiently explained in this notice. The research being done on the balance of the contaminants from the second Contaminant Candidate List (CCL2) is not discussed. The process for conducting the appropriate research and then making the appropriate regulatory decision for the 40 remaining contaminants needs to be clearly communicated to the drinking water community. For example, although national occurrence data from over 3,800 systems exists for acetochlor, molinate, and nitrobenzene, which were included in UCRM1 List 1, these three contaminants are not discussed at all in the May 1st *Federal Register*. It is unclear how the regulatory development process is driving EPA's research agenda.

AWWA recommends that, in the final notice, EPA develop a table on the information gaps for chemical contaminants similar to the table of pg. 24052 of the May 1st *Federal Register* for microbial contaminants. The limited research information in the current notice gives the appearance that little progress has been made since our 2002 comments on the first round of regulatory determinations. There is a strong need for appropriately communicating the body of research on CCL contaminants to the water sector.

AWWA wants to reiterate its concern that the 60-day comment period is not sufficient for adequately analyzing the complex issues surrounding perchlorate and for review, in general, of the associated background documentation. On May 22nd, AWWA requested an extension of the public comment period to 120 days and this extension was not granted. Not granting the requested extension is unfortunate, as the short comment period does not allow for adequate review by the drinking water community of the background documentation and for adequate debate on the complex policy issues. Perchlorate has been on EPA's regulatory agenda since its inclusion on the draft of the first CCL in 1997. While EPA has had over a decade to work through the complex policy issues surrounding perchlorate, the drinking water community had only 60 days to sift through these issues and make the appropriate policy decision.

Perchlorate

Perchlorate is a very important issue for the drinking water community, and the perchlorate options detailed in the May 1st *Federal Register* notice raise many complex issues. Perchlorate provides EPA with a critical opportunity to appropriately implement the standard setting provisions of the 1996 SDWA amendments and the CCL/UCMR process. Additionally, there has been significant public interest generated by press coverage and subsequent interest by legislative bodies in certain states and at the federal level.

Building upon our position previously communicated to EPA in letters on February 2, 2005 and May 27, 2005, we recommend that EPA now make the decision to regulate perchlorate. AWWA believes that EPA has enough information to make a positive regulatory determination, and then to move forward with a proposed perchlorate regulation consistent with the requirements of the Safe Drinking Water Act.

We make this recommendation for the following reasons, absent any one of which we might make a different recommendation:

1. The National Research Council (NRC) and the Centers for Disease Control and Prevention (CDC) have found that perchlorate may have an adverse impact on the health of persons.
2. Perchlorate is known to occur in public water supplies in a number of states.
3. While occurrence data does not suggest that perchlorate occurs at levels of public health concern in the vast majority of public drinking water supplies and the

population at risk appears to be small, that group does include a sensitive subpopulation (pregnant women and developing fetuses) of significant concern.
4. The Greer data and the Reference Dose (RfD) recommended by the National Research Council (NRC) now make it possible for EPA to determine a protective level for perchlorate with a degree of confidence appropriate to a national primary drinking water regulation.
5. There are appropriate and reliable analytical methods for utilities and others to measure perchlorate concentrations in public water supplies, as documented by UCMR sampling, and laboratory capacity is not an issue.
6. A number of states are moving to regulate perchlorate and a patchwork of different regulations will confuse the public and the regulated community. And
7. Strong anecdotal data suggests that the lack of a perchlorate MCL has impeded a number of cleanups at hazardous waste sites. Cleanup at these sites could benefit public water suppliers, among others.

In developing a drinking water regulation for perchlorate, EPA needs to address the Relative Source Contribution (RSC) for perchlorate in food and water. The proposal in the May 1st *Federal Register* notice is a starting point for making an appropriate RSC decision. AWWA recommends that EPA not adjust for RSC, since the subjects in the Greer study were exposed to background levels of perchlorate in addition to an experimental dose, as discussed on pg. 24046 of the May 1st *Federal Register* notice.

Alternatively, if EPA doesn't accept the above recommendation, then EPA should derive the value of average daily rate of intake from background sources ($ADRI_B$) from the mean (preferred approach) or upper tail (less preferred approach) of the NHANES data specific either to the entire sampled population or to individuals using bottled water. This background value should then be subtracted from the Reference Dose (RfD) and that result used to calculate the Drinking Water Equivalent Level (DWEL). This Modified ADRI approach better approximates the target average daily rate of intake (ADRI) that must be reached to ensure the RfD is not exceeded when water is added to the perchlorate contribution from all other sources combined ($ADRI_T$).

From a technical perspective, some of the options presentation in the May 1st *Federal Register* simply do not make sense. For example, the EPA option of a regression of the NHANES urinary data versus UCMR is not feasible and should not be considered. It would result in only a couple of dozen data points, an insufficient number to allow a meaningful regression.

Appendix A to these comments is a report by Dr. Douglas Crawford-Brown of the University of North Carolina-Chapel Hill that was prepared on behalf of AWWA. Dr. Crawford-Brown's report explains the above recommendations in greater detail, comparing and contrasting alternative approaches to selecting a valid RSC value. We ask that his report be considered to be part of these comments.

Metolachlor
AWWA does not have any additional occurrence data on metolachlor or its degradates, but believes that more research is needed on the occurrence and health effects of many herbicides and pesticides and their degradates. The results of this research then need to be appropriately included in regulatory decisions by the Office of Pesticide Programs (OPP) and the Office of Groundwater and Drinking Water (OGWDW).

For example, metolachlor was not included in OPP's Cumulative Risk Assessment (CRA) for the chloroacetanilides because it was not apparent from currently available data that it shares the same target site in the nasal tissue as acetochlor, alachlor and butachlor, even though it does distribute to the nasal turbinates and "might" metabolize to quinoneimine, the active agent (as do acetochlor, alachlor and butachlor). Propachlor was also excluded from the Cumulative Risk Assessment for similar reasons. EPA should promote further research to definitively determine whether or not metolachlor , a very widely used pesticide, is carcinogenic, as acetochlor, alachlor and metolachlor have very similar chemical structures.

The triazine herbicides are another example of the need to obtain the appropriate occurrence and health effects data of herbicides and pesticides and their degradates. AWWA has commented extensively in the past to OPP on the atrazine reregistration process. AWWA, through the Water Industry Technical Action Fund (WITAF) and a partnership with the Awwa Research Foundation (AwwaRF), has conducted extensive research on atrazine and its chlorinated metabolites. A listing of the published papers resulting from this research is enclosed as Appendix B.

The need for more occurrence and health effects data increases with the growing concern about potential reproductive and developmental effects from many herbicides and pesticides and their degradates. These new health endpoints will create monitoring and compliance challenges for water utilities, as the typical quarterly compliance monitoring is likely not appropriate for these new health endpoints. Both metolachlor and atrazine are on EPA’s recently released draft list of 73 pesticides for Initial Tier 1 Screening as a potential endocrine disruptor under the Federal Food, Drug, and Cosmetic Act.

Methyl tertiary-butyl ether (MTBE)
AWWA supports EPA’s decision not to make a regulatory determination for methyl tertiary-butyl ether (MTBE) at this time as the risk assessment is currently being revised. AWWA does not have any additional MTBE data to add to the topics listed in the May 1^{st} *Federal Register* notice.

Microbial Contaminants
An information summary describing the state of the knowledge on the prevention, treatment, and health effects of cyanobacteria and its toxins would be useful for utilities and for state primacy agencies. The information should be concise and practical to ensure the document will be useful to water utility personnel. The summary should also include information on occurrence and conditions that might favor growth of algae and production of toxins. A strategy for communicating this information to utility customers

should also be addressed. In addition to resources generated by EPA, the summary should include information of research funded by other organizations, particularly Awwa Research Foundation (AwwaRF).

Again, AWWA appreciates the opportunity to comment on these important drinking water issues. If you have any questions about these comments, please feel to call Alan Roberson or me in our Washington Office at 202-628-8303.

Yours Sincerely,

Thomas W. Curtis
Deputy Executive Director

cc: Ben Grumbles—USEPA OW
Cynthia Dougherty—USEPA OGWDW
Audrey Levine—USEPA ORD
Brian Mannix—USEPA OPEI
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APPENDIX A

OPTIONS ANALYSIS BY
DR. DOUGLAS CRAWFORD-BROWN
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Review and Analysis of RegDet2 Perchlorate Issues

A report to the American Water Works Association

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5-16-07

1. Introduction

This review covers the material presented by the EPA in Chapter 12 of Regulatory Determinations Support Document for Selected Contaminants from the Second Drinking Water Contaminant Candidate List (CCL2), EPA Report 815-D-06-007. While that document does not develop or propose regulatory limits for control of perchlorate in water, it considers several options for treatment of the fact that perchlorate exposures occur not only through water but through a variety of foods and other liquids. This issue is central to the establishment of a regulatory limit on allowed drinking water concentrations since the allowed concentration calculated assuming drinking water is the only route of exposure would be multiplied by a Relative Source Contribution (RSC) for drinking water to establish a final allowed concentration. The RSC in turn is the fraction of total perchlorate entering the body daily due solely to drinking water ingestion, and is calculated from:

(1) $RSC = ADRI_{DW} / ADRI_{T}$

Where $ADRI_{DW}$ is the average daily rate of intake from drinking water alone and $ADRI_{T}$ is the average daily rate of intake from all sources combined. The lower the value of the RSC, the more stringent the allowed concentration in drinking water is likely to be.

2. Obtaining the RSC

The EPA then considers a variety of ways to obtain the RSC. The present analysis reviews these approaches and assesses their strengths and weaknesses with respect to public health protection, scientific validity and transparency. In addition, at least one other approach is considered here based on the unique nature of the clinical studies on which the health effects conclusions are based.

2.1. Await further studies of the RSC.

The EPA notes in the current document that "the currently available food data…are inadequate to develop a better informed RSC (and HRL)". This might suggest that both the RSC and the HRL cannot be developed with reasonable confidence through the existing base of data, and that further collection of data from non-drinking-water pathways must be developed before this confidence can be increased above some threshold needed to establish an HRL with reasonable confidence. The authors of the document are correct that important food categories, which account for a significant fraction of food intake, are absent in the database on perchlorate concentrations. The result could be an underestimation of the contribution from non-drinking-water pathways by as much as a factor of 2 or more, which would result in an RSC that is too high and an HRL that is too high to be protective of public health as defined by current EPA practice. However, as discussed below, this limitation in the database could in part by corrected by using averages of the concentration in the food categories that HAVE been measured (perchlorate per unit food mass) as approximations to the concentration in the unmeasured food categories.

The first option, therefore, is to postpone development of an RSC and an HRL until the database on the RSC is better established. This is essentially Section 12.5.1 of the EPA document. This approach has the merit that it satisfies the criterion of minimal epistemic status, which states that no step of an assessment should proceed until it can be accomplished with reasonable confidence (Crawford-Brown, 2005). This first option requires that the various options described below each are judged to be below this minimal required level of epistemic status (otherwise, those other options would become reasonable). The EPA has identified a reasonable approach to enhancing the existing database through the inclusion of perchlorate measurements in the FDA's Total Diet Study, now underway. These data should become available by perhaps mid 2008. The weakness of the approach is that it delays regulatory determination for perchlorate while the enhanced database is being developed. However, this should not be considered a weakness if it is determined that a value of the RSC other than 1 must be applied (see Section 2.2) and the EPA judges that the current ability to establish an RSC value by all of the options in Sections 2.2 through 2.4 falls below the epistemic threshold.

2.2. Do not correct for an RSC.

This approach, discussed briefly (although not as an explicit option) in the EPA report, is based on the manner in which the RfD for ingestion of perchlorate might be developed from the existing clinical studies. The EPA cites the Greer et al (2002) study as the basis for discussions to date. It also was the body of data on which the National Research Council based their conclusions in their report Health Implications of Perchlorate Ingestion (NRC, 2005). That study produced a No Observed Effects Level (not considered a No Observed Adverse Effects Level because the biochemical changes measured were not consider adverse in and of themselves) of 0.007 mg/kg-day. The NRC further recommended a total uncertainty factor of 10 for intraspecies extrapolation (the data were from humans), resulting in a potential RfD of:

(2) $\mathrm{RFD} = 0.007 / 10 = 0.0007$ mg/kg-day

In normal EPA practice, this RfD would be multiplied by the RSC for ingestion of drinking water to obtain a limit on exposure. However, this practice arose from the common use of clinical, epidemiological or experimental animal studies in which individuals were exposed solely through the route of interest (e.g. ingestion of water). Given this sole route of exposure in determining the NOAEL or LOAEL, it was necessary to correct for the fact that individuals in the general population might be exposed to the compound through multiple routes. As a result, the application of an RSC in the regulatory process was based on the (often unstated, but nonetheless implicit) assumption that the study population was NOT exposed through routes other than the one of interest, while the general population was exposed through ALL routes.

This assumption is not fully warranted in the case of perchlorate because the individuals in the Greer et al (2002) studies maintained a normal diet during the period of the study. Therefore, they should have been exposed to perchlorate from non-drinking-water routes at an ADRI value roughly equivalent to that of the general population that is the target of regulatory determinations. If this is the case, application of a further RSC would in effect "double count" the influence of the non-drinking-water exposures, because the NOEL from the Greer et al (2002) study already reflected these background exposures (absent these background exposures, the NOEL would be expected to be higher than 0.007 mg/kg-day from drinking water alone).

The second option, therefore, is to not apply a further RSC in developing an allowed concentration in drinking water. This approach assumes that the ADRI from exposure pathways other than drinking water was approximately the same in the study and target population (which is women of reproductive age). The weaknesses of the approach are that (i) the actual ADRI value for non-drinking-water pathways was not measured in the Greer et al (2002) study and so it cannot be demonstrated that they are the same as in the population of interest, and (ii) this option differs from the typical EPA practice with respect to application of an RSC. However, as described above, the typical EPA practice arose from use of clinical, epidemiological or animal studies in which background exposures could be ignored, which is not the case for the study of perchlorate.

2.3. Use Urinary Excretion Data to Estimate an RSC.

This third approach relies on the assumption that the rate of excretion of perchlorate in urine is essentially equivalent to the rate of ingestion from all pathways combined. The authors of the document cite studies by Valentin-Blasini et al (2005), Tellez et al (2005) and Blount et al (2006) in support of this assumption, and these studies do indeed establish that excretion and intake are proportional. It also must be assumed that the fraction excreted does not depend on the vehicle of administration, but there is no reason to believe that this assumption is violated (especially since that fraction is so close to 1). As a result, it appears reasonable to assume that the daily rate of excretion of perchlorate equals approximately the daily rate of ingestion.

In the following discussion, the current author has modified, or at least clarified, the different approaches suggested in the EPA document and based on the urinary excretion data. The reason for doing this is that the EPA document as currently written is somewhat confusing on the differences between the approaches. The following options are the ones that are obtained when these confusions are removed.

2.3.1. Avoid an RSC, But Determine Whether Regulation is Effective.

This option focuses not on the RSC, but on whether regulation of perchlorate in drinking water is needed in the first place. The argument is as follows:

- Obtain the distribution of urinary daily excretion rates per unit body mass in the US population sampled in NHANES.
- Assume the urinary daily excretion rates per unit body mass equal the total intake rates per unit body mass (and hence ADRI) in that population.
- Compare some upper tail of the distribution of NHANES ADRI values against the RfD of 0.0007 mg/kg-day.
- If this upper tail ADRI value is significantly less than the RfD, there is no merit to establishing a regulatory control on exposures to total perchlorate intake.
- If there is no merit to controlling TOTAL perchlorate intake, there is also no merit to establishing control on intakes through drinking water.

As evidence for the possibility of this approach, the authors note that the current NHANES data show a median ADRI for perchlorate (all pathways combined) of 0.000066 mg/kg-day and a 95th percentile ADRI of 0.000234 mg/kg-day. Note that the median ADRI is a factor of 0.0007 / 0.000066 = 10.6 below an RfD of 0.0007 mg/kg-day; and the 95th percentile is a factor of 0.0007 / 0.000234 = 3 below an RfD of 0.0007 mg/kg-day. As a result, even the 95th percentile ADRI value is below the RfD. The same data show that even the 99th percentile ADRI is below an RfD of 0.0007 mg/kg-day. Since most EPA regulatory decisions use an upper-tail estimator at the 95th percentile or below, the above analysis suggests that environmental exposures to perchlorate from all routes combined (and hence by extension from drinking water alone) are below an RfD of 0.0007 mg/kg-day. This in turn suggests that reduction of the ADRI values in the population, through regulatory or other controls, would have no public health benefit for 99% or more of the population.

The third option, therefore, is to use the existing database on urinary excretion to justify dropping perchlorate from further regulatory consideration. The strength of this approach is that it is rooted in empirical data on actual ADRI values in the U.S. population, which reflect the actual exposures to those populations, rather than calculations of exposure based on models. It also is public health protective because it makes the decision on perchlorate in drinking water rest on the conservative assumption that ALL of the excreted perchlorate arose from intake through drinking water. A potential weakness is that the sample size at present causes the upper tails of the distribution to be uncertain, and larger sample size could cause a shift in the 95th and 99th percentiles. The sample size (slightly above 2800) makes it unlikely that the 95th percentile would shift upwards by more than a factor of 3, but the 99th percentile is particularly uncertain and could shift to well above 0.0007 mg/kg-day with a larger sample (or it could shift to well below this value). *If the larger sample did show an upward increase in the 95th and 99th percentiles to values above 0.0007 mg/kg-day, the* *need to develop an RSC would re-emerge and the other options explored here would need to be considered.*

In addition, the above analysis was completely conditional on 0.0007 mg/kg-day being the RfD. If the EPA were to decide that a lower RfD was justified, as has been happening in some states, the 95th percentile of the ADRI would likely rise above the RfD. To explore this issue, I fit the NHANES data with a lognormal distribution (median of 0.000066 mg/kg-day and GSD of 2.2 as a best fit). More than 99% of the population would be below an RfD of 0.0007 mg/kg-day; 97% of the population would be below an RfD of 0.0003 mg/kg-day; 70% of the population would be below an RfD of 0.0001 mg/kg-day; and 55% of the population would be below an RfD of 0.00007 mg/kg-day. ***This indicates that the reasonableness of this approach to excluding the need for development of an RSC depends critically on the RfD selected***.

2.3.2. Use the NHANES Data to Estimate the RSC.

The NHANES data might also be used to estimate the RSC through some form of regression. The procedure would require linking the NHANES data to another database on drinking water exposures; the authors of the document suggest the UCMR 1 database. The NHANES data would then be stratified by exposures through drinking water; i.e. sub-populations in the NHANES database would be assigned to different categories of water-borne perchlorate exposures through the values in the UCMR 1 database. From such a regression of urinary excretion rate (the Y-axis) against water concentration (the X-axis), the contribution from non-water pathways would be obtained from the Y-axis intercept. Let this regression equation be:

(3) $ADRI_T = ADRI_B + m \times C_W$

where $ADRI_T$ is the total intake rate per unit body mass (water plus other pathways combined) as measured in NHANES; $ADRI_B$ is the background intake rate per unit body mass (pathways other than water); C_W is the concentration of perchlorate in the water; and m is the slope of the regression line. Clearly, the RSC then would depend on the water concentration. The RSC is then:

(4) $RSC = m \times C_W / (ADRI_B + m \times C_W)$

The fourth option, therefore, is to obtain the RSC from a regression of the NHANES data against water concentration data. The strength of this approach is that it provides an empirical basis for determining the RSC. A weakness is that it requires the assumption that $ADRI_B$ is constant for all water concentration categories, which may be particularly problematic in regions where water is used for irrigation and where this irrigation is the major source of contamination of food products by perchlorate. A further weakness is that the ability to link individuals in the NHANES database to specific water concentrations is compromised both by the lack of full representativeness of the UCMR 1 (or other) water database, and the fact that individuals obtain water from a variety of sources throughout the day and the seasons. A further weakness is that the water database contains a very high fraction of results below the detection limit, significantly reducing the ability to identify the Y-axis intercept (the uncertainty in this intercept will be large). The assumption also must be made that the regression equation for public and non-public water supplies is the same; there is no reason to suspect it is not, but this has not been established empirically to date.

The difficulties facing this approach can be seen in the analysis of the UCMR perchlorate data by Brandhuber and Clark (2005). They supplemented the UCMR dataset with monitoring data collected in Massachusetts by the state's Department of Environmental Protection (MDEP), in California by the Department of Health Services (CaDHS) and in Arizona and Texas. For the UCMR sampling, the percentages of Community Water Supplies exceeding 4, 6, 10 and 20 µg/L were 2.6%, 1.6%, 0.9% and 0.2%, respectively (the detection limit is approximately 4 µg/L). Although over 5% of large systems in the UCMR database had some detectable perchlorate in at least one of the finished water samples, the concentrations in the set of "detects" were generally quite low. More than two-thirds (68%) of the measurable perchlorate concentrations were in the 4 ppb to 8 ppb range, and 86% were below 12 ug/L. Only 2.6% of the detected samples had concentrations above 24 ug/L. The highest observed level in the UCMR data was 420 ug/L.

The UCMR data are insufficient at present, therefore, to develop a probabilistic population-weighted distribution of concentrations in even the sampled systems, much less for the United States. Fortunately, the fraction of the NHANES urinary data having reliable above-detection-limit results is quite large due to the much lower detection level for measurements. Still, there are few geographic areas in which the perchlorate concentration both the water concentration in both urine and drinking water have been measured simultaneously, and are above detection limits, severely limiting the sample size on which this option can be based. It is very likely, therefore, that a significantly enhanced sampling program will be required, targeting geographic areas where the water concentrations are highest, before the regression in Equation 4 can be performed reliably.

2.3.3. Use the NHANES Data to Estimate the RSC Using the Bottled Water Subpopulation.

The NHANES data contain a subset of data specific to individuals who consume drinking water primarily through bottled water. These individuals should have negligible contributions to their $ADRI_T$ from drinking water, and hence the mean excretion rate per unit body mass from the NHANES subpopulation (bottled water users) could be set equal to $ADRI_B$.

The fifth option is to obtain the RSC value from Equation 5 using the mean of the bottled water subpopulation of NHANES to estimate the mean of $ADRI_B$ and the mean value of the concentration in water in the U.S. to estimate mean $ADRI_{DW}$ in Equation 1. It is important that the means be used since $ADRI_B$ is also the mean for the population. The RSC would then be:

(5) $RSC = ADRI_{DW} / (ADRI_{DW} + ADRI_B)$

This approach assumes that $ADRI_B$ obtained from the bottled water subpopulation applies to the general U.S. population. This can be problematic if the dietary habits differ between these two groups, which is a possibility given that bottled water can be quite expensive and, hence, a significant fraction of a family's food budget. This suggests in turn that the bottled water subpopulation may be wealthier on average than the general U.S. population, which in turn can cause dietary differences that will not be accounted for in this approach.

While there are limited data on the concentration of perchlorate in bottled water, the data that do exist suggest quite low concentrations (values below 1 µg/L, and a mean significantly less than 0.5 µg/L). With an assumed mean intake rate for water of 0.6 L/day and a body mass of 70 kg, this yields a mean ADRI for bottled water of less than 0.004 µg/kg-day or 0.000004 mg/kg-day. From the analysis in Option 3, the mean value of $ADRI_T$ for the U.S. population (using the same lognormal distribution as in that option) is 0.000089 mg/kg-day. As a result, the bottled water contribution represents a fraction equal to 0.000004 / 0.000089 = 0.04 or 4% of the total intake rate for perchlorate by all pathways. This contribution can be ignored, especially since it is likely that the actual mean bottled water concentration is significantly below the value of 0.5 µg/L assumed above.

A rough estimate of the actual mean value for bottled water may be obtained by assuming the same lognormal distribution characteristics (GSD of 2.2) as for the NHANES dataset. With 2 of the 51 values in the FDA dataset at approximately 0.5 µg/L (the mean of these two samples), this suggests the 95^{th} percentile of the distribution is approximately 0.5 µg/L. With a lognormal distribution and GSD of 2.2, the mean value would be approximately 0.38 x 0.5 = 0.19 µg/L (the value of 0.38 is the ratio of the mean over the 95^{th} percentile for a lognormal distribution with a GSD of 2.2). This yields a bottled water contribution of 0.0000016 mg/kg-day, or a fraction equal to 0.0000016 / 0.000089 = 0.018 or 1.8%, which again can be neglected.

However, it must be noted that the current sample of measurements in bottled water is small (51 in the FDA sample cited in the EPA document), with the large majority of samples (49) being below the detection limit. In addition, the samples are not from a population of suppliers that is known to be representative of the bottled water supplied to the individuals in the NHANES study. As a result, there is large uncertainty in the estimate of the mean concentration of perchlorate in bottled water for the subpopulation of bottled water drinkers in the NHANES study. Still, it seems unlikely that the true mean is so much higher than 0.19 µg/L as to make the bottled water contribution to $ADRI_T$ significant.

The sixth option is to obtain the RSC value from Equation 1 using the mean value of $ADRI_T$ in the bottled water subpopulation of NHANES to estimate the mean of $ADRI_B$ and the difference between the mean value of $ADRI_T$ in the non-bottled water

NHANES population and the mean value of $ADRI_T$ in the bottled water population as the estimate of the mean value of $ADRI_{DW}$. The RSC would then be:

(6) $$RSC = (ADRI_{TNB} - ADRI_{TB}) / ADRI_{TNB}$$

This approach assumes that the sole difference in the values of $ADRI_T$ in the two populations (with and without bottled water) is due to the substitution of low-perchlorate bottled water for tap water. This assumption has not been examined to date. And again, the problem remains that this assumes complete equality of the ADRI values for non-water pathways in the bottled water and general populations.

2.4. Use the Existing Food Data as a Surrogate for the Total Food Intake

The seventh option uses the limited data on perchlorate concentrations in food products to obtain an estimate of $ADRI_B$ needed in Equation 5. This option relies on the data contained in Exhibit 12-2 of the EPA document, or a similarly developed dataset (Exhibit 12-2 is, however, the most complete summary of data existing). Consider a foodstuff of type x (for example, x = 1 is iceberg lettuce in Exhibit 12-2). A mean value for the perchlorate concentration might be obtained; this is approximately a mean of 7.6 ppb or 0.0076 µg/g. The mean ingestion rate of lettuce in the U.S. is a function of age. Taking the values from the EPA Exposure Factors Handbook (Table 9-5 in U.S. EPA, 1999), the rate of intake for iceberg lettuce (assuming all lettuce consumed was iceberg) would be 0.211 g/kg-day (20-39 years). The mean ADRI from iceberg lettuce would then be 0.0076 x 0.211 = 0.0016 µg/kg-day or 0.0000016 mg/kg-day. This procedure would be followed for each food product x in Exhibit 12-2, using the population-averaged mean ingestion rate for each food product times the mean intake rate of the food product per unit body mass. The sum over all values of x of these individual ADRI values would then be the first approximation to $ADRI_B$.

As mentioned in the EPA document, however, the food products in Exhibit 12-2 constitute only about half of the total food intake in the population (in addition to other concerns mentioned below). If it were assumed that the concentration of perchlorate per unit food mass is approximately the same in the sampled and unsampled food products, the $ADRI_B$ value from the paragraph above could be multiplied by 2 as a first approximation to the total value of $ADRI_B$. This approach, however has several limitations that would cause the uncertainty in estimates of RSC to be high:

- The food data in Exhibit 12-2 are not completely geographically representative;
- The data are overly weighted towards food products that were expected *a priori* to contain perchlorate;
- Sample sizes for many of the products are small (often less than 10);
- It ignores correlations between intake rates for different food products;
- It ignores geographic differences that might cause concentrations to be related to dietary differences in different geographic regions (this could be dealt with by applying the procedure in different geographic regions separately, but the database is inadequate for such a stratification).

2.5. Replace Calculation of the RSC with a Background Subtraction Method

The eighth and final option replaces the RSC approach with one in which the value of $ADRI_B$ is determined (here, from the mean of the NHANES data as described previously) and then subtracted from the RfD in calculating something equivalent to a DWEL. The option would use either the mean of the complete NHANES dataset or the mean of the dataset restricted to bottled water intake. The former dataset is larger and more representative of a national average, but contains contributions from drinking water (and hence is not a completely justified estimate of background). The latter removes this problem of including drinking water contributions, but results in a significantly smaller and less representative dataset.

Such an approach differs from the classical application of an RSC. Specifically, it will result in a DWEL or equivalent concept that is higher than that produced by an approached rooted in an RSC calculation, with the two approaches converging onto each other as the RSC for drinking water gets closer to 1. This final approach, however, provides a more scientifically defensible means of determining the water concentration that will produce a target level of ADRI. As such, it is to be preferred to an option based on calculation and application of an RSC, however that RSC is calculated.

The use of a mean value for $ADRI_B$ from the NHANES data is preferable relative to some value in the tail unless the intakes from non-water sources are in some way positively correlated with the drinking water intakes (there is no evidence to suggest such a correlation). To the extent a non-mean value is used from the upper tail of the NHANES distribution, this will provide an additional degree of conservatism or margin of safety in the development of the DWEL or equivalent value.

3. Summary

Eight options are identified here for treatment of the RSC, taken from the EPA document under review. They are assigned here a purely subjective measure of desirability or feasibility (High, Medium, Low) based on the strengths and weaknesses of each option both internally and relative to each other.

1. Await further studies of the RSC before proceeding with regulatory determination or any other regulatory steps, based on the judgment that the existing database is inadequate for any attempt to estimate the RSC. (Medium desirability because it is fully feasible but (i) delays a decision and (ii) will still face the problem of correlations between diet and geographic area that may limit the interpretation of results).

2. Do not correct for the RSC at all, based on the argument that the NOEL and hence RfD from the Greer et al (2002) study already includes the effect of the RSC. (High desirability because it comports with the likely features of the study, although this would need to be better confirmed before proceeding with this option).

3. Use the existing NHANES database on urinary excretion rates as an approximation of the daily intake rate for perchlorate from all sources, and determine whether existing rates of intake are above or below the RfD. Only consider developing an RSC if they are above. (Medium desirability because it is conditional on the establishment of an RfD; but having established an RfD, this becomes highly feasible. The limitation is that the sample size of positive results in the NHANES dataset is small, resulting in significant uncertainty in the upper tails of the distribution of the urinary excretion rates. In addition, other options will be required if the calculated ADRI – at whatever percentile of the distribution is selected - ends up being above the established RfD).

4. Obtain the value of $ADRI_B$ via regression of the NHANES data against water concentration data, and then estimate $ADRID_W$ from the water concentration data. Use Equation 4 to estimate the value of RSC. (Low desirability because of the poor quality of the water concentration data and inability to reliably link the water and NHANES data spatially).

5. Obtain the value of $ADRI_B$ from the mean of the NHANES data specific to individuals using bottled water and then estimate $ADRID_W$ from the water concentration data. Use Equation 5 to estimate the value of RSC. (Medium desirability because the assumption that bottled water is only a slight contributor to $ADRI_B$ is good, but there is a chance that the resulting estimates are not representative of the exposures in the general population).

6. Obtain the value of $ADRI_B$ from the mean of the NHANES data specific to individuals using bottled water and then estimate $ADRID_W$ from the difference between ADRI in the general and bottled water populations. Use Equation 5 to estimate the value of RSC. (Medium desirability because the assumption that bottled water is only a slight contributor to $ADRI_B$ is good, but there is a chance that the resulting estimates are not representative of the exposures in the general population).

7. Obtain the estimate of $ADRI_B$ from the data in Exhibit 12-2 of the EPA document and multiply by a factor of approximately 2 to account for the missing food products. Then use Equation 5 to estimate RSC based on existing water concentration data. (Medium desirability because the approach follows standard EPA practice, but the database is poorly developed at present; desirability is low if the current database is used).

8. Obtain the value of $ADRI_B$ from the mean (preferred approach) or upper tail (less preferred approach) of the NHANES data specific either to the entire sampled population or to individuals using bottled water. Subtract this background value from the RfD and then develop a DWEL or equivalent concept. (High desirability because this option better approximates the target ADRI that must be reached to ensure the RfD is not exceeded when background is added to the water contribution to $ADRI_T$).

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APPENDIX B

WITAF/AwwaRF TRIAZAINE RESEARCH PUBLICATIONS

<u>PUBLICATIONS RESULTING FROM TRIAZINE RESERACH PROJECTS</u>

Adams, C., Jiang, H., McGuire, M., Graziano, M., Roberson, A and Frey, M. Accuracy and Interferences for Enzyme-Linked Immunoassay Tests for Atrazine. *Journal AWWA*, 96:12:126 (December, 2004).

Jiang, H., Adams, C., and Koffskey, W. Determination of Chloro-s-Triazines Including Didethylatrazine Using Solid-phase Extraction Coupled with Gas Chromotography-Mass Spectrometry. *Journal-Chromotography-A*, 1064:2:219.

Graziano, N., McGuire, M., Roberson, A., Adams, C., Jiang, H., and Blute, N. 2004 National Atrazine Occurrence Monitoring Program Using the Abraxis ELISA Method. *Environmental Science & Technology*, 40:4:1163.

Jiang, H., Adams, C., Graziano, N., Roberson, A., McGuire, M., and Khiari, D. Enzyme Linked Immunoassay Analysis (ELISA) of Atrazine in Raw and Finished Drinking Water. *Environmental Engineering Science*, 23:2:357.

Graziano, N., McGuire, M., Roberson, A., Adams, C., Jiang, H., and Blute, N. Using the ELISA Method To Track Atrazine Occurrence in a National Monitoring Program. *Journal AWWA*, 98:10:111 (October 2006)

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Jiang, H., and Adams, C. Treatability of Chloro-s-Triazines by Conventional Drinking Water Treatment Technologies. *Water Research* 40 (2006) 1657.

Adams, C., Jiang, H., Graziano, N., Roberson, A., McGuire, M., and Khiari, D. Occurrence and Removal of Chloro-s-triazines in Water Treatment Plants. *Environmental Science & Technology*, 40:11:3609.