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Regulating for the Public Health: Perchlorate Regulation Under the Safe Drinking Water Act Exceeds Statutory Authority

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Mary E. Jones

ABSTRACT

This paper recommends rethinking the statutory framework of the Safe Drinking Water Act (SDWA) to provide a more robust rubric, to include a scientific and objective focus, for proper regulation. The SDWA is evaluated through the lens of upcoming perchlorate regulation due in February 2013.

The United States Environmental Protection Agency (EPA) regulates acceptable contaminant levels and decontamination processes for all public water systems, pursuant to statutory authority granted by the SDWA. Where the policy at work is admirable, the execution falls short.

Perchlorate occurs naturally, but also as a by-product to rocket fuel, firework, and other explosive constructions. Scientific studies confirm that perchlorate inhibits iodide uptake in the thyroid – related to neurodevelopment in fetuses and infants, and metabolic regulation in adults – but differ on what constitutes safe levels of exposure.

Little scholarship or case law can be found relating to the SDWA and the literature becomes more scant when focused on perchlorate. This paper compiles the case law and scholarship on the topic and addresses two key issues by first analyzing the debatable constitutionality of the SDWA, and second, analyzing the SDWA to determine whether the EPA can regulate perchlorate in compliance with the statute.

Most challenges to the SDWA rest on the assertion that public water systems do not participate in interstate commerce and thus cannot be reached by the Commerce Clause authority of Article I. This argument historically fails in federal courts. Though the constitutionality of the SDWA remains in question, perchlorate regulation is improper because it does not meet the statutory mandates. Instead, such regulation is an example of overregulation and extra-statutory exercises of authority by the EPA in an effort to remain relevant and expand the sphere of potential future regulation.

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I. INTRODUCTION

More than 150,000 public water systems serve more than 300 million customers in the United States.¹ Approximately eighty percent of these systems are considered “very small” and

¹ *FACTOIDS: Drinking Water and Ground Water Statistics for 2009*, EPA 3 (Nov. 2009), available at http://water.epa.gov/scitech/datait/databases/drink/upload/data_factoids_2009.pdf.

serve five hundred or fewer customers.² All of them are subject to federal regulation under the Safe Drinking Water Act (SDWA).³ The cost of complying with a new water regulation usually involves installation of new technology, training of staff, monitoring contaminant levels, and assorted treatment costs.⁴ These costs remain relatively constant regardless of a water system’s size.⁵

In 2001, the United States Environmental Protection Agency (EPA)⁶ adopted a new standard for arsenic in drinking water at ten parts per billion, thereby replacing the old standard

² *Id.* For a full breakout of system size and population served:

Table 1 – System Size by Population Served

	Very Small: 500 or less	Small: 501-3,300	Medium: 3,301-10,000	Large: 10,001-100,000	Very Large: > 100,000	Total
# of systems	125,126	19,126	5,090	3,775	413	153,530
Population served.	14,163,274	25,109,752	29,574,177	107,658,660	137,380,529	313,886,392
% of systems	81.5%	12.46%	3.32%	2.45%	0.27%	100%
% of population	4.51%	8.0%	9.42%	34.3%	43.77%	100%

Id.

³ Pub. L. no. 93-523 (1974) (as amended by: Pub. L. no. 99-939 (1986); Pub. L. no. 104-182 (1996)) (codified at 42 U.S.C.A. §§ 300f – 300j-26 (West, Westlaw through Dec. 7, 2012)). Small systems may be eligible for a variance or exemption to certain regulations under 42 U.S.C.A. §§ 300g-4 and 300g-5.

⁴ *See, e.g.,* Caroline G. Russell, J. Alan Roberson, Zaid Chowdhury & Michael J. McGuire, *National Cost Implications of a Perchlorate Regulation*, 101 J. AM. WATER WORKS ASS’N 54, 56 (Mar. 2009) (outlining steps associated with determining costs for perchlorate regulation compliance).

⁵ *See, e.g.,* WATER SUPPLY & WATER RES. DIV., EPA, EPA/600/R-11/090, COSTS OF ARSENIC REMOVAL TECHNOLOGIES FOR SMALL WATER SYSTEMS: U.S. EPA ARSENIC REMOVAL TECHNOLOGY DEMONSTRATION PROGRAM 69 (2011) (showing that the cost of a removal system depends on the rate of flow of the water, not on the size of the system).

⁶ Environmental and administrative law can be rife with acronyms. To avoid confusion, I have included a glossary of the acronyms used in this paper. See *infra* Appendix 1: Glossary for a definition of all the acronyms used herein.

of fifty parts per billion.⁷ Regulation compliance was estimated to cost \$4.5 billion nationwide.⁸ While that number is staggering in and of itself, the most interesting numbers come when evaluating the annual cost per household of regulation compliance, as determined by system size: \$326.82 for a system serving 100 or fewer customers, as opposed to \$0.86 for a system serving a million or more customers.⁹

The EPA will propose a new regulation for perchlorate in February 2013.¹⁰ Promulgation of perchlorate regulation provides a useful lens to view the Safe Drinking Water Act, reassess the bounds of federalism, and reevaluate the use of science in the regulatory process. Although many

⁷ *Arsenic Rule*, U.S. EPA, <http://water.epa.gov/lawsregs/rulesregs/sdwa/arsenic/regulations.cfm> (last updated Mar. 6, 2012).

⁸ Russell et al., *supra* note 4, at 61.

⁹ National Primary Drinking Water Regulations, Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, 66 Fed. Reg. 6976, 7011 (Jan. 22, 2001). EPA provided a household cost analysis based on the size of the water system and alternative regulatory levels. That breakdown was:

Table 2 – Mean Annual Costs Per Household [in 1999 dollars]

System size	3 MUg/L	5 MUg/L	10 MUg/L	20 MUg/L
<100	\$317.00	\$318.26	\$326.82	\$351.15
101-500	166.91	164.02	162.50	166.72
501-1,000	74.81	73.11	70.72	68.24
1,001-3,300	63.76	61.94	58.24	54.36
3,301-10,000	42.84	40.18	37.71	34.63
10,001-50,000	38.40	36.07	32.37	29.05
50,001-100,000	31.63	29.45	24.81	22.63
100,001-1,000,000	25.29	23.34	20.52	19.26
>1,000,000	7.41	2.79	0.86	0.15
All categories	41.34	36.95	31.85	23.95

Id.

¹⁰ See *Drinking Water: Regulatory Determination on Perchlorate*, 76 Fed. Reg. 7762, 7765 (Feb. 11, 2011) (announcing the regulatory determination for perchlorate); Safe Drinking Water Act, 42 U.S.C.A. § 300g-1(b)(1)(E) (West, Westlaw through Dec. 7, 2012) (requiring promulgation of a National Primary Drinking Water Regulation within twenty-four months of the initial regulatory determination).

federal statutes could bear on this analysis, this Comment focuses only on the Safe Drinking Water Act.¹¹

¹¹ The Clean Water Act, Pub. L. no. 95-217 (1977) (as amended by: Pub. L. no. 96-148 (1979)) (codified at 33 U.S.C.A. §§ 1281a, 1294–97 (West, Westlaw through Dec. 7, 2012)), though clearly relevant to this area and important to consider in any holistic approach to federal water regulation, is beyond the scope of this Comment because of the differing statutory framework and enforcement mechanisms. For a discussion of the enforcement of the Clean Water Act, see William L. Andreen, *Motivating Enforcement: Institutional Culture and the Clean Water Act*, 24 PACE ENVTL. L. REV. 67, 69–78 (2007). For a constitutional critique of the Clean Water Act, see Charles S. Abell, Note, *Ignoring the Trees for the Forests: How the Citizen Suit Provision of the Clean Water Act Violates the Constitution’s Separation of Powers Principle*, 81 VA. L. REV. 1957, 1970–74 (1995).

Further, issues relating to the regulation of navigable waters (surface waters) under the Commerce Clause are beyond the scope of this Comment. For case law related to surface water regulation and the Clean Water Act, see *Solid Waste Agency of Northern Cook County v. United States Army Corps of Engineers*, 531 U.S. 159, 171–72 (2001), declining to extend regulatory authority under the Clean Water Act to purely intrastate waters that did not fit the definition of “navigable waters.”

Equally relevant to treatment and remediation is the Comprehensive Environmental Response, Compensation, and Liability Act, more commonly known as CERCLA. Pub. L. no. 96-510 (1980) (as amended by: Pub. L. no. 99-499 (1986); Pub. L. no. 103-429 (1994)) (codified at 42 U.S.C.A. §§ 9601–9675 (West, Westlaw through Dec. 7, 2012)). CERCLA, colloquially referred to as “Superfund,” aimed at developing a creative and innovative way to combine legal and financial institutions to combat the dangers of environmental pollution, specifically groundwater pollution. *Developments in the Law—Toxic Waste Litigation*, 99 HARV. L. REV. 1465, 1465, 1472 (1986). CERCLA is beyond the scope of this Comment because it relates more to cleanup of toxic waste sites than to regulation and treatment of drinking water. For a thorough discussion of the development of CERCLA and issues associated with its enforcement, see *Developments in the Law—Toxic Waste Litigation*, 99 HARV. L. REV. 1465 (1986). For a discussion of the oil and gas issues associated with CERCLA and CERCLA reauthorization, see Joseph R. Dancy & Victoria A. Dancy, *Oil and Gas Issues Involved in CERCLA Reauthorization*, 27 ST. MARY’S L.J. 103, 127–43 (1995).

Finally, this Comment will not address the administrative processes outlined by the Administrative Procedure Act, Pub. L. no. 79-404 (1946) (as amended by: Pub. L. no. 89-554 (1966); Pub. L. no. 94-409 (1976); Pub. L. no. 103-272 (1994); Pub. L. no. 111-305 (2011)) (codified at 5 U.S.C.A. §§ 500–596 (West, Westlaw through Dec. 7, 2012)), because they do not bear on regulatory promulgation or the constitutionality of the SDWA. For a discussion of the Administrative Procedure Act and the potential due process implications of informal rulemaking, see Note, *The Judicial Role in Defining Procedural Requirements for Agency Rulemaking*, 87 HARV. L. REV. 782, 785–95 (1974). For a discussion of the interplay between agency rulemaking capabilities under the Administrative Procedure Act and congressional sanctions, see Thomas W. Merrill & Kathryn Tongue Watts, *Agency Rules with the Force of Law: The Original Convention*, 116 HARV. L. REV. 476, 523–26 (2002).

This Comment addresses two main issues by first analyzing the debatable constitutionality of the SDWA and the powers under which it is enacted, and second, analyzing the SDWA to determine whether the EPA can regulate perchlorate in compliance with the statute. Part II.A begins with an explanation of the SDWA and how the EPA enacts regulation pursuant to that authority.¹² The Overview continues with a discussion of perchlorate regulation.¹³ Part II.C explores the constitutional issues surrounding the SDWA.¹⁴ Section II concludes with a discussion of the limited case law and scholarship related to the SDWA and regulation thereunder.¹⁵

Section III begins by showing that the SDWA, though arguably enacted under Commerce Clause authority, is subject to the bounds of federalism expressed in the Tenth Amendment and therefore is an unconstitutional grant of authority to the EPA.¹⁶ Part III.B shows that even if the SDWA were constitutional, the proposed perchlorate regulation does not conform to the statutory mandate and is beyond the pale of the EPA's authority.¹⁷ Finally, Part III.C addresses the legitimate public policy concerns over the public health and the role of federal regulation in

¹² See *infra* Part II.A.1 for a discussion of the SDWA requirements for regulation and Part II.A.2 for a discussion of the process for promulgating SDWA regulation.

¹³ See *infra* Part II.B for a discussion of the positive and negative effects on human health of perchlorate exposure, where and how frequently perchlorate occurs, and the history of perchlorate regulation to this point.

¹⁴ See *infra* Part II.C for a discussion of the constitutional authority exercised when enacting the SDWA and the limits of that authority as cabined by the federalist principles codified in the Tenth Amendment.

¹⁵ See *infra* Part II.D for a discussion of *Nebraska v. EPA*, 331 F.3d 995 (D.C. Cir. 2003), the leading case regarding relevant issues with the SDWA, and an elaboration of the most common challenges to SDWA regulation.

¹⁶ See *infra* Part III.A for a discussion of why the SDWA is not properly enacted under Commerce Clause authority and violates the Tenth Amendment.

¹⁷ See *infra* Part III.B for a discussion of why the proposed perchlorate regulations do not conform to the statutory requirements of the SDWA and exceed the EPA's authority.

promoting the public health.¹⁸ In order to reconcile the policy issues raised by the SDWA and the constitutional limitations thereon, the statute should be revised to correct issues of vagueness and arbitrariness. Section IV provides a brief summation and conclusion.

II. OVERVIEW

As described below, federal regulation of public water systems occurs under the SDWA.¹⁹ The regulatory process can be a long one, but it begins with the EPA Administrator's determination that a contaminant meets the statutory requirements for regulation.²⁰ The SDWA sets out three requirements for contaminant regulation.²¹ The three requirements are somewhat amorphous and spawn most of the public comment related to possible regulation.²² Perchlorate, a goitrogenic contaminant,²³ will be the subject of a proposed new federal regulation due in February 2013.²⁴ Regulatory history surrounding perchlorate shows a new and different working definition for two of the statutory requirements.²⁵ This change in definition allows for argument over what constitutes an "adverse health effect" or "sufficient frequency of occurrence."²⁶

¹⁸ See *infra* Part III.C for a discussion of why the SDWA, though bad law, makes for good policy and how it should be revised.

¹⁹ 42 U.S.C.A. § 300f(4)(A) (West, Westlaw through Dec. 7, 2012).

²⁰ See *id.* § 300g-1(b)(1)(A) (requiring the Administrator to determine that a contaminant meets the requirements before promulgating regulation).

²¹ *Id.* §§ 300g-1(b)(1)(A)(i)–(iii). See *infra* Part II.A.1 for a discussion of the three requirements for proper regulation under the SDWA.

²² Public comments on Agency action and proposals can be viewed at www.regulations.gov. The Preliminary Regulatory Determination on Perchlorate has a docket ID number of EPA-HQ-OW-2008-0692. The docket includes 2287 public comments, almost entirely centered on health effects and occurrence.

²³ Goitrogens are contaminants that tend to produce goiter and related thyroid disorders. 6 OXFORD ENGLISH DICTIONARY 652 (J.A. Simpson & E.S.C. Weiner eds., 2d ed. 1989).

²⁴ See *Drinking Water: Regulatory Determination on Perchlorate*, 76 Fed. Reg. 7762, 7763 (Feb. 11, 2011) (noting that the SDWA requires a regulation proposal within twenty-four months of the determination to regulate, and a final regulation within eighteen months thereafter).

²⁵ See *id.* (referring to iodide uptake inhibition as the health event triggering regulation); *contra* *Drinking Water: Preliminary Regulatory Determination on Perchlorate*, 73 Fed. Reg. 60,262, 60,266 (Oct. 10, 2008) (explaining that iodide uptake inhibition "although *not adverse*, is

Scholarship and authorities treating the SDWA are rare, and none of them have addressed the potential legal implications of perchlorate regulation.²⁷ The SDWA implicitly exercises the Commerce Clause authority granted to Congress in Article I of the Constitution.²⁸ The EPA asserts that several public water systems engage in interstate commerce by selling water over State lines, and thus the Act is not subject to a facial challenge.²⁹ While the Commerce Clause authority is expansive, recent cases have revitalized the Tenth Amendment and reasserted the province of state sovereignty, specifically with regard to the police power.³⁰

A. *The Safe Drinking Water Act*

The Safety of Public Water Systems, Safe Drinking Water Act, authorizes the EPA to promulgate contaminant³¹ regulation for the provision of drinking water by public water systems

the most appropriate *precursor event*") (emphasis added); *see also* 76 Fed. Reg. at 7763 (determining that perchlorate occurs with a frequency and at levels of health concerns); *contra* 73 Fed. Reg. at 60,275 (citing the same studies as the 2011 determination and concluding that perchlorate does not occur at with sufficient frequency and at levels of public health concern to warrant federal regulation).

²⁶ The difference between an "adverse health effect" and a "precursor event" is not insignificant with regard to placing limits on the EPA's authority to regulate drinking water. Health events can be thought of as a continuum, with no effect on one end and adverse effects on the other, and precursor events in the middle. A precursor event is a non-harmful health event on the continuum of possible health side effects from exposure and would necessarily precede any harmful or adverse health effect. *See, e.g.*, 73 Fed. Reg. at 60,266 (explaining that iodide uptake inhibition is a precursor event and outlining the general difference between the two terms). Additionally, the Agency's changed position on what constitutes "sufficient frequency" renders the statutory scheme less predictable, making the entire endeavor look arbitrary at best and capricious at worst.

²⁷ *See infra* Part II.D for a discussion of the relevant authorities on the SDWA.

²⁸ *See United States v. Morrison*, 529 U.S. 598, 607 (2000) (noting that every congressional act must exercise an affirmative grant of power from the Constitution); *Nebraska v. EPA*, 331 F.3d 995, 998 (D.C. Cir. 2003) (inferring that the authority for the statute derived from the Commerce Clause).

²⁹ Brief of Respondent at 21–22, *Nebraska v. EPA*, 331 F.3d 995 (D.C. Cir. 2003).

³⁰ *See infra* Part II.C for a discussion of Commerce Clause and Tenth Amendment jurisprudence.

³¹ The term "contaminant" is defined as "any physical, chemical, biological, or radiological substance or matter in water." 42 U.S.C.A. § 300f(10) (West, Westlaw through Dec. 7, 2012).

(PWSs).³² By its terms, the SDWA applies to all public water systems and requires the EPA to set standards for drinking water quality.³³ Binding regulation occurs in the form of National Primary Drinking Water Regulations (NPDWRs).³⁴ NPDWRs specify either a Maximum Contaminant Level (MCL) or an approved treatment technique for a given contaminant.³⁵ These regulations also outline quality control and testing procedures to ensure compliance.³⁶

There are two major facets to regulation under the SDWA: eligibility of contaminants and the process for promulgating regulation.³⁷ Contaminants become eligible for SDWA regulation upon the EPA Administrator's determination that said contaminant meets the statutory requirements.³⁸ After that decision, the EPA may decide regulation is not necessary or beneficial, or it may decide to begin the process of promulgation.³⁹ The first subsection deals with the three requirements and their somewhat murky character.⁴⁰ The second subsection deals with the general process of creating SDWA regulations.⁴¹

1. Statutory Backdrop

A contaminant must meet three criteria to be eligible for regulation under the SDWA. The EPA Administrator must determine that (1) “the contaminant may have an adverse effect on the health of persons;” (2) “the contaminant [occurs or is likely to occur] in public water systems with a frequency and at levels of public health concern;” and (3) “in the sole judgment of the

³² A “public water system” provides water for human consumption, through pipes or conveyances, and has at least fifteen service connections or regularly serves at least twenty-five individuals. *Id.* § 300f(4)(A).

³³ *Id.* § 300g-1(b).

³⁴ *Id.* § 300f(1).

³⁵ *Id.* § 300f(1)(C).

³⁶ *Id.* § 300f(1)(D).

³⁷ *Id.* § 300g-1.

³⁸ *Id.* § 300g-1(b)(1)(A).

³⁹ *Id.* § 300g-1(b)(1)(B).

⁴⁰ *Id.* §§ 300g-1(b)(1)(A)(i)–(iii).

⁴¹ *Id.* § 300g-1(b)(1)(B).

Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.”⁴² Jurisdictional clauses throughout the SDWA determine when and how stakeholders and interested individuals may bring petitions to a judicial body, and on what grounds.⁴³

The definition of an “adverse health effect” is not entirely clear.⁴⁴ One source defines it as “the causation, promotion, facilitation and/or exacerbation of a structural and/or functional abnormality, with the implication that the abnormality produced has the potential of lowering the quality of life, contributing to a disabling illness, or leading to a premature death.”⁴⁵ Another source defines the term as “a change in body function or cell structure that might lead to disease or health problems.”⁴⁶ The EPA does not offer direct guidance as to what constitutes an adverse health effect for non-carcinogens.⁴⁷ However, the agency states that it calculates a contaminant

⁴² *Id.* § 300g-1(b)(1)(A)(i)-(iii).

⁴³ For example, 42 U.S.C.A. § 300g-1(b)(1)(B)(i)(III) states that the determination of which unregulated contaminants are selected for a given Contaminant Candidate List, and therefore possible future regulation, is not subject to judicial review. Section 300j-7 contains the general judicial review provisions of the SDWA and requires, among other things, that actions pertaining to the establishment of regulations be filed only in the D.C. Circuit. Jurisdiction clauses will not be the focal point of this Comment. Research has revealed no scholarship on the jurisdictional clauses of the SDWA. For an interesting look at the role of executive (including agencies) acquiescence in jurisdiction stripping clauses, see Tara Leigh Grove, *The Article II Safeguards of Federal Jurisdiction*, 112 COLUM. L. REV. 250 (2012). This Comment will largely not touch the issue of enforcement. For these purposes, it suffices to say that, pursuant to § 300g-2, individual States will generally have enforcement responsibility for all SDWA regulations.

⁴⁴ See *supra* note 26 for a functional definition of the difference between an adverse health effect and a precursor event.

⁴⁵ Russell P. Sherwin, *What Is an Adverse Health Effect?*, 52 ENVTL. HEALTH PERSPECTIVES 177–182, 177 (Oct. 1983), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1569343/?page=1>.

⁴⁶ GREENFACTS SCIENTIFIC BOARD, *Glossary: Adverse health effect*, GREENFACTS – FACTS ON HEALTH AND THE ENVIRONMENT (July 26, 2012), <http://www.greenfacts.org/glossary/abc/adverse-health-effect-adverse-effect-harmful-health-effect.htm>.

⁴⁷ See *Drinking Water: Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List—Preliminary Determinations*, 72 Fed. Reg. 24,016,

reference dose (RfD) “without an appreciable risk of deleterious effects during a lifetime,” and takes into consideration the health effects of contaminants on particularly vulnerable subgroups.⁴⁸ In previous instances, “adverse health effects” giving rise to regulation included conditions ranging from stomach distress, brain damage, skin damage, and circulatory problems.⁴⁹ As of this writing, all NPDWRs cite an observable adverse health effect as the reason for regulation.⁵⁰

The second prong, dealing with the occurrence and frequency of a contaminant in PWSs, proves similarly difficult to define. Prior regulations, and the statute, offer little guidance.⁵¹ The EPA uses Unregulated Contaminant Monitoring Regulation (UCMR) data to determine where and at what levels a contaminant exists in PWSs.⁵² For the UCMR data to be useful, the EPA

24,021 (May 1, 2007) (discussing the use of carcinogenic and non-carcinogenic health data for creating a health reference level).

⁴⁸ OFFICE OF GROUND WATER AND DRINKING WATER, EPA, EPA 815-R-08-012, REGULATORY DETERMINATIONS SUPPORT DOCUMENT FOR CCL 2, CHAPTER 2: EVALUATION OF HEALTH AND OCCURRENCE DATA, 2-9 (June 2008), *available at* http://www.epa.gov/safewater/ccl/pdfs/reg_determine2/report_ccl2-reg2_supportdocument_ch02_datasources.pdf; § 300g-1(b)(1)(C); *see also* Drinking Water: Preliminary Regulatory Determination on Perchlorate, 73 Fed. Reg. 60,262, 60,264 (Oct. 10, 2008) (giving examples of vulnerable subgroups, including infants, children, and pregnant women).

⁴⁹ *See* 40 C.F.R. § 141.54(b)(1) (2012) (requiring that PWSs provide their customers information with respect to health effects of arsenic).

⁵⁰ *See, e.g., id.* (outlining the possible adverse health effects of arsenic).

⁵¹ *See, e.g.,* 42 U.S.C.A. § 300g-1(b)(1)(A)(ii) (West, Westlaw through Dec. 7, 2012) (creating the frequency requirement but failing to outline any threshold measure).

⁵² *Occurrence Data: Accessing Unregulated Contaminant Monitoring Data*, EPA, <http://water.epa.gov/lawsregs/rulesregs/sdwa/ucmr/data.cfm> (last updated Aug. 16, 2012). There are three sets of UCMR data, referred to as UCMR 1, UCMR 2, and UCMR 3. All data sets can be accessed at the above website.

calculates a Health Reference Level (HRL) using an RfD established to be protective of human health,⁵³ such that the overall formula is:

$$\text{HRL} = [(\text{RfD} \times \text{BW})/\text{DWI}] \times \text{RSC}.$$
⁵⁴

UCMR data is then compared with the HRL to determine how frequently a contaminant occurs in PWSs at levels of public health concern.⁵⁵ While the process for determining how frequently a contaminant occurs and at what levels is relatively easy, the EPA does not offer guidance as to what frequency is sufficient to trigger regulation.⁵⁶

Finally, the SDWA contains a subjective third prong for proper regulation. The third prong requires that, “*in the sole judgment* of the [EPA] Administrator, regulation of [a given] contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.”⁵⁷ On its face, the EPA Administrator’s evaluation of health risk reduction is necessarily subjective and amounts to an individual decision without any objective standard or

⁵³ An RfD that is protective of human health may be established at the “no-observed-effect-level” (NOEL) or “no-observed-adverse-effect-level” (NOAEL). Drinking Water: Preliminary Regulatory Determination on Perchlorate, 73 Fed. Reg. 60,262, 60,267 (Oct. 10, 2008).

⁵⁴ OFFICE OF GROUND WATER AND DRINKING WATER, *supra* note 48, at 2-10 (where BW is a presumed adult body weight of seventy kilograms, DWI is the presumed daily adult drinking water intake of two liters per day, and RSC is the relative source contribution to overall contaminant levels and is set at a default value of twenty percent); *see, e.g.*, 73 Fed. Reg. at 60,275 (using the same formula).

⁵⁵ *See, e.g.*, 73 Fed. Reg. at 60,269–71, 60,275–77 (discussing the UCMR data on perchlorate, the health reference level, and concluding that perchlorate occurs infrequently at levels of health concern in public water systems).

⁵⁶ None of the NPDWR announcements include a discussion of what percentage of PWSs must reach threshold levels for a contaminant to occur “sufficiently frequently” to be a public health concern.

⁵⁷ 42 U.S.C.A. § 300g-1(b)(1)(A)(iii) (West, Westlaw through Dec. 7, 20120) (emphasis added).

external review.⁵⁸ No EPA guidance exists that explains when regulation will present a meaningful opportunity for public health risk reduction.⁵⁹

A contaminant that meets these three criteria is eligible for listing on a Contaminant Candidate List (CCL) and for potential future regulation.⁶⁰ Neither the Administrator's decision to include an unregulated contaminant on a CCL, nor the determination that a given contaminant meets the statutory criteria, is subject to judicial review.⁶¹

2. Promulgating Regulation Under the SDWA

Regulation under the SDWA is a complex and protracted exercise. Multiple steps are required before regulation can be enacted, and the process may take years.⁶² Throughout the regulatory process, opportunities exist for public input and comment that can be utilized to shape and inform the direction of regulation.⁶³

⁵⁸ The statute goes on to say that “[t]he [EPA] Administrator’s decision whether or not to select an unregulated contaminant for a [Contaminant Candidate List and possible future regulation] ... shall not be subject to judicial review.” *Id.* § 300g-1(b)(1)(B)(i)(III).

⁵⁹ The EPA provides a basic information website related to the SDWA, where it addresses the question of how the EPA makes determinations to regulate. The EPA’s answer to this question is a restatement of the three prong test from the SDWA and does not further expound on what qualifies as a “meaningful opportunity” to reduce public health risks. *See Regulating Public Water Systems and Contaminants Under the Safe Drinking Water Act*, EPA, <http://water.epa.gov/lawsregs/rulesregs/regulatingcontaminants/basicinformation.cfm> (last updated May 21, 2012).

⁶⁰ *See* 42 U.S.C.A. § 300g-1(b)(1)(B)(i) (outlining the requirements for listing a contaminant to be considered for future regulation).

⁶¹ *See supra* note 43 for a discussion of 42 U.S.C.A. § 300g-1(b)(1)(B)(i)(III), limiting judicial review of CCLs, and why it is not the focus of this Comment.

⁶² For example, the SDWA, enacted August 6, 1996, required the EPA Administrator to promulgate a NPWDR for arsenic no later than January 1, 2001. 42 U.S.C.A. §300g-1(b)(12)(A). The EPA adopted the new arsenic standard on January 22, 2001, with an effective date of February 22, 2002, and a date of compliance for all systems of January 23, 2006. *Arsenic Rule*, EPA, <http://water.epa.gov/lawsregs/rulesregs/sdwa/arsenic/regulations.cfm> (last updated Mar. 6, 2012).

⁶³ The opportunity for public comment on unregulated contaminants begins before the publication of a CCL. 42 U.S.C.A. § 300g-1(b)(1)(B)(i)(I). A new CCL is published every five years, after consultation with the Scientific Advisory Board and public comment. *Id.* The public

The original enactment of the SDWA required the Administrator to assemble and maintain a National Contaminant Occurrence Database (NCOD) for drinking water as of August 6, 1996.⁶⁴ The database contains information on the occurrence of regulated and unregulated contaminants in PWSs.⁶⁵ UCMR data is published periodically and includes occurrence and frequency information for a list of unregulated contaminants.⁶⁶

Beginning no later than February 1998, and every five years thereafter, the statute requires the Administrator to publish a CCL of presently unregulated contaminants that occur or may occur in PWSs, and may require SDWA regulation.⁶⁷ The regulatory process commences before publication of the CCL, when the Administrator consults with the scientific community, including the Science Advisory Board (SAB), the NCOD,⁶⁸ and the public to determine which contaminants should be listed for observation and ultimately included in the CCL.⁶⁹ When using scientific evidence in the decision making process, the EPA Administrator must consult peer-reviewed studies and supporting studies conducted according to objective scientific principles and must use data collected by accepted methods.⁷⁰

then has an opportunity to comment on any contaminants selected for regulatory determinations. *Id.* § 300g-1(b)(1)(B)(ii)(I). Every step of the regulatory process involving a maximum contaminant level is open for public comment. *Id.* § 300g-1(b)(3)(C)(i). When a regulation involves specific treatment techniques, the EPA Administrator is required to seek public comment on proposed technologies and any available alternatives. *Id.* § 300g-1(b)(3)(C)(ii).

⁶⁴ *Id.* § 300j-4(g)(1).

⁶⁵ *Id.*

⁶⁶ See *Occurrence Data: Accessing Unregulated Contaminant Monitoring Data*, *supra* note 52.

⁶⁷ 42 U.S.C.A. § 300g-1(b)(1)(B)(i)(I).

⁶⁸ *Id.* § 300g-1(b)(1)(B)(i).

⁶⁹ *Id.* § 300g-1(b)(1)(B)(i)(I).

⁷⁰ *Id.* § 300g-1(b)(3)(A).

Determinations to regulate require findings that a contaminant fulfills the three SDWA criteria.⁷¹ Such findings must be based on the NCOD and other available sources of public health information.⁷² Once the Administrator determines that a given contaminant will be regulated, the Administrator must propose a Maximum Contaminant Level Goal (MCLG) and an NPDWR within twenty-four months.⁷³ MCLGs must be set at the level at which there are no known or anticipated adverse health effects and should provide a margin of safety for the most vulnerable populations.⁷⁴ The EPA must set MCLs as close to the MCLG as feasible,⁷⁵ considering costs and the best technology and treatment techniques available.⁷⁶

When proposing an NPDWR that specifies an MCL, and any alternative MCLs under consideration, the Administrator must analyze and seek public comment on the following seven factors:

- 1) Quantifiable and non-quantifiable health risk reduction benefits for which there is evidence to conclude such benefits are likely to occur as a result of compliance with each level;
- 2) Quantifiable and non-quantifiable health risk reduction benefits for which there is evidence to conclude such benefits are likely to occur from reduction in co-occurring contaminants that may reasonably be attributed to compliance with the MCL;
- 3) Quantifiable and non-quantifiable costs for which there is evidence to conclude such costs are likely to occur solely as a result of compliance with the MCL and monitoring requirements;
- 4) Incremental costs and benefits associated with alternative MCLs;
- 5) Effects of the contaminant on the general population and on vulnerable subgroups;
- 6) Increased health risks that may occur as a result of compliance, including the risk of co-occurring contaminants; and
- 7) Any other relevant factors, including the quality and extent of information used for the above analyses.⁷⁷

⁷¹ *Id.* § 300g-1(b)(1)(A).

⁷² *Id.* § 300g-1(b)(1)(B)(ii)(II).

⁷³ *Id.* § 300g-1(b)(1)(E).

⁷⁴ *Id.* § 300g-1(b)(4)(A).

⁷⁵ *Id.* § 300g-1(b)(4)(B).

⁷⁶ *Id.* § 300g-1(b)(4)(D).

⁷⁷ *Id.* §§ 300g-1(b)(3)(C)(i)(I)–(VII).

The EPA must promulgate a final MCLG and NPDWR within eighteen months of the proposal.⁷⁸

Perchlorate regulation follows this process, complex as it may be.

B. *Perchlorate Regulation Under the SDWA*

Analyzing perchlorate regulation requires an understanding of how perchlorate operates in the body and the potential health risks, as well as an understanding of the myriad sources of perchlorate exposure, and finally a survey of the regulatory process to-date. Perchlorate competitively inhibits iodide uptake in the thyroid through higher affinity bonding with the sodium iodide symporter and may lead to hypothyroidism⁷⁹ or other thyroid disruptions.⁸⁰ Some water sources contain naturally occurring perchlorate, but it is more commonly found near industrial sites manufacturing explosives.⁸¹ Perchlorate exposure often occurs through food ingestion.⁸² Beginning in 1998, the EPA has monitored perchlorate concentrations through UCMR data and announced a preliminary decision to not regulate in October 2008.⁸³ In February 2011, the EPA announced a regulatory determination that perchlorate regulation presents a meaningful opportunity to reduce public health risks and thereby began the process of regulatory

⁷⁸ The deadline may be extended by nine months through notice in the Federal Register. *Id.* § 300g-1(b)(1)(E).

⁷⁹ For the sake of definitional clarity: Hypothyroidism is “a condition in which the thyroid gland does not make enough thyroid hormone,” or an underactive thyroid. A.D.A.M. Med. Encyclopedia, *Hypothyroidism*, PUBMED HEALTH (June 4, 2012) <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001393/>. Hyperthyroidism, on the other hand, involves an over active thyroid that produces too much thyroid hormone. A.D.A.M. Med. Encyclopedia, *Hyperthyroidism*, PUBMED HEALTH (June 4, 2012) <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001396/>.

⁸⁰ NAT'L RESEARCH COUNCIL, HEALTH IMPLICATIONS OF PERCHLORATE INGESTION 36–37 (2005), *available at* http://books.nap.edu/catalog.php?record_id=11202.

⁸¹ *Perchlorate*, AM. WATER WORKS ASS'N, <http://www.awwa.org/Government/Content.cfm?ItemNumber=1065&navItemNumber=3833> (last visited Aug. 30, 2012).

⁸² Drinking Water: Preliminary Regulatory Determination on Perchlorate, 73 Fed. Reg. 60,262, 60,271 (Oct. 10, 2008).

⁸³ *Id.*

promulgation.⁸⁴ A final regulation should be proposed by February 11, 2013, twenty-four months after the official determination to regulate.⁸⁵

1. Health Effects of Perchlorate

Perchlorate⁸⁶ is a naturally occurring and man-made anion that is used to form a variety of salts.⁸⁷ Although primarily used as an oxidizer in solid rocket fuel and other propellants, perchlorate can also be found in fireworks, common explosives, bleach, some fertilizers, and air-bag inflation devices.⁸⁸ Unrelated to its industrial uses, perchlorate has been used successfully to treat hyperthyroidism.⁸⁹ For non-hyperthyroidic individuals, perchlorate may disrupt the thyroid's ability to produce hormones needed for normal growth and development, especially in pregnant women, young children, and developing fetuses.⁹⁰ Individuals with a lower iodine intake, especially women, seem to be more susceptible to these issues.⁹¹ Iodine deficiency, and conditions that prevent the use of iodine in making thyroid hormone, can lead to a decrease of thyroid hormone circulating in the blood and manifest in symptoms of hypothyroidism.⁹²

⁸⁴ Drinking Water: Regulatory Determination on Perchlorate, 76 Fed. Reg. 7762, 7765 (Feb. 11, 2011).

⁸⁵ See 42 U.S.C.A. § 300g-1(b)(1)(E) (West, Westlaw through Dec. 7, 2012). The perchlorate regulation was not proposed by February 11, 2013.

⁸⁶ "Perchlorate" is the name for the ion with chemical formula ClO_4^- . *Perchlorate*, AM. WATER WORKS ASS'N, *supra* note 81.

⁸⁷ *Id.*; *Perchlorate*, EPA, <http://water.epa.gov/drink/contaminants/unregulated/perchlorate.cfm> (last updated Sept. 26, 2012).

⁸⁸ *Perchlorate*, AM. WATER WORKS ASS'N, *supra* note 81.

⁸⁹ See Ann F. Godley & John B. Stanbury, *Preliminary Experience in the Treatment of Hyperthyroidism with Potassium Perchlorate*, 14 J. CLINICAL ENDOCRINOLOGY & METABOLISM 70, 70 (Jan. 1954) (discussing how perchlorate has been used to treat hyperthyroidism).

⁹⁰ See generally *Perchlorate*, EPA, *supra* note 87; *Perchlorate*, AM. WATER WORKS ASS'N, *supra* note 81.

⁹¹ Nat'l Ctr. for Env'tl. Health, *Perchlorate Fact Sheet October 5, 2006*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/nceh/publications/factsheets/perchlorate.htm> (last updated Jan. 7, 2009).

⁹² *Id.*

Public health concerns involving perchlorate exposure focus exclusively on thyroid function.⁹³ Properly functioning thyroid glands remove iodide from the oxygenated bloodstream and concentrate the iodide anion in the processes of hormone synthesis and storage.⁹⁴ Iodide is an essential component of two thyroid hormones, T3 and T4, and therefore the transfer of iodide from the blood to the thyroid is an essential step in this synthesis.⁹⁵ The sodium iodide symporter (NIS) molecule governs iodide transport from the blood into the thyroid.⁹⁶ NIS molecules bond tightly with iodide and with high affinity, but they will also bind and transport similarly shaped and electrically charged molecules, such as perchlorate.⁹⁷ NIS has a higher affinity for perchlorate and other similar substances than for iodide.⁹⁸ Perchlorate competitively inhibits iodide transfer into the thyroid via NIS molecules and may thus interfere with normal thyroid function.⁹⁹ Iodide transport inhibition can result in an intrathyroidal iodide deficiency, leading to a decrease in T3 and T4 production owing to lack of iodide availability.¹⁰⁰

Thyrotropin, the thyroid-stimulating hormone produced by the anterior pituitary gland, stimulates thyroid function.¹⁰¹ T4, T3, and thyrotropin create something akin to a feedback loop, such that T4 and T3 inhibit thyrotropin secretion and thereby decrease the production of NIS

⁹³ *Perchlorate and Health*, PERCHLORATE INFORMATION BUREAU, <http://perchlorateinformationbureau.org/content/perchlorate-and-health>.

⁹⁴ John B. Stanbury & James B. Wyngaarden, *Effect of Perchlorate on the Human Thyroid Gland*, 1 METABOLISM: CLINICAL & EXPERIMENTAL 533, 533 (1952).

⁹⁵ NAT'L RESEARCH COUNCIL, HEALTH IMPLICATIONS OF PERCHLORATE INGESTION, *supra* note 80, at 36–37.

⁹⁶ Orsolya Dohán et al., *The Sodium/Iodide Symporter (NIS): Characterization, Regulation, and Medical Significance*, 24 ENDOCRINE REVS. 48, 48 (2003).

⁹⁷ *Id.* at 49.

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ NAT'L RESEARCH COUNCIL, HEALTH IMPLICATIONS OF PERCHLORATE INGESTION, *supra* note 80, at 39.

molecules.¹⁰² Iodide deficiency interferes with this feedback loop and stimulates production of NIS independent of thyrotropin levels.¹⁰³ To maintain blood serum levels of thyroid hormones, the body compensates for low-level iodide deficiency through increased thyrotropin secretion and the subsequent increase in T4 and T3 production.¹⁰⁴ Generally, the body compensates for iodide deficiency and individuals have no clinical consequences or abnormalities, that is, they maintain normal blood serum levels of T4 and thyrotropin, and the thyroid does not become enlarged.¹⁰⁵

Hypothyroidism, of varying degrees, results from continued and severe iodide deficiency or other thyroidic perturbations.¹⁰⁶ While sustained changes in T4 and thyrotropin secretion may result in thyroid hypertrophy and hyperplasia,¹⁰⁷ thyroid hormone production must fall and remain substantially low for a prolonged period before adverse effects occur.¹⁰⁸ Subclinical hypothyroidism generally presents asymptotically and may be found in 4–8.5% of adults in the United States.¹⁰⁹

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ F.M. Delange, *Iodine Deficiency*, in THE THYROID: A FUNDAMENTAL AND CLINICAL TEXT 295–316 (L.E. Braverman & R.D. Utiger eds., 8th ed. 2000).

¹⁰⁵ *Id.*

¹⁰⁶ NAT'L RESEARCH COUNCIL, HEALTH IMPLICATIONS OF PERCHLORATE INGESTION, *supra* note 80, at 49. Hypothyroidism may be termed subclinical, overt, primary, or central (pituitary), and may be permanent, transient, congenital or acquired. *Id.* at 49–50. The varying subtypes classify hypothyroidism of varying degrees and resultant from differing causes. *Id.*

¹⁰⁷ Drinking Water: Preliminary Regulatory Determination on Perchlorate, 73 Fed. Reg. 60,262, 60,266 (Oct. 10, 2008).

¹⁰⁸ NAT'L RESEARCH COUNCIL, HEALTH IMPLICATIONS OF PERCHLORATE INGESTION, *supra* note 80, at 50.

¹⁰⁹ Martin I. Surks et al., *Subclinical Thyroid Disease: Scientific Review and Guidelines for Diagnosis and Management*, 291 J. AM. MED. ASS'N 228, 231 (Jan. 2004). Subclinical thyroidism can also be found in 2.5% of pregnant women, a number statistically lower than the prevalence in the general population. R. Z. Klein et al., *Prevalence of Thyroid Deficiency in Pregnant Women*, 35 CLINICAL ENDOCRINOLOGY 41, 41 (1991).

Studies of perchlorate's effects have been mixed, with one study showing no effect on blood serum hormone levels and another identifying such effects.¹¹⁰ The National Research Council, in its 2005 survey of available perchlorate/thyroid research, concluded that the available epidemiologic evidence did not support a causal link between perchlorate exposure and congenital hypothyroidism, changes in thyroid function in healthy newborns, or thyroid disorders in adults.¹¹¹

2. Sources and Occurrence of Perchlorate

Multiple sources contribute to human intake or ingestion of perchlorate.¹¹² Human exposure occurs by drinking water or eating food that contains perchlorate, or by working in manufacturing areas that include production of perchlorate-containing products.¹¹³ Highly water-soluble, perchlorate may enter water through natural or undefined sources.¹¹⁴ Perchlorate may also be found in proximity to sites where solid rocket fuel is used or manufactured.¹¹⁵

A full and fair assessment of perchlorate exposure necessarily considers exposure from sources other than drinking water, that is, relative source contributions.¹¹⁶ The EPA primarily

¹¹⁰ See 73 Fed. Reg. at 60,266 (citing Yona Amitai et al., *Gestational Exposure to High Perchlorate Concentrations in Drinking Water and Neonatal Thyroxine Levels*, 17 THYROID 843 (2007) and Benjamin C. Blount et al., *Urinary Perchlorate and Thyroid Hormone Levels in Adolescent and Adult Men and Women Living in the United States*, 114 ENVTL. HEALTH PERSPECTIVES 1865 (2006)).

¹¹¹ NAT'L RESEARCH COUNCIL, HEALTH IMPLICATIONS OF PERCHLORATE INGESTION, *supra* note 80, at 109–11.

¹¹² Nat'l Ctr. for Env'tl. Health, *Perchlorate Fact Sheet October 5, 2006*, *supra* note 91.

¹¹³ *Id.*

¹¹⁴ *Perchlorate*, AM. WATER WORKS ASS'N, *supra* note 81.

¹¹⁵ *Id.*

¹¹⁶ Drinking Water: Preliminary Regulatory Determination on Perchlorate, 73 Fed. Reg. 60,262, 60,271 (Oct. 10, 2008). The EPA notes that individuals are likely to be exposed to contaminants from sources other than drinking water, and that "total exposure to a contaminant is more relevant to . . . adverse health effects than . . . exposure . . . from drinking water alone." *Id.*

used two studies to evaluate dietary source contributions to perchlorate exposure.¹¹⁷ Combining data from the two studies, the EPA determined that pregnant women at the ninetieth percentile of food-source perchlorate intake were at the greatest risk for perchlorate contamination through drinking water.¹¹⁸

3. Regulatory History of Perchlorate

Perchlorate appeared on the first CCL (CCL 1) in 1998.¹¹⁹ Preliminary regulatory decisions for CCL 1 were announced on June 3, 2002, and perchlorate was not on the list for potential regulation.¹²⁰ The EPA announced formal regulatory decisions for CCL 1 contaminants on July 18, 2003.¹²¹ A draft of the second CCL (CCL 2) appeared in April 2004, and again

¹¹⁷ *Id.* The first study, the *Total Diet Study*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/TotalDietStudy/default.htm> (last updated Feb. 27, 2012), used nationwide sampling and analysis of a large variety of food items and nationwide surveys of food intake to estimate dietary-source exposure rates for myriad demographics in the U.S. The second study involved EPA and Centers for Disease Control analysis of the National Health and Nutrition Examination Survey, *National Health and Nutrition Examination Survey Homepage*, CENTERS FOR DISEASE CONTROL, <http://www.cdc.gov/nchs/nhanes.htm> (last updated Dec. 19, 2012). This analysis combined survey data and UCMR monitoring to estimate perchlorate exposure from food and water sources. 73 Fed. Reg. at 60,271.

¹¹⁸ *Id.* at 60,277.

¹¹⁹ Announcement of the Drinking Water Candidate List, 63 Fed. Reg. 10,274, 10,276 (Mar. 2, 1998); *CCL 1 List and Regulatory Determinations*, EPA, <http://water.epa.gov/scitech/drinkingwater/dws/ccl/cc11.cfm#list> (last updated May 9, 2012).

¹²⁰ See Announcement of Preliminary Regulatory Determinations for Priority Contaminants on the Drinking Water Contaminant Candidate List, 67 Fed. Reg. 38,222, 38,228 (June 3, 2002) (listing the nine contaminants to be regulated at the time: perchlorate was not one of them); *CCL 1 List and Regulatory Determinations*, *supra* note 117 (listing contaminants on the first CCL, not including perchlorate); see also 73 Fed. Reg. at 60,264 (discussing history of perchlorate regulation).

¹²¹ Announcement of Regulatory Determinations for Priority Contaminants on the Drinking Water Contaminant Candidate List, 68 Fed. Reg. 42,898 (July 18, 2003); *CCL 1 List and Regulatory Determinations*, *supra* note 119; see also 73 Fed. Reg. at 60,264 (discussing history of perchlorate regulation).

included perchlorate.¹²² The final list was published ten months later, in February 2005.¹²³ In January 2006, the EPA issued guidance under the National Oil and Hazardous Substances Contingency Plan—for protective measures and potential cleanup levels—at a preliminary goal of 24.5 micrograms per liter, or 24.5 parts per billion.¹²⁴

The EPA published preliminary regulatory determinations for eleven contaminants on May 1, 2007.¹²⁵ While the EPA did not publish a regulatory determination for perchlorate at that time, the notice did mention that making such a determination was a high priority.¹²⁶ As of the 2007 notice, the EPA needed more information to make an adequate determination of whether perchlorate regulation was appropriate under the SDWA.¹²⁷ Specifically, the EPA needed more information about perchlorate exposure and whether regulation would present a meaningful opportunity for public health risk reduction.¹²⁸

¹²² Drinking Water Contaminant Candidate List 2; Notice, 69 Fed. Reg. 17,406, 17,411 (Apr. 2, 2004).

¹²³ Drinking Water Contaminant Candidate List 2; Final Notice, 70 Fed. Reg. 9071, 9073 (Feb. 24, 2005); *CCL 2 List and Regulatory Determinations*, EPA, <http://water.epa.gov/scitech/drinkingwater/dws/ccl/ccl2.cfm> (last updated May 9, 2012).

¹²⁴ Drinking Water: Preliminary Regulatory Determination on Perchlorate, 73 Fed. Reg. 60,262, 60,265 (Oct. 10, 2008); see Memorandum to EPA Regional Administrators from Susan Bodine, Assistant Administrator of the Office of Solid Waste and Emergency Response, *Assessment Guidance for Perchlorate*, EPA, <http://www.epa.gov/fedfa/pdf/perchlorate-guidance.pdf> (last visited Sept. 2, 2012).

¹²⁵ Drinking Water: Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List—Preliminary Determinations, 72 Fed. Reg. 24,016 (May 1, 2007); see also 73 Fed. Reg. 60,262, 60,264–65 (discussing history of perchlorate regulation).

¹²⁶ 72 Fed. Reg. 24,016, 24,038.

¹²⁷ *Id.*

¹²⁸ *Id.*

Final determinations for the eleven contaminants were published on July 30, 2008,¹²⁹ and a preliminary regulatory determination for perchlorate came in October of the same year.¹³⁰ In October 2008, the EPA made a “preliminary regulatory determination . . . that a national primary drinking water rule [was] not necessary for perchlorate because a national primary drinking water regulation would not provide a meaningful opportunity to reduce health risk.”¹³¹ To make such a determination, the EPA had to evaluate the other two SDWA requirements for proper regulation, and found that, at sufficiently high doses, perchlorate “may have an adverse effect on the health of persons,”¹³² and that it “occurs infrequently at levels of public health concern in public water systems.”¹³³

In 2009, the Office of Water for the EPA published an Interim Drinking Water Health Advisory for Perchlorate with a health advisory level of 15 parts per billion.¹³⁴ In accordance with the statute, the EPA then accepted public comment, specifically on the use of science in a regulatory determination and whether perchlorate regulation would present a meaningful opportunity to reduce public health risks.¹³⁵ Individuals and stakeholders submitted more than six thousand comments on the 2009 notice, largely focused on alternative methods of assessing

¹²⁹ Drinking Water: Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List, 73 Fed. Reg. 44,251, 44,252 (July 30, 2008); *see also* 73 Fed. Reg. 60,262, 60,264 (discussing history of perchlorate regulation).

¹³⁰ 73 Fed. Reg. 60,262.

¹³¹ *Id.* at 60,265.

¹³² *Id.* at 60,274.

¹³³ *Id.* at 60,275.

¹³⁴ EPA, Interim Drinking Water Health Advisory for Perchlorate, EPA 822-R-08-025, December 2008, at 25, *available at* http://www.epa.gov/ogwdw/contaminants/unregulated/pdfs/healthadvisory_perchlorate_interim.pdf.

¹³⁵ Drinking Water: Regulatory Determination on Perchlorate, 76 Fed. Reg. 7762, 7763 (Feb. 11, 2011). The EPA published a response to comment document and the public comments to the 2009 notice. This information is available at <http://www.regulations.gov> with a Docket ID number of EPA-HQ-OW-2009-0297.

whether potential perchlorate regulation would offer a meaningful opportunity to reduce public health risks.¹³⁶

On February 11, 2011, the EPA announced its Regulatory Determination on Perchlorate.¹³⁷ Therein, the EPA announced its finding that perchlorate regulation presents a meaningful opportunity for health risk reduction, that perchlorate exposure may have adverse health effects, and that perchlorate occurs with sufficient frequency at levels of public health concern to justify initiating the process of proposing a perchlorate NPDWR.¹³⁸

The health effect that the EPA referred to is iodide uptake inhibition, which is considered a biochemical precursor event.¹³⁹ The first adverse health effect of perchlorate exposure, according to the National Research Council of the National Academy of Sciences, is hypothyroidism.¹⁴⁰ In terms of frequency, the EPA adjusted its analysis for the 2011 regulatory decision. Although the HRL derived by the EPA in 2008 was 15 parts per billion, a level considered to be protective of the most sensitive populations, the EPA used multiple HRLs for the 2011 determination that reversed the October 2008 preliminary determination.¹⁴¹ Fewer than

¹³⁶ *Id.*; see also *Drinking Water: Perchlorate Supplemental Request for Comments*, REGULATIONS.GOV, <http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OW-2009-0297> (last visited Dec. 20, 2012).

¹³⁷ 76 Fed. Reg. 7762.

¹³⁸ *Id.* at 7765.

¹³⁹ *Id.* at 7763. See *supra* notes 25–26 for an explanation of the difference between adverse health effects and precursor events.

¹⁴⁰ *Drinking Water: Preliminary Regulatory Determination on Perchlorate*, 73 Fed. Reg. 60,262, 60,266 (Oct. 10, 2008); see also NATIONAL RESEARCH COUNCIL, HEALTH IMPLICATIONS OF PERCHLORATE INGESTION, *supra* note 80, at 165–66 (noting that, while the EPA defined an adverse effect as a change in serum thyroid hormone concentrations, the committee considered these changes precursor events and “conclude[d] that hypothyroidism [was] the first adverse effect”).

¹⁴¹ 76 Fed. Reg. at 7765.

forty-five of the 3,865 samples PWSs had perchlorate detections at the 15 parts per billion level during the collection of UCMR 1.¹⁴²

Based on the statutory time limitations, an MCLG and proposed NPDWR for perchlorate were due by February 11, 2013: twenty-four months after the official determination to regulate.¹⁴³ The EPA did not meet its February 11 deadline and did not post any kind of notice in the Federal Register.¹⁴⁴

C. *Constitutionality of the SDWA*

When Congress passes a law, it must be, explicitly or implicitly, exercising its allotted authority under the Constitution and be operating within those bounds.¹⁴⁵ The SDWA presumably invokes Commerce Clause authority teamed with the Necessary and Proper Clause.¹⁴⁶ The Tenth Amendment cabins Article I authority, and any exercise thereof must comply with federalist principles and the vertical separation of powers.¹⁴⁷ One of the powers reserved to the states is the police power to regulate for the public health.¹⁴⁸ Regulating for the public health is the same purpose espoused by legislators for enacting the SDWA.¹⁴⁹

¹⁴² *Id.* at 7764; *see also Occurrence Data: Accessing Unregulated Contaminant Monitoring Data*, *supra* note 52.

¹⁴³ 42 U.S.C.A. § 300g-1(b)(1)(E) (West, Westlaw through Dec. 7, 2012).

¹⁴⁴ A search of the Federal Register and www.regulations.gov revealed nothing from the EPA about a proposed perchlorate regulation or an explanation for the delay. As of this writing, there remains no perchlorate MCLG or proposed NPDWR.

¹⁴⁵ *United States v. Morrison*, 529 U.S. 598, 607 (2000).

¹⁴⁶ *See Nebraska*, 331 F.3d at 998 (inferring that, because several PWSs may sell drinking water over state lines, the authority for the statute derived from the Commerce Clause).

¹⁴⁷ *Hammer v. Dagenhart*, 247 U.S. 251, 274 (1918), *overruled in part by United States v. Darby*, 312 U.S. 100, 116–17 (1941).

¹⁴⁸ *Hillsborough Cnty v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985); *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905); *England v. Louisiana State Bd. of Med. Exam'rs*, 298 F.2d 661, 667–68 (5th Cir. 1959) (quoting *Watson v. Maryland*, 218 U.S. 173, 176 (1910)); *Pickup v. Brown*, 2012 WL 6021465, 24 (E.D. Cal. Dec. 4, 2012); *Boone v. Boozman*, 217 F. Supp. 2d 938, 954 (E.D. Ark. 2002).

¹⁴⁹ H.R. Rep. No. 1185, 1974 U.S.C.C.A.N. 6454, 6454.

1. The Commerce Clause

Powers and limitations of the federal government are laid out in the Constitution. For the houses of Congress, Article I governs.¹⁵⁰ Article I outlines the composition and election of both houses, vests the legislative powers of the United States, and outlines specific powers of the Congress, including the ability to borrow funds on behalf of the United States, establish procedures of naturalization, and declare war, amongst other specifically enumerated grants of power.¹⁵¹ Article I specifically prohibits certain powers to the Congress, including the inability to legislate retroactively, to tax state exports, or to grant titles of nobility, among others.¹⁵²

Potentially the two most well-known Article I powers are the Commerce Clause¹⁵³ and the Necessary and Proper Clause.¹⁵⁴ The Necessary and Proper Clause allows Congress “[t]o make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested . . . in the Government of the United States”¹⁵⁵ Under the Commerce Clause, Congress has the power “[t]o regulate commerce with foreign Nations, and among the several States, and with the Indian Tribes.”¹⁵⁶ Teamed together, the two clauses provide a powerful foundation for most federal regulation.¹⁵⁷

¹⁵⁰ See U.S. CONST. art. I, § 8 (enumerating the powers of Congress); U.S. CONST. amend. X (reserving to the states and the people all powers not given to Congress in the Constitution).

¹⁵¹ See generally U.S. CONST. art. I.

¹⁵² See generally U.S. CONST. art. I, § 9.

¹⁵³ U.S. CONST. art. I, § 8, cl. 3.

¹⁵⁴ U.S. CONST. art. I, § 8, cl. 18.

¹⁵⁵ U.S. CONST. art. I, § 8, cl. 18.

¹⁵⁶ U.S. CONST. art. I, § 8, cl. 3.

¹⁵⁷ See, e.g., *Gonzales v. Raich*, 545 U.S. 1, 34 (2005) (Scalia, J., concurring) (discussing the interaction of the Commerce Clause and the Necessary and Proper Clause with regard to interstate and intrastate regulation); *United States v. Lopez*, 514 U.S. 549, 588 (1995) (Thomas, J., concurring) (asserting that Commerce Clause authority added to Necessary and Proper clause authority renders other enumerated powers superfluous); *New York v. United States*, 505 U.S. 144, 158–59 (1992) (noting that the Court’s “broad construction of . . . [the Commerce Clause] has . . . been guided . . . by the Constitution’s Necessary and Proper Clause”).

The Commerce Clause enjoys extensive current and historical treatment in legal scholarship and case law.¹⁵⁸ Much of the relevant treatment relates to the definitions of “commerce,”¹⁵⁹ or “affecting commerce,”¹⁶⁰ and “among the States.”¹⁶¹ Modern case law evinces “three broad categories of activity” that Congress may properly regulate under the Commerce Clause.¹⁶² First, regulation is proper when it regards the channels used for interstate commerce, such as navigable waters.¹⁶³ Second, Congress may regulate the instrumentalities, people, and things involved in interstate commerce, even when such things have an intrastate character.¹⁶⁴

¹⁵⁸ A quick WestlawNext search of secondary sources for “commerce clause” returns 9,980 law review and journal articles on the varying aspects of the subject. A similar search of all state and federal case material returns more than 10,000 cases dealing with the Commerce Clause, of which 550 are Supreme Court cases.

¹⁵⁹ *See, e.g.*, *Gibbons v. Ogden*, 22 U.S. 1, 3 (1824) (“commerce” includes traffic, navigation, transportation of goods); *N.L.R.B. v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 31 (1937) (defining commerce as “trade, . . . transportation, or communication among the several States . . .”) (quoting the National Labor Relations Act, now found at 29 U.S.C.A. § 152(6) (West, Westlaw through Dec. 7, 2012)); *City of Philadelphia v. New Jersey*, 437 U.S. 617, 622 (1978) (stating that no “objects of interstate trade” are excluded by the definition of commerce).

¹⁶⁰ *See, e.g.*, *N.L.R.B.*, 301 U.S. at 31 (defining “affecting commerce” as “in commerce, or burdening or obstructing commerce or the free flow of commerce, or having led or tending to lead to a . . . burdening or obstructing [of] commerce or the free flow of commerce”) (quoting the National Labor Relations Act, now found at 29 U.S.C.A. § 152(7) (West, Westlaw through Dec. 7, 2012)); *Nat’l Fed’n of Indep. Bus. v. Sebelius (The ACA)*, 132 S. Ct. 2566, 2578–79 (2012) (listing activities that have been said to “substantially affect interstate commerce,” including “a farmer’s decision to grow wheat” and “a loan shark’s extortionate collections from a neighborhood butcher shop”) (internal references omitted).

¹⁶¹ *See, e.g.*, *Wickard v. Filburn*, 317 U.S. 111, 123–25 (1942) (interstate commerce includes those intrastate activities that directly affect interstate commerce); *United States v. E.C. Knight Co.*, 156 U.S. 1, 16–17 (1895) (interstate commerce does not include manufacturing because it is a purely intrastate activity); *see also* *Swift & Co. v. United States*, 196 U.S. 375, 398 (1905) (stating that “commerce among the states is not a technical legal conception, but a practical one, drawn from the course of business).

¹⁶² *United States v. Lopez*, 514 U.S. 549, 558 (1995) (citing *Perez v. United States*, 402 U.S. 146, 150 (1971)); *see also* *The ACA*, 132 S. Ct. at 2578 (noting the three categories of proper regulation); *Raich*, 545 U.S. at 16–17 (discussing the three categories of Commerce Clause regulation).

¹⁶³ *The ACA*, 132 S. Ct. at 2578; *Raich*, 545 U.S. at 16–17; *Lopez*, 514 U.S. at 558.

¹⁶⁴ *The ACA*, 132 S. Ct. at 2578; *Lopez*, 514 U.S. at 558; *see also* *Perez v. United States*, 402 U.S. 146, 150 (1971) (listing the category of regulation and providing examples).

Third, Commerce Clause authority extends to regulating “those activities having a *substantial* relation to interstate commerce.”¹⁶⁵

Modern cases deal almost exclusively with the third category, as it is the hardest to define.¹⁶⁶ Activities held to have a substantial relation to interstate commerce include growing wheat for personal use,¹⁶⁷ the intrastate price of milk,¹⁶⁸ and local extortion.¹⁶⁹ While the Commerce Clause authority has expanded over the last hundred years, not all instances of its exercise have been upheld.¹⁷⁰ In *United States v. Lopez*, for example, the Court struck down a federal provision criminalizing the possession of a gun in a school zone because it had no connection to even the broadest definition of commerce.¹⁷¹ The Court further noted that the statute lacked a jurisdictional hook that would ensure, on a case-by-case basis, that gun possession in the school zone actually impacted interstate commerce.¹⁷²

¹⁶⁵ *Lopez*, 514 U.S. at 558–59 (emphasis added); see also *The ACA*, 132 S. Ct. at 2578 (stating the same category); *Raich*, 545 U.S. at 16–17 (same); *Perez*, 402 U.S. at 150 (same).

¹⁶⁶ See, e.g., *Perez*, 402 U.S. at 150 (stating that the case concerned only the third category).

¹⁶⁷ *Wickard v. Filburn*, 317 U.S. 111, 127–29 (1942) (upholding limits on personal wheat production as part of interstate commerce).

¹⁶⁸ *United States v. Wrightwood Dairy Co.*, 315 U.S. 110, 119 (stating that Congress could regulate the price of intrastate milk under the Commerce Clause).

¹⁶⁹ *Perez*, 402 U.S. at 155 (stating that a congressional finding that local loansharking impacts national credit markets constituted a rational basis for federal power under the Commerce Clause).

¹⁷⁰ See generally *Lopez*, 514 U.S. at 552–61 (describing development of Commerce Clause case history).

¹⁷¹ 514 U.S. at 560–62.

¹⁷² *Id.* This seems to suggest that regulation or legislation otherwise beyond the ambit of federal authority under the Commerce Clause can be made proper when it contains a jurisdictional hook ensuring implications of interstate commerce on a case-by-case basis. The *Lopez* Court cites to *United States v. Bass*, 404 U.S. 336 (1971), for an instance of judicial interpretation implying the required connection to interstate commerce when the statute was otherwise ambiguous. *Id.* at 562.

2. The Necessary and Proper Clause

Jurisprudence related to the Necessary and Proper Clause remains somewhat sparse. The most recent case directly analyzing the clause is *United States v. Comstock*.¹⁷³ *Comstock* involved federal civil-commitment for the detainment of mentally ill sex-offenders, beyond the end of their incarceration.¹⁷⁴ The question to the Court was whether the Necessary and Proper Clause granted adequate authority to enact the statute.¹⁷⁵ Upholding Congress’s authority to enact the statute using the Necessary and Proper Clause, the Court noted five considerations for the exercise of that authority.¹⁷⁶ The five considerations were: “breadth of the Necessary and Proper Clause;” the “history of federal involvement” in the subject matter; the government’s interest in the statute; the balancing of state and federal interests in the statute; and “the statute’s narrow scope.”¹⁷⁷

Far from utilizing arbitrary considerations to uphold the statute, the *Comstock* Court evaluated more than two hundred years of case law.¹⁷⁸ The Necessary and Proper Clause offers Congress broad authority to legislate.¹⁷⁹ “Necessary” has not been held to mean “absolutely necessary,” but rather an exercise of power using appropriate and adapted means to a legitimate end, not otherwise prohibited by the Constitution.¹⁸⁰ Exercise of this authority requires a “means-

¹⁷³ 130 S. Ct. 1949 (2010).

¹⁷⁴ *Id.* at 1954.

¹⁷⁵ *Id.* at 1956.

¹⁷⁶ *Id.* at 1965. The Court expressly declined to reach any due process concerns in this case. *Id.*

¹⁷⁷ *Id.*

¹⁷⁸ *Id.* at 1956–65.

¹⁷⁹ *Id.* at 1956; *see McCulloch v. Maryland*, 4 Wheat. 316, 408 (1819) (stating that a government entrusted with enumerated powers must be given broad means to execute those powers).

¹⁸⁰ *McCulloch*, 4 Wheat. at 421; *see also Jinks v. Richland County*, 538 U.S. 456, 462 (2003) (reemphasizing that the Necessary and Proper Clause does not require the congressional act to be “absolutely necessary”).

end rationality”¹⁸¹ analysis addressing “whether the means chosen are ‘reasonably adapted’ to the attainment of a legitimate end.”¹⁸²

Historical involvement by the federal government does not inherently support or undermine the constitutionality of a proposed congressional statutory scheme.¹⁸³ Rather than bearing on the constitutionality of a congressional act, legislative history bears on the “reasonableness of the relation” between a new or proposed scheme and existing government interests.¹⁸⁴ Further, the federal interest at stake in the congressional scheme must not contravene the letter or spirit of the constitution.¹⁸⁵ Part of this constitutional-end analysis includes balancing state and federal domains of power.¹⁸⁶ Finally, the Court consistently cautions against upholding statutes too attenuated from an explicit Article I power.¹⁸⁷

¹⁸¹ *Sabri v. United States*, 541 U.S. 600, 605 (2004).

¹⁸² *Gonzales v. Raich*, 545 U.S. 1, 37 (2005) (quoting *United States v. Darby*, 312 U.S. 100, 121 (1941)); *see also Comstock*, 130 S. Ct. at 1956–57 (incorporating the prior jurisprudence into the Court’s analysis for the first consideration under the Necessary and Proper Clause).

¹⁸³ *Comstock*, 130 S. Ct. at 1958; *Raich*, 545 U.S. at 21 (noting that a history of federal involvement can be helpful in assessing the substance of the congressional scheme) *see also* *Walz v. Tax Comm’n of City of New York*, 397 U.S. 664, 678 (1970) (“[N]o one acquires a vested or protected right in violation of the Constitution by long use”); *cf.* *United States v. Morrison*, 529 U.S. 598, 612–14 (2000) (stating that a history of federal involvement is neither necessary nor sufficient when evaluating exercise of Article I authority).

¹⁸⁴ *Comstock*, 130 S. Ct. at 1958.

¹⁸⁵ *See McCulloch*, 4 Wheat. at 421 (noting that a statute must “not [be constitutionally] prohibited”).

¹⁸⁶ *Comstock*, 130 S. Ct. at 1962. The Court tests the statute against the Tenth Amendment, discussed *infra* in Subsection II.C.3.

¹⁸⁷ *See, e.g., Comstock*, 130 S. Ct. at 1963 (stating that the link between the federal civil-commitment statute at issue and the enumerated power was not “too attenuated”); *United States v. Lopez*, 514 U.S. 549, 567 (1995) (cautioning against “pil[ing] inference upon inference” in upholding congressional actions).

3. The Tenth Amendment

Where the Commerce Clause grants Congress expansive authority to regulate instances of interstate commerce,¹⁸⁸ the entirety of Article I powers is limited by the Tenth Amendment.¹⁸⁹ Even in the most extraordinary of instances, Congress cannot legislate beyond its realm of authority as limited by the Tenth Amendment.¹⁹⁰ Federalist principles built into the Constitution reserve the police power to the States.¹⁹¹ The police power includes the authority of States to regulate for the protection of public health within their territory.¹⁹²

The Tenth Amendment states simply that “[t]he powers not delegated to the United States by [the] Constitution, nor prohibited by it to the States, are reserved to the States, respectively, or to the people.”¹⁹³ A Tenth Amendment analysis involves not only whether Congress has the affirmative authority under Article I to regulate a given activity, but whether the chosen method invades state sovereignty.¹⁹⁴ Described both as “a tautology”¹⁹⁵ and slightly differently as a

¹⁸⁸ Notably, the recent decision in *The ACA* case placed a check on congressional exercise of the Commerce Clause. 132 S. Ct. 2566, 2591 (2012). With regard to the individual mandate, the Court held that “[t]he proximity and degree of connection between the mandate and the subsequent commercial activity is too lacking to justify [federal legislation].” *Id.* It remains unclear how the new check on Commerce Clause power will impact future jurisprudence in the area.

¹⁸⁹ *Hammer v. Dagenhart*, 247 U.S. 251, 274 (1918), *overruled in part by* *United States v. Darby*, 312 U.S. 100, 116–17 (1941) (“[t]he grant of authority over a purely federal matter was not intended to destroy the local power always existing and carefully reserved to the states in the Tenth Amendment”).

¹⁹⁰ *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 528 (1935).

¹⁹¹ *See* U.S. CONST. amend. X (reserving to the states or the people those powers not explicitly granted to the federal government); *The ACA*, 132 S. Ct. at 2578 (reiterating that the police power is “possessed by the States but not by the Federal Government”).

¹⁹² *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985) (“regulation of health and safety matters is primarily, and historically, a matter of local concern”); *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905); *see The ACA*, 132 S. Ct. at 2578 (explaining that the police power is a “general power [to] govern[]” that includes many “vital functions of modern government”).

¹⁹³ U.S. CONST. amend. X.

¹⁹⁴ *Ass’n of Cmty. Orgs. for Reform Now v. Edwards*, 81 F.3d 1387, 1393 (5th Cir. 1996).

positive expression of the limits on federal power,¹⁹⁶ the Tenth Amendment affirmatively states that federal power has limits and the States retain a degree of sovereignty.¹⁹⁷

One such area of sovereignty is the so-called police power.¹⁹⁸ In 1905, the Supreme Court affirmed that the police power was not surrendered to the federal government as part of the Constitution.¹⁹⁹ Though lacking any definite limits, the police power includes the “distinctly recognized authority of a state to enact . . . ‘health laws of every description’”²⁰⁰ Phrased differently, the States retain the power to enact reasonable regulations to protect and promote public health and safety.

Most recently, in *National Federation of Independent Business v. Sebelius*,²⁰¹ commonly referred to as *The ACA*, the Court reiterated, “the police power is controlled by [fifty] different States instead of one national sovereign.”²⁰² This diffusion of sovereign power to the States

¹⁹⁵ *New York v. United States*, 505 U.S. 144, 157 (1992); *see also* *United States v. Darby*, 312 U.S. 100, 124 (1941) (stating that the Tenth Amendment “states but a truism” and that “nothing in the history of its adoption . . . suggest[s] that it was more than declaratory of the relationship between the national and state governments”).

¹⁹⁶ *The ACA*, 132 S. Ct. at 2578 (quoting THE FEDERALIST NO. 45, at 293 (James Madison)); *Koog v. United States*, 79 F.3d 452, 455 (5th Cir. 1996).

¹⁹⁷ *See id.* at 2578 (stating that the police power resides with the States and the Federal Government has no such power); *New York*, 505 U.S. at 156 (positing that congressional power is restrained by the Tenth Amendment); *see also* *Ass’n of Cmty. Orgs. for Reform Now v. Edwards*, 81 F.3d 1387, 1393 (5th Cir. 1996) (stating that the Tenth Amendment “incorporates extra-textual limitations upon Congress’ exercise of its Article I powers”).

¹⁹⁸ *The ACA*, 132 S. Ct. at 2578; *Bond v. United States*, 131 S. Ct. 2355, 2364 (2011); *United States v. Morrison*, 529 U.S. 598, 615 (2000); *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905).

¹⁹⁹ *Jacobson*, 197 U.S. at 25.

²⁰⁰ *Id.* Later jurisprudence holds the police power to include “punishing street crime, running public schools, and zoning property for development,” *The ACA*, 132 S. Ct. at 2578, and the regulation of land use, *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1009 (1992), to name a few. For a thorough discussion of the history of the police power, see Santiago Legarre, *The Historical Background of the Police Power*, 9 U. PA. J. CONST. L. 745 (2007).

²⁰¹ 132 S. Ct. 2566 (2012).

²⁰² *Id.* at 2578.

ensured that matters involving everyday life are governed by local governments, accountable to the people in those communities, and not the federal government.²⁰³

Recent Supreme Court jurisprudence also shows a trend that holds the Tenth Amendment to prohibit the federal government from commanding States to act, or commandeering State officials to enforce a federal regulatory program.²⁰⁴ Beginning in 1992, the Court held a federal act requiring states to enact legislation to provide for the disposal of radioactive waste created within state borders violated the Tenth Amendment.²⁰⁵ Building on *New York v. United States*,²⁰⁶ the Court held in *Printz v. United States*²⁰⁷ that it was impermissible under the Tenth Amendment for a federal statute to make state officials agents of a federal regulatory scheme.²⁰⁸ Congress could thus not rely on Commerce Clause authority to force state officials to conduct background checks on gun purchasers.²⁰⁹

These judicial developments set the backdrop for analyzing the SDWA and provide the framework for understanding why its constitutionality is subject to debate.

²⁰³ *Id.*

²⁰⁴ *E.g.*, *The ACA*, 132 S. Ct. at 2578; *Printz v. United States*, 521 U.S. 898, 935 (1997); *New York*, 505 U.S. at 186–87; see Robert V. Percival, *Environmental Implications of the Rehnquist Court's New Federalism*, 17 NAT. RESOURCES & ENV'T 3, 3 (Summer 2002) (arguing that the Court, beginning with *New York v. United States*, 505 U.S. 144 (1992) and going through *Fed. Mar. Comm'n v. South Carolina State Ports Auth.*, 535 U.S. 743 (2002), has begun “revitalizing constitutional limits on federal authority while strengthening state sovereignty” and “reinterpreted the Commerce Clause and the Tenth . . . Amendment[] . . . to limit Congress’ regulatory powers”).

²⁰⁵ *New York*, 505 U.S. at 187–88; see also Lori Potter, *Recent Decisions in the U.S. Supreme Court on Environmental Law*, 27 COLO. LAW. 59, 60 (Apr. 1998)

²⁰⁶ 505 U.S. 144 (1992).

²⁰⁷ 521 U.S. 898 (1997).

²⁰⁸ *Id.* at 935; see also Potter, *supra* note 205, at 60.

²⁰⁹ *Printz*, 521 U.S. at 935.

D. *Legal History of the SDWA: Case Law and Scholarship*

There exists little case law or scholarship relating to the SDWA, and none specifically addressed to perchlorate. Several cases challenged the SDWA on constitutional grounds and met with varying success.²¹⁰

The leading case with regard to the constitutionality of the SDWA is *Nebraska v. E.P.A.*,²¹¹ in which the State of Nebraska and other petitioners presented a facial challenge to the SDWA. Petitioners argued that the SDWA exceeds congressional authority because it “regulates the *intrastate* distribution and sale of drinking water.”²¹² The D.C. Circuit noted that a successful facial challenge would require a finding that under “no set of circumstances” would the statute be constitutional.²¹³ Citing to the EPA website,²¹⁴ the court noted that several PWSs sell “substantial volumes of drinking water across state lines.”²¹⁵ Pursuant to the second category of proper congressional regulation under the Commerce Clause, the *Nebraska* court upheld the SDWA because each of the interstate sales of drinking water presented a valid opportunity to exercise the commerce power.²¹⁶ Noting that petitioners failed to meet the burden of a facial challenge to the SDWA, the court declined to address whether the intrastate sale of drinking water has a “sufficiently substantial impact on interstate commerce” to warrant federal

²¹⁰ See *infra* notes 211–42 and attendant text for a discussion of the major cases involving the SDWA, and notes 243–47 for the most relevant scholarship on the topic.

²¹¹ 331 F.3d 995 (D.C. Cir. 2003).

²¹² *Id.* at 998 (emphasis added).

²¹³ *Id.* at 998 (citing *Amfac Resorts, L.L.C. v. United States Dep’t of Interior*, 282 F.3d 818, 826 (D.C. Cir. 2002), *vacated in part on other grounds sub nom. Nat’l Park Hospitality Ass’n v. Dep’t of Interior*, 538 U.S. 803 (2003)).

²¹⁴ To find this information, see the EPA website at <http://www.epa.gov/safewater/data/getdata.html>.

²¹⁵ *Nebraska*, 331 F.3d at 998.

²¹⁶ *Id.* at 998 (citing *United States v. Lopez*, 514 U.S. 549, 558 (1995)).

regulation.²¹⁷ The court further held that, because the SDWA does not “compel the states to pass legislation or to enforce federal standards . . . [but r]ather . . . regulates the states only in their capacity as public water system owners,” it does not run afoul of federalist principles and therefore comports with the Tenth Amendment.²¹⁸

The petitioners in *Nebraska* raised constitutional issues specifically with regard to the “Arsenic Rule”—a standard that regulates arsenic levels in drinking water.²¹⁹ The court found that those arguments had not been adequately preserved at the agency level.²²⁰ Judge Randolph noted that “[a]gencies do not ordinarily have jurisdiction to pass on the constitutionality of federal statutes;” thus, petitioners were not required to raise constitutional questions related to the SDWA directly to the EPA during the administrative phases.²²¹ However, because petitioners failed to raise any issues related to the Arsenic Rule during the administrative phases, and thereby failed to give the EPA an opportunity to hear arguments or fashion a more narrowly tailored rule, those arguments were not preserved and could not be heard on appeal.²²²

The Fifth Circuit had occasion to review a specific provision of the SDWA—the Lead Contamination Control Act of 1988²²³—that, amongst other things, required “States to establish remedial action programs for the removal of lead contaminants from school drinking water systems.”²²⁴ The relevant provision²²⁵ required that each State “establish a program,” consistent

²¹⁷ *Id.* at 998.

²¹⁸ *Id.* at 999.

²¹⁹ *Id.* at 997. The “Arsenic Rule” can be found at National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, 66 Fed. Reg. 6976, 6981 (Jan. 22, 2001). The MCLG for arsenic stands at 0 parts per billion, and the “enforceable MCL” is 10 parts per billion. *Id.*

²²⁰ *Nebraska*, 331 F.3d at 997–98.

²²¹ *Id.* at 997.

²²² *Id.* at 997–98.

²²³ Pub. L. No. 100-572, 102 Stat. 2884.

²²⁴ *Ass’n of Cmty. Orgs. for Reform Now v. Edwards*, 81 F.3d 1387, 1389 (5th Cir. 1996).

with the statute, to aid local educational institutions in remediating potential lead contaminations.²²⁶ Further, States were potentially subject to civil enforcement proceedings or fines, under another provision of the statute, if they did not establish such a program.²²⁷

In *Ass'n of Cmty. Orgs. for Reform Now v. Edwards*, the court held that Congress could properly exercise Commerce Clause authority to regulate lead contamination in drinking water “by regulating drinking water coolers that move in interstate commerce.”²²⁸ However, to exercise that power, Congress would have to regulate individuals directly, and not States “as conduits to the people.”²²⁹ As such, the court held that provision of the SDWA to be an “unconstitutional intrusion upon the States’ sovereign prerogative to legislate as it sees fit.”²³⁰

Other cases have challenged specific regulations, and those regulations have been struck down on varying grounds.²³¹ All of these cases have two things in common: first, they are after-the-fact challenges to specific regulations; and second, petitioners consistently argue that the rules are arbitrary and capricious, or fly in the face of existing scientific studies, and are therefore beyond the pale of EPA’s statutory authority under the SDWA.²³²

²²⁵ Originally codified as 42 U.S.C. § 300j-24(d).

²²⁶ *Edwards*, 81 F.3d at 1394.

²²⁷ *Id.* The court did not go into any Eleventh Amendment concerns over the abrogation of State sovereign immunity. For a discussion of state sovereign immunity doctrine and the Eleventh Amendment, see *Federalism—Abrogation of State Sovereign Immunity in Federal Courts*, 103 HARV. L. REV. 207 (1989).

²²⁸ 81 F.3d at 1394.

²²⁹ *Id.*

²³⁰ *Id.*

²³¹ See, e.g., *W.R. Grace & Co. v. EPA*, 261 F.3d 330, 342 (3d Cir. 2001) (challenging cleanup standards related to ammonia regulation); *Chlorine Chemistry Co. v. EPA*, 206 F.3d 1286, 1291 (D.C. Cir. 2000) (vacating chloroform regulation). In fairness, not all challenges to specific regulations have been upheld. See, e.g., *City of Waukesha v. EPA*, 320 F.3d 228, 254 (D.C. Cir. 2003) (upholding radionuclide limits).

²³² See, e.g., *W.R. Grace & Co.*, 261 F.3d at 342 (deeming the cleanup standard for ammonia to be arbitrary and capricious); *Chlorine Chemistry Co.*, 206 F.3d at 1291 (holding the chloroform MCLG arbitrary and capricious)

In *W.R. Grace & Co. v. EPA*,²³³ the EPA exercised emergency action authority pursuant to §1431(a) of the SDWA²³⁴ to require a reduction of ammonia levels in Lansing, Michigan, to 1.2 micrograms per liter.²³⁵ To arrive at this level, the EPA charged the newly-formed Saginaw Aquifer Technical Evaluation Team with evaluating four approaches to protecting the public health in Lansing.²³⁶ The Team settled on the 1.2 micrograms per liter level, but failed to explain how or why that number came into being, and failed to cite any technological study supporting the level.²³⁷ Petitioners filed a petition for review of the EPA’s authority to mandate a cleanup level of 1.2 micrograms per liter.²³⁸ The court found that the cleanup level was not “rationally based on the facts . . . to protect the public’s health” and vacated the EPA order for “fail[ing] to provide a rational explanation for concluding that [this] remediation . . . [was] necessary to protect the . . . public’s health.”²³⁹

In *Chlorine Chemistry Council v. EPA*,²⁴⁰ the D.C. Circuit found that the EPA had exceeded its statutory authority by setting a 0 microgram per liter MCLG for chloroform because it was not scientifically necessary and therefore the regulation was arbitrary and capricious.²⁴¹ Conversely, in *City of Waukesha v. EPA*,²⁴² the D.C. Circuit upheld the EPA’s regulation of

²³³ 261 F.3d 330 (3d Cir. 2001).

²³⁴ 42 U.S.C.A. § 300i(a) (West, Westlaw through Dec. 7, 2012) (allowing the EPA Administrator to take necessary action to protect the public health from an immediate and substantial threat created by contamination of a PWS).

²³⁵ 261 F.3d at 340.

²³⁶ *Id.* at 335.

²³⁷ *Id.* at 341.

²³⁸ *Id.* at 337.

²³⁹ *Id.* at 344.

²⁴⁰ 206 F.3d 1286 (D.C. Cir. 2000).

²⁴¹ *Id.* at 1291.

²⁴² 320 F.3d 228 (D.C. Cir. 2003).

radionuclides and found that the regulation was not arbitrary or capricious because the EPA had used the best science available at the time.²⁴³

The cases, regardless of outcome, show similar strands of reasoning: the regulations must be reasonably related to the protection of public health and must be supported by the best available science. Scholarship on the SDWA, however, focuses more on the statute than on individual regulations.

As mentioned, scholarly works relating the SDWA are few and far between. The most persuasive challenge to the SDWA has been on Commerce Clause grounds.²⁴⁴ Arguably the only article giving treatment to the constitutional aspects of the SDWA, Garrett Johnson argues that the SDWA invades the realm of health regulation, effectively eliminating state and local governments “from . . . policy-making.”²⁴⁵ Johnson’s argument traces modern Commerce Clause jurisprudence and the *Nebraska* case, ultimately concluding that the SDWA exceeds congressional authority because it is not an economic regulation.²⁴⁶ Other articles address aspects of the SDWA and federalism,²⁴⁷ or federalism as it relates to environmental law in general.²⁴⁸

²⁴³ *Id.* at 257.

²⁴⁴ See Garrett W. Johnson, *Constitutional Limits to Federal Environmental Regulation: The Commerce Clause Challenge to the Safe Drinking Water Act*, 10 QUINNIPIAC HEALTH L.J. 77 (2006) (arguing that the SDWA is beyond the scope of congressional authority under the Commerce Clause). For a more individual case-study approach to safe drinking water and the issues within a single metropolitan area, see James W. Moeller, *Legal Issues Associated with Safe Drinking Water in Washington, D.C.*, 31 WM. & MARY ENVTL. L. & POL’Y REV. 661 (2007).

²⁴⁵ *Id.* at 78–79.

²⁴⁶ *Id.* at 84–93.

²⁴⁷ See, e.g., A. Dan Tarlock, *Safe Drinking Water: A Federalism Perspective*, 21 WM. & MARY ENVTL. L. & POL’Y REV. 233 (1997).

²⁴⁸ See, e.g., Richard L. Revesz, *Federalism and Environmentalism: A Public Choice Analysis*, 115 HARV. L. REV. 553 (2001); Jonathan H. Adler, *Judicial Federalism and the Future of Federal Environmental Regulation*, 90 IOWA L. REV. 377 (2005); Bradley C. Bobertz, *Blowing the Whistle on Postmodern Federalism*, 21 PACE ENVTL. L. REV. 83 (2003); Robert L. Glicksman, *From Cooperative to Inoperative Federalism: The Perverse Mutation of Environmental Law and Policy*, 41 WAKE FOREST L. REV. 719 (2006); Kirsten H. Engel,

The SDWA is a complex federal statute that gives rise to ever more complex regulatory schemes. There has never been a serious constitutional challenge to the statute as a whole,²⁴⁹ and the breadth of scholarship treating the topic remains underwhelming. Despite this lack of legal history, the SDWA is an unconstitutional exercise of congressional authority.²⁵⁰

III. DISCUSSION

In its current incarnation, the SDWA boasts laudable policy objectives, but it oversteps the bounds of congressional authority and is unconstitutional.²⁵¹ Implicitly exercising a very broad Commerce Clause authority, the drafters of the SDWA failed to take account of the limiting principles of the Tenth Amendment and exceeded their constitutional authority in granting such unsupervised power to the EPA.²⁵²

Even if the SDWA itself is a proper execution of congressional authority, the proposed perchlorate regulation does not comply with the Act and is outside the scope of the EPA's regulatory powers.²⁵³ Regulations must be predicated on adverse effects on human health, not an amorphous "precursor event" as outlined in the perchlorate proposals.²⁵⁴ Furthermore,

Harnessing the Benefits of Dynamic Federalism in Environmental Law, 56 EMORY L.J. 159 (2006).

²⁴⁹ Johnson, *supra* note 243, at 78 n.6.

²⁵⁰ See *infra* Part III.A for a discussion of why Congress lacked the authority to enact the SDWA.

²⁵¹ See *infra* Part III.C.1 for a discussion of the policy objective of the SDWA, and see *infra* Part III.A for a discussion of how the SDWA goes beyond the limits of congressional authority.

²⁵² See *supra* notes 189–209 and accompanying text for a discussion of the how the Tenth Amendment operates and how Tenth Amendment jurisprudence has developed.

²⁵³ See *infra* Part III.B for a discussion of how the proposed regulation of perchlorate does not comply with the SDWA.

²⁵⁴ See 42 U.S.C.A. § 300g-1(b)(A)(i) (West, Westlaw through Dec. 7, 2012) (requiring a contaminant to have an adverse effect on human health).

perchlorate does not occur with sufficient frequency, at levels of public health concern, as compared with previous NPDWRs, to warrant regulation.²⁵⁵

Ultimately, safe drinking water is something everyone, at every level of government and regardless of political affiliation, can get behind.²⁵⁶ To bring the policy and the legal limits of authority in line with one another, the SDWA should be revised to be more objective and have a solid, principled framework for the use of scientific studies in determining which contaminants are ripe for regulation and at what level to set those limits.²⁵⁷ The focus of such revisions ought to be addressing the federalist concerns by instituting vertical limits, such that the federal power may only come into play if a threshold number of States and systems would be affected, and on ensuring that the scientific community receives due deference from the regulators.²⁵⁸

²⁵⁵ See Table 4, *infra* note 304 for a look at how frequently and at what levels perchlorate actually occurs.

²⁵⁶ See, e.g., Niki Woodard, *Streamlining California's Approach to Clean Drinking Water*, CALIFORNIA FORWARD, <http://www.cafwd.org/reporting/entry/streamlining-californias-approach-to-clean-drinking-water> (Feb. 20, 2013) (noting that “[a]ll Californians should have access to clean drinking water”); *Gambia: Safe Drinking Water for All*, ALLAFRICA.COM, <http://allafrica.com/stories/201302270909.html> (Feb. 27, 2013) (originally printed in THE POINT, a Gambian newspaper) (asserting that “[a]ccess to safe-drinking [sic] water by all is an integral part of development”); *Safe Drinking Water and Hazardous Contamination*, CONGRESSMAN ED MARKEY, <http://markey.house.gov/issues/safe-drinking-water-and-hazardous-contamination-0> (last visited Mar. 3, 2013) (including news, legislation, and other documents related to safe drinking water); *Robot Butler and the Redistribution of Wealth*, ROARINGREPUBLICAN.COM, <http://roaringrepublican.com/blog/2010/02/19/robot-butlers-and-the-redistribution-of-weath/> (Feb. 19, 2010) (reiterating that “[n]o one is against clean drinking water”). Regardless of political affiliation, level of government, or country of origin, we can all agree that safe drinking water is important.

²⁵⁷ See *infra* Part III.C for a discussion of the public policy objective of the SDWA and how to reform the statute to achieve that goal and comply with constitutional limitations.

²⁵⁸ See *infra* Part III.C.3 for a discussion of how the statute should be revised to handle the vertical separation of powers.

A. *Congress Lacked the Authority to Enact the SDWA*

The SDWA purports to exercise Commerce Clause authority, teamed with the Necessary and Proper Clause, to regulate all PWSs.²⁵⁹ Commerce Clause authority is limited by the federalist principles of the Tenth Amendment.²⁶⁰ The SDWA thus goes beyond the pale of congressional authority.

1. The Commerce Clause Argument

The argument in favor of finding the SDWA constitutional rests on Commerce Clause authority.²⁶¹ However, many PWSs do not sell across state lines, or *sell* water at all, and are purely local in nature.²⁶² The Commerce Clause as a justification for the SDWA still fails because of limitations imposed by the police power.²⁶³

As clearly articulated by the Supreme Court, Congress may, under Commerce Clause authority, regulate the channels of interstate commerce, the instrumentalities of interstate commerce, and “those activities having a substantial relation to interstate commerce.”²⁶⁴ When the petitioners in *Nebraska* challenged the constitutionality of the SDWA, the EPA directed the

²⁵⁹ *Nebraska v. EPA*, 331 F.3d 995, 998 (D.C. Cir. 2003).

²⁶⁰ See *supra* Part II.C.3 for a discussion of how the Tenth Amendment operates and limits congressional authority.

²⁶¹ See, e.g., *Nebraska*, 331 F.3d at 998 (D.C. Cir. 2003).

²⁶² See *Drinking Water Factoids: Drinking Water & Ground Water Statistics for 2004*, EPA (2004), http://www.epa.gov/safewater/data/pdfs/data_factoids_2004.pdf (discussing transient non-community water systems and non-transient non-community water systems, such as public gas stations). As an interesting aside, Garrett Johnson notes in his article that Congress may only regulate purely local activity when the overall federal scheme would be undermined without regulating the local activity. Johnson, *supra* note 243, at 98. In order to pull local activity within the ambit of the overall federal scheme, Congress would have to show that a “total incidence” of the activity threatens the national market. *Id.* (quoting *Gonzales v. Raich*, 545 U.S. 1, 18 (2005)).

²⁶³ See *infra* Part III.A.2 for a discussion of how Commerce Clause authority is limited by the Tenth Amendment.

²⁶⁴ *United States v. Lopez*, 514 U.S. 549, 558–59 (1995). See *supra* Part II.C.1 for a discussion of Commerce Clause authority, how it has developed, and how it operates.

court to several large PWSs that sell water across state lines.²⁶⁵ Sale of drinking water across state lines makes drinking water a thing involved in, or moving in, interstate commerce.²⁶⁶ With some drinking water moving in interstate commerce, drinking water sold purely *intrastate* takes on the character of the third classification—activities having a substantial relation to interstate commerce.²⁶⁷ Therefore, the argument goes, the SDWA is a proper exercise of congressional authority under the Commerce Clause to regulate the sale of drinking water.²⁶⁸

However, this argument applies only to PWSs that *sell* water. In the text of the SDWA, the drafters clearly recognized that federal authority to regulate contaminants in drinking water could not extend to the use of private wells or the sale of water by a “system” with fewer than twenty-five regular customers or fewer than fifteen connections.²⁶⁹ More than fifteen million households in the United States regularly rely on private wells for drinking water.²⁷⁰ It remains unclear how many individuals regularly use well water, but the number of household well users is approximately fifteen percent that of PWS users.²⁷¹ Fifteen percent of the market in groundwater opting out of the commercial market could arguably rise to the level of having a substantial effect on interstate commerce.²⁷²

²⁶⁵ *Nebraska*, 331 F.3d at 998.

²⁶⁶ See *supra* text accompanying note 164 for a discussion of the authority to render drinking water, sold across state lines, a thing moving in interstate commerce.

²⁶⁷ See *supra* notes 165–72 and accompanying text for a discussion of how the Commerce Clause operates with regard to this third category of interstate commerce.

²⁶⁸ See *Nebraska*, 331 F.3d at 998 (upholding the SDWA on Commerce Clause grounds because some PWSs sell across state lines).

²⁶⁹ 42 U.S.C.A. § 300f(4) (West, Westlaw through Dec. 7, 2012).

²⁷⁰ U.S. CENSUS BUREAU, CURRENT HOUSING REPORTS, SERIES H150/07, AM. HOUSING SURVEY FOR THE UNITED STATES 5 (2007), available at <http://www.census.gov/prod/2008pubs/h150-07.pdf>.

²⁷¹ *Id.*

²⁷² See *Wickard v. Filburn*, 317 U.S. 111, 127–29 (1942) (upholding limits on personal wheat production as part of interstate commerce).

In order to regulate all PWSs, the Commerce Clause authority is teamed with the Necessary and Proper Clause, such that Congress would be using reasonable means to achieve an appropriate goal.²⁷³ The problem here is that the SDWA does not regulate the *sale* of drinking water at all. The regulation is not economic in nature, but rather one that aims to protect the public health, a sphere generally reserved to the states and an inappropriate realm of congressional regulation.²⁷⁴

2. The Tenth Amendment, Cabined Authority, and Non-Economic Regulation

No scholarship exists, and no court has thoroughly treated, the potential Tenth Amendment challenges to the SDWA, or how federalist principles bear on and limit Commerce Clause authority with regard to legislation and regulation that involves specific governance under the police power.²⁷⁵ The police power, a power reserved explicitly to the States,²⁷⁶ traditionally includes the power to regulate for the protection of public health and safety within a State's territory.²⁷⁷

The SDWA, explicitly designed to authorize federal regulation for protection of the public health, runs headlong into the federalist principles of the Tenth Amendment and the police power.²⁷⁸ As the Tenth Amendment is exactly that—an Amendment that modifies the entire foregoing constitution, including the Article I Commerce Clause—congressional authority under

²⁷³ See *supra* Part II.C.2 for a discussion of the Necessary and Proper Clause.

²⁷⁴ See *supra* notes 199–200 and accompanying text for a brief discussion of how and why the police power, including regulation for the public health, has been reserved to the states.

²⁷⁵ See *supra* Part II.D for a discussion of the relevant case law and scholarship related to the SDWA.

²⁷⁶ See *supra* notes 198–203 for a discussion of the police power.

²⁷⁷ *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905).

²⁷⁸ H.R. Rep. No. 1185, 1974 U.S.C.C.A.N. 6454, 6454.

the Commerce Clause is limited by federalist principles.²⁷⁹ Furthermore, Commerce Clause authority has been limited by federalist principles by the Supreme Court when it noted that “[e]ven . . . modern-era precedents which have expanded congressional power under the Commerce Clause confirm that this power is subject to outer limits.”²⁸⁰

Perhaps more to the point, the SDWA is not an economic regulation at all. It does not regulate the *sale* of anything.²⁸¹ Regulation for the public health falls within the ambit of the police power, an unenumerated realm of the powers reserved to the States by the Tenth Amendment.²⁸²

For the above reasons, that the Commerce Clause is limited by federalist principles, and the SDWA does not regulate economic activity of any kind, the SDWA is beyond the scope of congressional authority and therefore unconstitutional. Even if the SDWA itself is a proper exercise of congressional authority, the proposed perchlorate regulation still goes outside the grant of statutory authority.

B. *Perchlorate Regulation is Improper*

The constitutionality of the SDWA is not on the firmest ground, but regardless, the proposed perchlorate regulation fails to meet statutory requirements. The administrative history

²⁷⁹ See *supra* Part II.C.3 for a discussion of the Tenth Amendment and its limiting principles. See also *The ACA*, 132 S. Ct. 2566, 2591 (2012), placing a check on congressional exercise of the Commerce Clause.

²⁸⁰ *United States v. Morrison*, 529 U.S. 598, 608 (2000) (quoting *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 37 (1937)).

²⁸¹ See 42 U.S.C.A. §§ 300f–300j-26 (West, Westlaw through Dec. 7, 2012) (regulating the PWSs, but failing to specify that system must *sell* water).

²⁸² See *supra* notes 198–203 for a discussion of the police power and its reservation to the states.

of perchlorate regulation evinces the arbitrary and capricious nature of this regulation under the statute.²⁸³

There are two main issues with the current perchlorate regulation proceedings and the precedential value that such regulation will carry. First, the use of a biochemical “precursor event,” as opposed to the “adverse health effect” required by the SDWA, sets a less rigorous regulatory precedent and does not conform to statutory requirements.²⁸⁴ Second, the EPA seems to have changed its mind as to what constitutes perchlorate occurrence with sufficient frequency and at levels of public health concern, and this shifting definition is unsupported by the UCMR data or the health advisory levels.²⁸⁵

1. No Precedent or Authority to Regulate Based on Precursor Events

There exists no precedent for regulating or drafting an MCL based on biological precursor events. In Federal Register notices and discussions, the EPA consistently addresses the

²⁸³ *Compare* Drinking Water: Preliminary Regulatory Determination on Perchlorate, 73 Fed. Reg. 60,262, 60,265 (Oct. 10, 2008) (making a preliminary regulatory determination with regard to perchlorate that a national primary drinking water regulation was inappropriate because it would not “provide a meaningful opportunity to reduce health risk”) *with* Drinking Water: Regulatory Determination on Perchlorate, 76 Fed. Reg. 7762, 7765 (Feb. 11, 2011) (finding that perchlorate regulation would present a meaningful opportunity to reduce health risk). The latter Federal Register notice directs the reader to the discussion of perchlorate’s regulatory history in the October 10, 2008, notice. There is no indication that the science involved in regulatory determinations changed between October 2008 and February 2011.

²⁸⁴ *See* 42 U.S.C.A. § 300g-1(b)(1)(A)(i) (West, Westlaw through Dec. 7, 2012) (requiring that a contaminant “may have an adverse effect on the health of persons); 73 Fed. Reg. at 60,266 (calling iodide inhibition a precursor event); *see also* BOARD ON ENVIRONMENTAL STUDIES AND TOXICOLOGY, HEALTH IMPLICATIONS OF PERCHLORATE INGESTION 167 (National Research Council 2005).

²⁸⁵ *See Occurrence Data: Accessing Unregulated Contaminant Monitoring Data*, *supra* note 52; EPA, Interim Drinking Water Health Advisory for Perchlorate, EPA 822-R-08-025, December 2008, at 25, available at http://www.epa.gov/ogwdw/contaminants/unregulated/pdfs/healthadvisory_perchlorate_interim.pdf.

question: “May [this contaminant] have an adverse effect on the health of persons?”²⁸⁶ A search of www.regulations.gov (the online address for the Federal Register) reveals that the EPA has used the term “precursor event” in three publications: two involving perchlorate, and once in a 1998 Notice discussing water quality criteria with regard to carcinogens.²⁸⁷ Current NPDWRs deal exclusively with adverse effects on human health.²⁸⁸

The SDWA specifically requires the EPA Administrator to find a contaminant may have an *adverse effect* on human health for proper regulation.²⁸⁹ Promulgating regulation predicated on a precursor event, as opposed to an adverse health effect, would, if upheld, give the EPA precedential authority to regulate any contaminant based on precursor events.²⁹⁰ With regard to endocrine disruptors and goitrogens, such as perchlorate, the life stages analysis proposed by the EPA presents an equally slippery precedential slope.²⁹¹ This approach to perchlorate regulation, using the statistical presence of a biological precursor event, as opposed to the existence of an

²⁸⁶ *E.g.*, 73 Fed. Reg. at 60,266; *see also* Drinking Water: Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List—Preliminary Determinations, 72 Fed. Reg. 24,016, 24,020–21 (May 7, 2007) (discussing “Evaluation of Adverse Health Effects”).

²⁸⁷ Notice, Draft Water Quality Criteria Methodology Revisions: Human Health, 63 Fed. Reg. 43,756 (Aug. 14, 2008), available at <http://www.gpo.gov/fdsys/pkg/FR-1998-08-14/pdf/98-21517.pdf>.

²⁸⁸ *E.g.*, National Primary Drinking Water Regulations; Radionuclides; Final Rule, 65 Fed. Reg. 76,708 (Dec. 7, 2000) (codified at 40 C.F.R. §§ 9, 141, 142 (West 2012)). For a list of currently regulated inorganic contaminants and their respective MCLs, see 40 C.F.R. § 141.62 (West 2012).

²⁸⁹ § 300g-1(b)(1)(A)(i).

²⁹⁰ Supposing such a regulation were never challenged, the EPA would still be able to cite to the previously unchallenged use of precursor events as precedent for future regulations.

²⁹¹ In its announcement of a decision to regulate perchlorate, the EPA cited to the National Research Council’s identification of fourteen distinct life stages, or age groups, that present different and unique needs and concerns with regard to perchlorate consumption. Drinking Water: Regulatory Determination on Perchlorate, 76 Fed. Reg. 7762, 7764 (Feb. 11, 2011). A life stages analysis sets a different health reference level and reference dose for each age group, based on average consumption for individuals in each stage. *Id.* The idea is to determine the most at-risk population and then establish a level protective of the ninetieth percentile rate of consumption for that age group.

adverse health effect, renders such regulation out of compliance with the SDWA and beyond the grant of statutory authority.²⁹² Perchlorate regulation, as proposed, lacks precedential or statutory authority and is improper under the SDWA.

2. Perchlorate Occurrence and Levels of Public Health Concern

Application of the occurrence requirement to perchlorate regulation has been, at best, inconsistent and requires revision to implement a clear, concise, principled method to evaluate whether perchlorate is sufficiently prevalent in PWSs to warrant regulation.

In the 2008 preliminary determination to not regulate perchlorate and the 2011 regulatory determination, the EPA used data from UCMR 1 to justify its decision.²⁹³ Clearly, the data has not changed.²⁹⁴ The 2008 determination used a health reference level of fifteen micrograms per liter, but in August 2009, the EPA proposed alternative health reference levels for fourteen life stages.²⁹⁵ These levels ranged from one microgram per liter to forty-seven micrograms per liter.²⁹⁶

UCMR 1 contained a minimum reporting level of four parts per billion, or four micrograms per liter.²⁹⁷ Of more than 150,000 PWSs in the United States,²⁹⁸ UCMR 1 analyzed

²⁹² M.A. Greer, G. Goodman, R.C. Pleuss, and S.E. Greer, *Health Effect Assessment for Environmental Perchlorate Contamination: The Dose Response for Inhibition of Thyroidal Radioiodine Uptake in Humans*, 110 ENVTL. HEALTH PERSPECTIVES 927, 931 (2002).

²⁹³ Drinking Water: Preliminary Regulatory Determination on Perchlorate, 73 Fed. Reg. 60,262, 60,269–70 (Oct. 10, 2008); Drinking Water: Regulatory Determination on Perchlorate, 76 Fed. Reg. 7762, 7764–65 (Feb. 11, 2011).

²⁹⁴ See *supra* notes 129–36 and 141–42, as well as the accompanying text, for a discussion of how the view of perchlorate’s occurrence has changed over time.

²⁹⁵ Drinking Water: Perchlorate Supplemental Request for Comments, 74 Fed. Reg. 41,883, 41,888 (Aug. 9, 2009).

²⁹⁶ 76 Fed. Reg. at 7764.

²⁹⁷ See *Occurrence Data: Accessing Unregulated Contaminant Monitoring Data*, *supra* note 52.

²⁹⁸ *FACTOIDS: Drinking Water and Ground Water Statistics for 2009*, EPA 3 (Nov. 2009), available at http://water.epa.gov/scitech/datait/databases/drink/upload/data_factoids_2009.pdf.

data on perchlorate from 3,865 systems between 2001 and 2005.²⁹⁹ 160 of the 3,865 systems test, roughly four percent, had at least one analytical detection of perchlorate at level greater than or equal to the minimum reporting level of four parts per billion.³⁰⁰ Less than two percent of the more than thirty four thousand samples collected contained perchlorate concentrations at or above the minimum reporting level.³⁰¹ The average and median perchlorate concentrations, for those samples with positive detections, were 9.85 micrograms per liter and 6.40 micrograms per liter, respectively.³⁰² While not a particularly widespread contaminant, perchlorate also does not impact a large swath of the population.³⁰³

²⁹⁹ 76 Fed. Reg. at 7764; *see Occurrence Data: Accessing Unregulated Contaminant Monitoring Data*, *supra* note 52.

³⁰⁰ *Occurrence Data: Accessing Unregulated Contaminant Monitoring Data*, *supra* note 52.

³⁰¹ *Id.*

³⁰² Drinking Water: Preliminary Regulatory Determination on Perchlorate, 73 Fed. Reg. 60,262, 60,269 (Oct. 10, 2008).

Table 3 – UCMR 1 Occurrence of Perchlorate at Concentrations Greater Than or Equal To Four Micrograms per Liter

	# of samples	Samples w/ detects	Sampling points tested	Sampling points w/ detects	Sampled systems	Systems w/ detects
Small Systems	3,295	15	1,454	8	797	8
Large Systems	31,036	622	13,533	379	3,068	152
Total Systems	34,331	637	14,987	387	3,865	160

Id.

³⁰³ *See generally* 76 Fed. Reg. at 7764–65; Drinking Water: Perchlorate Supplemental Request for Comments, 74 Fed. Reg. 41,883, 41,889 (Aug. 19, 2009); *Occurrence Data: Accessing Unregulated Contaminant Monitoring Data*, *supra* note 52.

Table 4 – Percent PWS Estimates for Perchlorate Above Thresholds of Interest

Threshold Concentration	PWSs w/ at least 1 detection > threshold of interest	PWS entry or sample points w/ at least 1 detection > threshold of interest	Range of population (millions) served by PWSs w/ at least 1 detection
4 µg/L	155 (4.0%)	371 (2.5%)	5.1 – 16.6
5 µg/L	122 (3.16%)	281 (1.88%)	14.6
6 µg/L	97 (2.5%)	219 (1.5%)	3.0 – 11.8

Even at the 2006 guidance level of 24.5 parts per billion, at most 0.39% of PWSs and 0.33% of entry points would have perchlorate concentrations above the recommended level, already determined to be adequately protective of public health.³⁰⁴ Further, the 2008 health reference level was set at fifteen parts per billion and was determined to be protective of pregnant women, the most at-risk population, to a factor of ten.³⁰⁵ At this level, 0.80% of PWSs and 0.29% of entry points have perchlorate concentrations above the protective level.³⁰⁶

The steadily decreasing reference dose, incredibly small number of affected systems and populations, and lack of additional scientific evidence supporting a regulation, suggest that perchlorate does not occur frequently or at levels of public health concern and is therefore regulation would not be a proper exercise of statutory authority. Despite the fact that perchlorate itself is not a proper subject for regulation under the SDWA, the overall aim of the statute—protecting and promoting public health—should be encouraged through other methods.

7 µg/L	82 (2.12%)	171 (1.14%)	7.2
9 µg/L	56 (1.5%)	115 (0.77%)	1.6 – 5.2
10 µg/L	52 (1.35%)	97 (0.65%)	5.0
12 µg/L	42 (1.09%)	63 (0.42%)	3.6
13 µg/L	36 (0.93%)	56 (0.37%)	No data
14 µg/L	33 (0.85%)	48 (0.32%)	0.9 – 2.1
15 µg/L	31 (0.80%)	44 (0.29%)	2.0
17 µg/L	27 (0.70%)	36 (0.24%)	1.9
19 µg/L	24 (0.62%)	30 (0.20%)	0.7 – 1.6
20 µg/L	19 (0.49%)	24 (0.16%)	1.5
23 µg/L	15 (0.39%)	19 (0.13%)	0.4 – 1.0
25 µg/L	14 (0.36%)	18 (0.12%)	1.0

Where µg/L is micrograms per liter and population estimates are rounded. Note also that five systems presented levels at four micrograms per liter and are not presented in the table.

³⁰⁴ 73 Fed. Reg. at 60,265.

³⁰⁵ See 74 Fed. Reg. at 41,888 (discussing the 2008 level, and noting that the No Observed Effect Level was actually 151 parts per billion).

³⁰⁶ See Table 4, *supra* note 303.

C. *Reconciling Authority and Public Policy*

Legal authority and the public policy behind the SDWA can be brought together with a little effort. Issues with the constitutionality of the SDWA and the propriety of proposed perchlorate regulations aside, safe drinking water is something everyone wants.³⁰⁷ Perchlorate regulation highlights the three main problems with the SDWA: health and public safety are state issues that should be dealt with on a state level, the statute uses vague and ambiguous language, and there is no defined procedure for consulting and incorporating scientific studies into the regulatory process.³⁰⁸ These three problems can be confronted head-on and can be fixed without reworking the entire framework of environmental law.³⁰⁹

1. Public Policy in Favor of the SDWA

In July 1974, the House Committee on Interstate and Foreign Commerce issued a report recommending the passage of the SDWA.³¹⁰ The committee report included a statement of legislative purpose, and said that purpose was “for protection of public health.”³¹¹ From the House Committee in 1974, to the United Nations Children’s Fund,³¹² to sitting Congressman,³¹³

³⁰⁷ See *infra* Part III.C.1 for a discussion of the public policy in favor of the SDWA.

³⁰⁸ See *supra* Part III.B for a discussion of the problems with regulating perchlorate.

³⁰⁹ See *infra* Part III.C.3 for suggestions on how the SDWA should be revised.

³¹⁰ H.R. REP. NO. 93-1185 (1974), *reprinted in* 1974 U.S.C.C.A.N. 6454, 6454.

³¹¹ *Id.*

³¹² *Clean Water Campaign*, UNICEF USA, <http://www.unicefusa.org/work/water/> (last visited Mar. 3, 2013).

³¹³ *Safe Drinking Water and Hazardous Contamination*, CONGRESSMAN ED MARKEY, <http://markey.house.gov/issues/safe-drinking-water-and-hazardous-contamination-0> (last visited Mar. 3, 2013).

and conservative blog op-eds,³¹⁴ everyone agrees that safe drinking water is important and makes for good public policy.³¹⁵

Where the ends are surely sound, the means—the SDWA—not only go beyond the limits of congressional authority, but also have serious problems in the current incarnation.³¹⁶ The SDWA has problems built into the statute that require reconsideration and revision to bring the policy objectives in step with the limits of legal authority.³¹⁷

2. Problems with the Statutory Language

Three main issues within the text of the SDWA necessitate revision. First, while the purpose of the NPDWRs is to protect and promote the public health, these aims are part of the police power traditionally reserved to the States, and unsupervised encroachment by the EPA raises significant issues of federalism. Second, the statute is vague: the three requirements for regulation are inadequately defined and lead to uncertainty and unpredictability in the regulatory process. Finally, while the SDWA requires the EPA Administrator to consult scientific studies and authority, there remains no standard for how much weight should be lent to those authorities or how the information should be incorporated in the regulatory process.

³¹⁴ *Robot Butler and the Redistribution of Wealth*, ROARINGREPUBLICAN.COM, <http://roaringrepublican.com/blog/2010/02/19/robot-butlers-and-the-redistribution-of-weath/> (Feb. 19, 2010).

³¹⁵ See, e.g., Niki Woodard, *Streamlining California's Approach to Clean Drinking Water*, CALIFORNIA FORWARD, <http://www.cafwd.org/reporting/entry/streamlining-californias-approach-to-clean-drinking-water> (Feb. 20, 2013) (noting that “[a]ll Californians should have access to clean drinking water”); *Gambia: Safe Drinking Water for All*, ALLAFRICA.COM, <http://allafrica.com/stories/201302270909.html> (Feb. 27, 2013) (originally printed in THE POINT, a Gambian newspaper) (asserting that “[a]ccess to safe-drinking [sic] water by all is an integral part of development”).

³¹⁶ See *supra* Part III.A for a discussion of the constitutional problems with the SDWA.

³¹⁷ See *infra* Part III.C.2 for a discussion of the problems with the statutory language of the SDWA.

The police power allows States to regulate for the protection of public health.³¹⁸ State and local governments are obviously in greater proximity to their populations and thus better positioned to evaluate local needs and problems.³¹⁹ These localized governments are in the best position to evaluate the quality of their source waters, the relative risk various contaminants pose to their populations, and the most efficient balancing of costs and benefits.³²⁰

Regulations that have a direct and substantial effect on the States, the distribution of power and responsibilities amongst the levels of governments, or the relationship between the federal and state governments, implicates federalism.³²¹ NPDWRs promulgated under the SDWA require State monitoring and enforcement, and therefore have a direct and substantial effect on the States.³²² These regulations therefore have federalist implications that need to be addressed in the statute.

The SDWA does not adequately address or codify a process by which to evaluate the direct impact on States or incorporate States into the regulatory process to ensure harmony between the levels of government.³²³ Silence on this issue requires the SDWA to be reconsidered and amended.

³¹⁸ See *supra* notes 191–200 for a discussion of the police power and regulating for the public health.

³¹⁹ Exec. Order No. 13,132, *Federalism*, 64 Fed. Reg. 43,255, 43,255 (Aug. 4, 1999).

³²⁰ See *Bond v. United States*, 131 S. Ct. 2355, 2364 (2011) (stating that the “federal structure allows local policies ‘more sensitive to the diverse needs of a heterogeneous society’ . . . [and] enables greater citizen ‘involvement in democratic processes,’ [that] make[] government ‘more responsive’” (quoting *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991))).

³²¹ *Id.*

³²² See *supra* note 43 for a brief discussion of enforcement responsibilities.

³²³ See 42 U.S.C.A. §§ 300f–300j-26 (West, Westlaw through Dec. 7, 2012) (lacking any language requiring the Administrator to *use* the information he or she obtains from consultation with scientific community).

The statute also suffers from impermissible vagueness.³²⁴ Nowhere in the SDWA or attendant regulations are the terms “adverse effect on human health,” “sufficient frequency,” or “levels of public health concern” defined.³²⁵ Additionally, the statute and regulations provide no method for stakeholders and interested parties to reasonably foresee regulation based on external and objective factors.

While Congress may reasonably include a degree of vagueness in statutory drafting to allow designated agencies and subject-matter experts to use their skills to achieve congressional objectives, overbreadth deprives States and interested parties the opportunity to foresee regulation and self-police their activities. The requirement for an Administrator to find that a contaminant *may* have an adverse effect on the health of persons before promulgating regulation is highly subjective.³²⁶ This prong includes no threshold definition of “adverse effect” or any method of evaluating or incorporating peer-reviewed science.³²⁷ Additionally, regulation based on previously unused and undefined markers, such as precursor events and life stage analyses, looks more like a search for expanded authority than an effort to fulfill the policy goal of protecting the public health in compliance with the statutory mandate.

³²⁴ See *supra* notes 44–59 and accompanying text for a discussion of the three prongs required for regulation and the difficulty encountered when trying to define those requirements.

³²⁵ See 42 U.S.C.A. §§ 300f–300j-26 (lacking any definition of these terms).

³²⁶ See *supra* notes 44–50 and accompanying text for a discussion of this prong.

³²⁷ It is important to remember that the statutory definition for a contaminant, with regard to drinking water, is literally anything other than H₂O. 42 U.S.C.A. § 300f(6). A quick perusal of the Cancer Research UK website shows the broad spectrum of things that could cause cancer: age, lifestyle, DNA damage, carcinogens, inherited gene faults, viruses, problems with the immune system, etc. *What Causes Cancer?*, CANCER RESEARCH UK, <http://info.cancerresearchuk.org/cancerandresearch/all-about-cancer/what-is-cancer/what-causes-cancer/what-causes-cancer2> (last visited Aug. 9, 2012). Using this list as an example, without narrowing the definition of “adverse health effect,” almost anything that could occur in drinking water, other than pure water, would be subject to federal regulation under the SDWA.

The second requirement, that a contaminant occur with sufficient frequency at levels of public health concern,³²⁸ lacks objective definition. The EPA uses UCMR data and information from the National Inorganic Radionuclide Survey to evaluate contaminant occurrence and exposure.³²⁹ While these data sources are readily accessible to the public, they provide no guidance as to what constitutes “sufficient occurrence” of a contaminant that will trigger federal regulation. A related issue, what constitutes occurrence at a level of public health concern,³³⁰ remains equally undefined.

The final prong, requiring the Administrator to find that regulating a contaminant presents a “meaningful opportunity to reduce public health risks,”³³¹ is the most problematic. This finding, which is not subject to judicial review,³³² bears no external evaluation or review any kind. It does not encourage effective and efficient governance, but rather encourages, at a minimum, the perception of over-regulation at best and politicized regulation at worst. The requirement is arbitrary and capricious because it neither requires expert opinion or scientific evidence nor allows for objective review of the determination.

Finally, the SDWA offers no guidance on how the EPA Administrator is to use scientific information.³³³ Multiple sections of the statute require the Administrator to consult with

³²⁸ See *supra* notes 51–56 for a discussion of this requirement.

³²⁹ Drinking Water: Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List—Preliminary Determinations, 72 Fed. Reg. 24,016, 24,022 (May 1, 2007).

³³⁰ See *supra* Part III.B.2 for a discussion of occurrence and levels of public health concern as they relate to perchlorate, and how the definition has changed over time.

³³¹ See *supra* notes 57–59 for a discussion of this requirement.

³³² See *supra* note 43 for a discussion of the limited judicial review under the SDWA, and why it is not the focus of this Comment.

³³³ The statute does require the Administrator to consult with the scientific community, but makes no mention as to how that information should be used.

scientists and scientific data³³⁴ or require that studies used in the decision making process be peer-reviewed and conducted according to objective principles.³³⁵ However, the SDWA makes no mention as to how the information should be used or the relative weight it ought to be accorded in the regulatory process.³³⁶ Regulation based on adverse health effects, occurrence data, and levels of public health concern, necessarily involves intensive scientific valuations.

The SDWA has serious problems written into the statute. These problems decrease efficiency, clarity, and transparency in the regulatory process, and discourage reasonably responsible behavior by PWSs by decreasing the predictability of future regulation. For the foregoing reasons, the SDWA should be reconsidered and revised to promote clarity, transparency, efficiency, and predictability in the regulatory process.

3. Revising the SDWA

Three major issues relating to the SDWA and regulatory promulgation should be considered for revision: federalism concerns; clarity and transparency of the regulatory process; and the approach to using scientific studies and principles in developing NPDWRs. The key in revising the SDWA will be focusing on the introduction of a standard approach to using scientific studies, principles, and findings when making regulatory determinations and promulgating NPDWRs.

Revisions revolving around federalism should focus on denying the EPA authority to regulate when fewer than, for example, fifteen or twenty States would be affected by a given regulation. States like Massachusetts and California have elected to self-regulate contaminants

³³⁴ See, e.g., 42 U.S.C.A. § 300g-1(b)(1)(B)(i) (West, Westlaw through Dec. 7, 2012).

³³⁵ See, e.g., *id.* at § 300g-1(b)(3)(A).

³³⁶ See *supra* note 333.

like perchlorate before the federal government ever gets involved.³³⁷ Rather than occupying the field of drinking water regulation, Congress should build into the SDWA provisions encouraging States to self-regulate and provide matching cleanup funds or decreased interest rates to facilitate necessary capital improvements.

To promote clarity, objectivity, and transparency in the regulatory process, Congress or the EPA needs to clarify definitions for “adverse health effect,” “sufficiently frequent occurrence,” and “levels of public health concern.”³³⁸ Additionally, the third prong of the SDWA—allowing for regulation at the sole judgment and determination of the EPA Administrator—should be rescinded. “In the sole judgment of the Administrator” can be nothing but an entirely subjective requirement, and should be replaced with deference to the scientific community and the best available data.³³⁹

A starting point for clarifying definitions and increasing transparency should be to codify deference to the National Research Council’s determinations for adverse health effects of a given contaminant, and allow the EPA to regulate at a factor of 0.6 of the contaminant level causing that effect. Contaminant occurrence that is sufficiently frequent to warrant federal regulation may be occurrence in at least fifteen states with a spectrum of PWSs reporting at levels of public health concern, where such level is defined as one half the reference dose.³⁴⁰ Replacing the

³³⁷ See 310 MASS. CODE REGS. 22.06 (codifying perchlorate regulation in Massachusetts); CAL. CODE REGS. tit. 22, § 64431 (same in California).

³³⁸ See *supra* notes 44–56 and accompanying text for a discussion of these requirements, and Part III.B for a discussion of the problems with perchlorate regulation, centered on these two definitions.

³³⁹ See *supra* notes 57–59 and accompanying text for a discussion of this prong

³⁴⁰ The exact threshold for how many states or PWSs need to report contamination at levels of public health concern is an issue more appropriately covered by the legislature in conjunction with the scientific community.

subjective component of regulation dovetails nicely with increasing the role of scientific studies and deference to that community.

IV. CONCLUSION

The SDWA advances the admirable goal of providing safe drinking water across the nation. Ostensibly enacted by pairing Commerce Clause authority with the Necessary and Proper Clause, the SDWA exceeds congressional power because it does not bear on interstate commerce but rather intrastate activity that ought to be regulated by the States.³⁴¹ The police power reserved to the States includes the authority to regulate for the public health, which is exactly what the SDWA purports to do. In its current form, the SDWA oversteps congressional authority and runs afoul of the Tenth Amendment and is, therefore, unconstitutional.³⁴²

Furthermore, even if the SDWA is a proper exercise of congressional authority, perchlorate regulation thereunder does not comply with the statute.³⁴³ Regulating a precursor event is not the same as regulating an adverse effect.³⁴⁴ Perchlorate does not occur with sufficient frequency to fall under the SDWA authority.³⁴⁵

To comply with the law, the SDWA should be rewritten with a focus on definable thresholds and statutorily required deference to the scientific community and the National Academy of Sciences in particular.³⁴⁶ The revised SDWA should also contain a jurisdictional hook, such that only those PWSs involved in interstate commerce are subject to regulation or

³⁴¹ See *supra* Part III.A for a discussion of the problems with enacting the SDWA.

³⁴² See *supra* Part III.A for a more thorough articulation of this point.

³⁴³ See *supra* Part III.B for a discussion of why perchlorate regulation is inappropriate, even if the SDWA is constitutional.

³⁴⁴ See *supra* notes 25–26 for a brief articulation of the difference between these terms.

³⁴⁵ See *supra* notes 293–306 and accompanying text for a discussion of how *infrequently* perchlorate occurs.

³⁴⁶ See *supra* Part III.C.3 for a discussion of how the SDWA should be revised.

federal regulation can only be triggered when a threshold number of States experience contamination at levels of public health concern.

Arsenic regulation cost rural American households more than three hundred dollars a year, to be protected at an unnecessarily low level. We cannot afford unnecessary expansions of regulatory authority into communities that do not need it, do not want it, and are better equipped to handle the issue themselves.

GLOSSARY OF ACRONYMS

- BW Body Weight
- CCL..... Contaminant Candidate List
- CERCLA..... Comprehensive Environmental Response, Compensation and Liability Act
- DWI..... Daily Water Intake
- EPA..... Environmental Protection Agency
- HRL..... Health Reference Level
- MCL..... Maximum Contaminant Level
- MCLG..... Maximum Contaminant Level Guideline
- NCOD National Contaminant Occurrence Database
- NPDWR National Primary Drinking Water Regulation
- PWS Public Water System
- RfD..... Reference Dose
- RSC..... Relative Source Contribution
- SAB..... Science Advisory Board
- SDWA..... Safe Drinking Water Act
- UCMR..... Unregulated Contaminant Monitoring Data