Research needs in drinking water: a basis in regulations in the United States

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ABSTRACT

Regulations are one of the primary drivers for research on contaminants in drinking water in the United States. Since the original Safe Drinking Water Act (SDWA), enacted in 1974, the United States Environmental Protection Agency (USEPA) has developed a series of drinking water regulations. These regulations are focused on protecting public health. When evaluating available information on whether or not to regulate a constituent in drinking water, USEPA considers available information on health effects and occurrence of the constituent. The authors provide their view of the research needed for these contaminants. For inorganics, more data are needed on perchlorate. For organics, greater treatment and health effects information is warranted for N-nitrosodimethylamine (NDMA), methyl tertiary butyl ether (MTBE) and pharmaceuticals and personal care products. Finally, more research is needed on analytical methods for noroviruses and other emerging pathogens.

Key words | regulations, maximum contaminant level, research needs, carcinogen, health effects

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INTRODUCTION

From the original 1974 Safe Drinking Water Act (SDWA) (US Government 1974) up until today, the United States Environmental Protection Agency (USEPA) has developed a series of increasingly complex and encompassing drinking water regulations. While the original SDWA gave the federal government, through the newly created EPA, the authority to regulate drinking water in the US, it was amendments authorized in 1986 and 1996 (US Government 1986; US Government 1996) that were key to spurring the development of additional regulations.

The salient requirement from the SDWA is that EPA establish regulations to protect public health. When evaluating available information on whether or not to regulate a constituent in drinking water, EPA considers available information on health effects and occurrence of the constituent. Health effects information comes from human studies (e.g., epidemiological studies) and animal toxicology studies. Occurrence information can come from a variety of sources including a series of EPA regulations

which have required utilities to monitor for unregulated contaminants.

The first step in the regulatory process of a water constituent is the establishment of a maximum contaminant level goal (MCLG). The MCLG is a non-enforceable health goal set at a level at which "no known or anticipated adverse effect on the health of persons occur and which allows an adequate margin of safety." Depending on whether EPA considers a given constituent to be a carcinogen, based on the available health effects information, will determine the process through which EPA uses to establish the MCLG (and thereafter the maximum contaminant level (MCL)).

At the same time EPA establishes an MCLG, they also establish a National Primary Drinking Water Regulation (NPDWR), which can be an MCL or a treatment technique (TT). While the MCLG reflects the risk assessment portion of drinking water regulations, the NPDWR reflects the risk management portion of the equation and takes into

consideration the ability of analytical methodologies, availability and efficacy of treatment technology and costs when establishing the MCL or TT.

Under the 1996 Amendments (US Government 1986), EPA is required to review and revise, as necessary, existing regulations every 6 years. Any revision to a regulation must provide for equal or greater protection of public health. When establishing new regulations or when conducting their required 6-year review of regulations, EPA needs to use available scientifically-sound data on areas such as: health effects (human and animal studies), analytical methodologies, treatment technologies, occurrence information and exposure assessments. Many research issues stem from the overall questions that can be asked as a result of regulatory initiatives:

1. Is the research essential to review current or anticipated regulations?
2. Is the research essential for development of new regulation?
3. Is there an information need to be filled?
4. If the research were not carried out now and in the future, would that have a significant impact on development of regulations?
5. Is there a way to evaluate how this information could impact the regulatory outcome?
6. Assuming funding is available, can the research be conducted before it is required for the regulatory process?

The objective of this paper is to provide an overview of the current and future drinking water regulations that form the basis of research needs. The paper then provides comparative research needs for selected contaminants.

OVERVIEW OF REGULATIONS

Under the SDWA, EPA has established numerous regulations for inorganic, organic, and microbial contaminants in drinking water. Drinking water regulations include: (1) identification of which analytical methods are approved for use, (2) where and how frequently to collect samples, (3) how to determine compliance, and (4) the establishment of reporting and record keeping requirements. Table 1 presents the current EPA drinking water regulations.

IMPORTANT FUTURE REGULATIONS AND SELECTED CONTAMINANTS

Several important drinking water regulations are anticipated in the next 5 to 10 years. These include the following: Stage 2 Disinfection Byproduct (DBP) Rule, Long-term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR),

Table 1 | Current USEPA Drinking Water Regulations

National Primary Drinking Water Regulations originally adopted standards for 22 compounds as "interim" standards (1975)
National Primary Regulations for Radionuclides (1976)
National Secondary Drinking Water Regulations (1979, 1986, 1991)
Total trihalomethane (TTHM) regulation (1979)
Phase I regulations for 8 volatile organic chemicals (1987)
Surface Water Treatment Rule (1989)
Revised Total Coliform Rule (1989)
Phase II and V regulations covering SOCs and IOCs (1991, 1992).
Lead and Copper Rule (1991)
Information Collection Rule (1996)
Stage 1 D/DBP Rule (1998)
Interim Enhanced Surface Water Treatment Rule (1998)
Consumer Confidence Report Rule (1998)
Candidate Contaminant List (1998)
Unregulated Contaminant Monitoring Rule (1999)
Revised regulations for radionuclides (2000)
Public Notification Rule (2000)
Revised MCL for arsenic (2001)
Filter Backwash Water Rule (2001)
Long Term (1) Enhanced Surface Water Treatment Rule (2002)

Radon, a Groundwater Rule (GWR), a Distribution System Rule as well as others. These anticipated regulations as well as a short discussion of some selected contaminants, are discussed briefly below.

Microbial/DBP Regulations

In 1998, EPA promulgated the Stage 1 Disinfectant/ Disinfection By-Product (D/DBP) Rule (USEPA 1998) and the Interim Enhanced Surface Water Treatment Rule (ESWTR) (USEPA 2002). The next iteration of both of these regulations, the LT2ESWTR and the Stage 2 DBP rule, were proposed in August, 2003. The LT2ESWTR will require surface water systems to conduct two years of monitoring for *Cryptosporidium*. Future treatment requirements will be based on the results of that monitoring. The Stage 2 DBP Rule will make changes to sample locations and the method of compliance determination that will make compliance with the MCLs more stringent. The combination of these two regulations will make ensuring compliance with microbial and DBP regulations increasingly challenging for utilities. As of this writing these regulations are scheduled to be published in December 2005, or early 2006.

Radon

In November, 1999, EPA proposed a radon MCL of 300 pCi/l, based on carcinogenicity from inhalation. At the same time, EPA also proposed an Alternate MCL (AMCL) of 4,000 pCi/l. Utilities would be allowed to comply with the AMCL (instead of the MCL) only if there was an approved multi-media mitigation program (e.g., reduction of indoor air radon concentrations). A final regulation was supposed to be published by August 6, 2000, but has not yet been released. The final rule appears to be delayed until 2007 or later.

Groundwater Rule

In 2000, EPA published the proposed GWR. The proposed GWR included requirements for sanitary surveys, identification of "significant deficiencies," source monitoring for indicators of possible fecal contamination and requirements that some systems will be triggered to provide 4-log virus inactivation. A final GWR could be published in mid to late 2006.

Distribution System Rule

In 2002, EPA released nine white papers on potential public health risks associated with various distribution system issues (USEPA 2002). The nine white papers are as follows: (1) intrusion; (2) cross-connection control; (3) aging infrastructure and corrosion; (4) permeation and leaching; (5) nitrification; (6) biofilms/growth; (7) covered storage; (8) decay in water quality over time and (9) new or repaired water mains. EPA anticipates publishing a proposed Distribution System Rule in 2006 and a final regulation by 2008.

Perchlorate

Ammonium, potassium and sodium perchlorate (ClO_4^-) salts have a number of industrial and military uses. Ammonium perchlorate has been used as an oxygen-adding component in solid fuel propellant for rockets, missiles and fireworks. Perchlorate is very mobile in aqueous systems and it can persist under typical groundwater and surface water conditions for decades. Since the beginning of 1997, (with the development of a low level detection methodology), perchlorate has been detected in various drinking water supplies. Perchlorate is on the 1998 Candidate Contaminant List (CCL) and monitoring for perchlorate occurrence was required through the Unregulated Contaminant Monitoring Rule (UCMR).

On January 10, 2005 a National Research Council (NRC) expert panel released a report reviewing perchlorate health effects information. The NRC panel calculated what is referred to as a reference dose (RfD) for perchlorate. The determination of an RfD is the one of the first steps towards establishing a maximum contaminant level (MCL) for a non-carcinogen. The RfD calculated by the NRC panel was 20 times higher than a draft RfD previously determined by EPA. The NRC based its RfD calculation on results from a human exposure study while EPA's RfD was based upon the results of animal (rat) feeding studies. EPA agreed with the conclusions of the panel and adopted the NRC's RfD.

The next step towards determination of an MCL would be to calculate the drinking water equivalent level (DWEL) using the RfD. The DWEL represents a level that assumes all exposure to a contaminant is from drinking water. Based

on the NRC's RfD, the DWEL for perchlorate would be 24.5 micrograms per liter.

After determining the DWEL, EPA would then evaluate the extent of perchlorate exposure from other sources (e.g. food products). The greater the exposure to perchlorate from other sources, the lower the MCL could end up.

N-nitrosodimethylamine (NDMA)

NDMA is a semi-volatile organic chemical which is soluble in water. It was manufactured and used as an intermediate in the production of 1,1-dimethylhydrazine, a storable liquid rocket fuel that contained approximately 0.1% NDMA as an impurity, from the mid-1950s until 1976. NDMA has also been used as an inhibitor of nitrification in soil, as a plasticizer for rubber and polymers, as a solvent in the fiber and plastics industry, an antioxidant, a softener of copolymers, and as an additive to lubricants.

In 1999, the California Department of Health Services (CDHS) became aware that NDMA could also be present at very low levels (less than 0.01 part per billion (ppb)) in treated drinking water (California Department of Health Services 2004). Research to date suggests that NDMA's presence in drinking water is related to disinfection processes.

Hormonally Active Agents/Pharmaceuticals/Personal Care Products

The newest emerging water quality issue is the possible presence of pharmaceuticals, personal care products and hormonally active agents in the environment. Domestic wastes are the primary sources of these personal care products and hormonally active agents in the environment. Hormonally active agents can also originate from concentrated animal feeding operations. There are a broad variety of pharmaceuticals and personal care products (Table 2) that can be released into the environment.

In addition, other types of compounds are being examined as potentially being hormonally active agents. These include such compounds as pesticides, plastic additives, polychlorinated biphenyls, brominated flame retardants, dioxins, and hormones and their metabolites.

Table 2 | Pharmaceuticals and personal care products detected in the environment

Fragrances	Analgesics
Hormones	Antibiotics
Hair care products	Anti-epileptic medicines
Oral hygiene products	Anti-inflammatory medicine
Skin care products	Bath additives
Stimulants	Blood lipid regulators
Sunscreens	Cough syrup
Detergents	

The public health impacts of exposure to low levels of these contaminants have not been well defined. Potential health impacts include disruption of the male and female reproductive systems, the hypothalamus and pituitary, and the thyroid. The 1996 Amendments to the Safe Drinking Water Act required EPA to develop a screening and testing program to determine which chemical substances have possible endocrine disrupting effects in humans.

CONTAMINANT CANDIDATE LIST

In March 1998 EPA published the final Drinking Water Contaminant Candidate List (CCL) (USEPA 1998) as required under the SDWA Amendments of 1996. The purpose of the CCL is to serve as the starting point for possible future regulations (however, at any time, EPA could decide to regulate a contaminant not on the CCL). The contaminants on this list are not subject to any current or proposed drinking water regulation, are known or anticipated to occur in public water systems, "and may require regulation under SDWA."

Under the SDWA, by August 2001, EPA was to select five or more contaminants from the list and determine whether to regulate them. If EPA determined that regulations were necessary, then the regulations were to be proposed by August 2003 and finalized by February 2005. The bottom-line criterion that EPA will use to determine if a

regulation is needed is whether regulating a compound presents "a meaningful opportunity to reduce health risk."

Table 3 presents the final 1998 drinking water CCL (USEPA 1998). The list is composed of 50 chemical and 10 microbial contaminants.

When reviewing compounds on the CCL, to pursue a regulatory determination, EPA will need to conduct a risk assessment for a given compound (e.g., review of available information on health effects and exposure). In assessing health effects information, EPA will take into consideration and evaluate the following:

1. exposure from drinking water and other media (to determine the relative source contribution from water if possible),
2. toxicokinetics,
3. what is the adverse health impact of concern,
4. dose-response assessment, and
5. overall characterization of risk from drinking water.

Then, similar to the process used when EPA establishes an MCLG as part of the NPDWR, EPA calculates a Health Reference Level (HRL). The first step for the HRL calculation is to determine whether or not a contaminant is a carcinogen or a noncarcinogen. If EPA considers a contaminant to be a carcinogen, the one-in-a million (i.e. 10^{-6}) risk level is used for the HRL. If the contaminant is considered to be a noncarcinogen, EPA calculates a reference dose (RfD), uses a relative source contribution factor of 20%, a 70 kg body weight and a 2 liter per day water consumption to calculate the HRL.

Occurrence data used to evaluate contaminants on the CCL came primarily from the UCMR and the National Inorganic and Radionuclides Survey (NIRS).

When EPA published the final CCL, EPA sorted the 60 contaminants into various categories which represent the needed next steps in terms of research and data collection before evaluating whether a regulation was justified. Table 4 presents those categories and the contaminants which EPA put into each category.

In July, 2003, EPA completed a review of 9 contaminants from the initial CCL and concluded that regulations were not needed at this time (USEPA 2003). The 9 contaminants were: (1) *Acanthamoeba*; (2) aldrin; (3) dieldrin; (4) hexachlorobutadiene; (5) manganese; (6) metribuzin;

(7) naphthalene; (8) sodium and (9) sulfate. Some contaminants of interest, due to groundwater contamination, remain on the CCL, including perchlorate (a byproduct of rocket fuel production) and MTBE (a gasoline oxygenate additive).

A second CCL (CCL2) was proposed in 2004 and included the remaining 51 compounds from the initial CCL. It is important to note that at any time EPA can begin the process of regulating a contaminant in drinking water whether or not the contaminant is on the CCL. EPA published the final CCL2 on February 24, 2005. As proposed, the final CCL2 brings forward the remaining 51 compounds from the initial CCL (42 chemical substances and 9 microbiological contaminants). EPA intends to determine by 2006 whether or not to regulate at least 5 compounds from the CCL2.

SUMMARY: COMPARATIVE RESEARCH NEEDS

Regulations are one of the paramount drivers for research on contaminants in drinking water. As noted above, adequate information on the contaminant in terms of analytical methods, occurrence in water supplies, treatment and health effects are necessary in order for USEPA to develop a regulation. Table 5 presents the authors' view in qualitative terms of the comparative research needs for selected contaminants. It should be noted that research is needed in all areas for all of the contaminants; however, they are assessed here, based on the need relative to each other, i.e., more is known for some contaminants in certain categories than others.

For inorganics, in general, more data are needed on perchlorate than the other contaminants listed. For organics, greater treatment and health effects information is warranted for NDMA, MTBE and pharmaceuticals and personal care products in comparison to halogenated disinfection by-products. Finally, more research is needed on analytical methods for noroviruses as compared to the other microorganisms presented.

Table 6 presents the authors' view in qualitative terms of the comparative research needs for treatment of selected contaminants; it should be read in conjunction with Table 5. With the exception of halogenated disinfection by-products,

Table 3 | Drinking water contaminant candidate list

Chemical contaminants

1,1,2,2-tetrachloroethane	Disulfoton
1,2,4-trimethylbenzene	Diuron
1,1-dichloroethane	EPTC (s-ethyl dipropylthiocarbamate)
1,1-dichloropropene	Fonofos
1,2-diphenylhydrazine	Hexachlorobutadiene
1,3-dichloropropane	p-Isopropyltoluene
1,3-dichloropropene	Linuron
2,4,6-trichlorophenol	Manganese
2,2-dichloropropane	Methyl bromide
2,4-dichlorophenol	Metolachlor
2,4-dinitrophenol	Metribuzin
2,4-dinitrotoluene	Molinate
2,6-dinitrotoluene	MTBE
2-methyl-Phenol	Naphthalene
Acetochlor	Nitrobenzene
Alachlor ESA (and other degradation products of acetanilide pesticides)	Organotins
	Perchlorate
Aldrin	Prometon
Aluminum	RDX (hexahydro-1,3,5-trinitro-1,3,5-triazine)
Boron	Sodium
Bromobenzene	Sulfate
DCPA mono-acid degradate	Terbacil
DCPA di-acid degradate	Terbufos
DDE	Triazines and degradation products
Diazinon	Vanadium
Dieldrin	

Microbial contaminants

Acanthamoeba	Coxsackieviruses
Adenoviruses	Echoviruses
Aeromonas hydrophila	*Helicobacter pylori*
Cyanobacteria (blue-green algae), other freshwater algae and their toxins	Microsporidia (*Enterocytozoon* and *Septata*)
Caliciviruses	*Mycobacterium avium* intracellulare complex

Table 4 | Research and data collection needs for CCL listed contaminants

Regulatory determination priorities	Research priorities			
	Health research	Treatment research	Analytical methods research	Occurrence priorities
Acanthamoeba (guidance)	*Aeromonas hydrophila*	Adenoviruses	Adenoviruses	Adenoviruses
1,1,2,2-tetrachloroethane	Cyanobacteria (blue-green algae) and other freshwater algae and their toxins	*Aeromonas hydrophila*	Cyanobacteria and their toxins	*Aeromonas hydrophila*
1,1-dichloroethane		Cyanobacteria	Caliciviruses	Cyanobacteria and other freshwater algae and their toxins
1,2,4-trimethylbenzene		Caliciviruses Coxsackieviruses	*Helicobacter pylori* Microsporidia	
1,3-dichloropropene	Calicivirus	Echoviruses	1,2-diphenylhydrazine	Caliciviruses
2,2-dichloropropane	*Helicobacter pylori*	*Helicobacter pylori*	2,4,6-trichlorophenol	Coxsackieviruses
Aldrin	Microsporidia	Microsporidia	2,4-dichlorophenol	Echoviruses
Boron	*Mycobacterium avium* intercellulare (MAC)	*Mycobacterium avium* intracellulare	2,4-dinitrophenol	*Helicobacter pylori*
		Aluminum	2-methyl-Phenol	Microsporidia 1,2-diphenylhydrazine
Bromobenzene	1,1-dichloropropene	MTBE	Acetochlor	2,4,6-trichlorophenol
Dieldrin	1,3-dichloropropane aluminum	Perchlorate	Alachlor ESA	2,4-dichlorophenol
Hexachlorobutadiene			Fonofos	2,4-dinitrophenol
p-Isopropyltoluene	DCPA mono-acid & di-acid degradates		Perchlorate	2,4-dinitrotoluene
Manganese	Methyl bromide		RDX	2,6-dinitrotoluene
	MTBE			2-methyl-phenol
Metolachlor	Perchlorate			Alachlor EA and Acetochlor
Metribuzin	Sodium (guidance)			DCPA mono-acid and di-acid degradates
Naphthalene				DDE
Organotins				Diazinon
Triazines & degradation products				
Sulfate Vanadium				Disulfoton Diuron
				EPTC
				Fonofos
				Linuron
				Molinate
				MTBE Nitrobenzene
				Perchlorate
				Prometon
				RDX Terbacil
				Terbufos

Table 5 | Comparative needs for research on selected contaminants

	INORGANICS				ORGANICS				MICROORGANISMS			
Category	**Perchlorate**	**Arsenic**	**Lead**	**Radon**	**MTBE**	**NDMA**	**EDC's, Pharm, PHCP**	**X-DBPs**	**Norovirus**	**MAC**	**Adenovirus**	***Cryptosporidium***
Analytical Methods	++	+	+	+	++	++	+	+	+++	++	++	++
Occurrence	+	+	+++	+	+	+++	++	+	++	++	++	++
Treatment	+++	+	++	+	+++	+++	+++	+	++	+	++	++
Health Impacts	+++	++	+	+	+++	+++	+++	+	++	++	++	+

+ = low research need
++ = medium research need
+++ = high research need

Table 6 | Comparative needs for research on treatment of selected contaminants

	INORGANICS				ORGANICS				MICROORGANISIMS			
	Perchlorate	**Arsenic**	**Lead**	**Radon**	**MTBE**	**NDMA**	**EDC's, Pharm, PHCP**	**X-DBPs**	**Norovirus**	**MAC**	**Adenovirus**	***Cryptosporidium***
Conventional Treatment	++	+	+	+	++	++	++	+	+	+	+	+
High Pressure Membranes	++	+	+	+	+++	+++	+++	+	++	+	++	+
Low Pressure Membranes	+++	+	+	+	+++	+++	+++	+	+++	+	++	+
Granular Activated Carbon	+	+	+	+	++	++	++	+	+	+	+	+
Ozone	+	+	+	+	++	++	++	+	++	+	+	+
Ultraviolet Irradiation	+	+	+	+	++	++	++	++	++	+	+++	+

+ = low research need
++ = medium research need
+++ = high research need

more research is needed on the treatment of organic contaminants in relation to inorganics or microorganisms; this is particularly apparent for both high-pressure and low-pressure membrane processes.

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