

**Senate Committee on Environment and Public Works
Chair, Senator Barbara Boxer**

**Oversight Hearing on USEPA's Implementation of the Safe Drinking Water Act's
Unregulated Contaminants Program**

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**Joseph A. Cotruvo, Ph D
President: Joseph Cotruvo and Associates
Washington, DC**

Good morning Senator Boxer and members of the committee.

My name is Joseph Cotruvo. I have spent more than 35 years engaged in public health and environmental matters. My doctorate is in Physical Organic Chemistry. I was the first Director of EPA's Office of Drinking Water Criteria and Standards Division after passage of the Safe Drinking Water Act, where I had a role in developing many of the existing drinking water regulations and regulatory methodologies, and later in the Risk Assessment Division in Pollution Prevention and Toxics. Those regulations included comprehensive microbial protection, trihalomethanes, radionuclides, Surface Water Filtration, corrosion control, Volatile Synthetic Organic chemicals (VOCs) and numerous other organic and inorganic chemicals. Currently, I work internationally in water quality, health and technology including helping to establish a drinking water regulatory program in Singapore, and on desalination and health related issues and epidemiology in the Middle East, and on development of small water treatment technologies for home and small systems applications, as well as on some basic toxicology studies. I serve on several independent advisory groups dealing with drinking water safety issues, including many years with the World Health Organization's Drinking Water Quality Committee, which last week issued the 4th edition of the Guidelines for Drinking Water Quality. These are the benchmarks that most of the world outside of the US try to apply to define drinking water safety. I am also a member alternate of the Washington DC Water and Sewer Authority.

I am not here representing any organization or institution; these are my personal thoughts and conclusions, and I am not receiving any compensation for this presentation.

- **Drinking Water Quality and Safety**

Almost all public community water systems in the United States provide safe drinking water --including Washington, DC-- contrary to what some believe, and that is no small accolade and accomplishment when dealing with the 60,000 entities providing drinking water, which range in population from as few as 25 persons to millions. The quality and safety of drinking water in the United States is very good and almost always more consistent and better than the limited number of nations that have substantial drinking water regulatory and enforcement programs in place. We always strive for improvement. US policies and processes for safe drinking water provision have clear leadership standing in the world and many if not most of the existing methodologies for assessing and regulating drinking water quality and safety were developed here first.

The EPA's and the states and water suppliers' implementation of the Safe Drinking Water Act of 1974 and the later amendments has significantly improved the safety of drinking water in the United States. It is indeed a joint effort that is implemented 24/7 by the often underappreciated professionals in the national drinking water delivery community that we all rely on to actually produce and deliver safe water. The comprehensive protection program includes regulation, advice, monitoring and system assessments and operations, supported by an enforcement program, and significant financial support from the federal government. The underpinning of it all is that there is that cadre of dedicated water professionals who manage and operate those water systems.

The record shows that reported waterborne infectious disease outbreaks have declined since implementation of the SDWA began, but the portion of outbreaks due to distribution system infrastructure deficiencies has been increasing. That is a clear indication that the water coming out at the tap isn't always as good as the treated water leaving the plant. It is a symptom of our ageing infrastructure. Fixing and maintaining infrastructure and reducing leaks and contamination in distribution is where our priorities now belong.

- **Current Regulations**

The 1986 amendments to the SDWA specified a long list of chemicals to be regulated, and also a requirement to regulate 25 additional substances every 3 years, which was physically impossible. As a result several MCLs were produced for substances that were unlikely to be present in significant amounts or nationally widespread or of significant concern. The compliance monitoring over the years has aptly demonstrated that, so there are actually more current regulations than needed to assure drinking water quality. The 1996 amendments required EPA to produce a Contaminant Candidate List (CCL) every 5 years (3 produced to date), make a determination every 3 years whether up to 5 meet the criteria to warrant possible regulation, and also to periodically generate lists of unregulated contaminants to be analyzed (UCMR) in a number of locations to determine occurrence and exposure from water. In my opinion the CCLs and UCMRs have generally not been critically prepared to isolate high probability substances of potential concern in drinking water. Although systematic processes have been utilized to produce them, there must be a serious flaw in the decision logic as has been demonstrated by their results.

The current regulations contain Maximum Contaminant Levels or Treatment Requirements for a broad spectrum of contaminants:

- 81 MCLs for Organics and Inorganics including:
 - 27 pesticides and 9 DBPs (indicators)
 - 21 Inorganics
 - 24 VOCs and other synthetic organics
- Microbial: 6 Treatment requirements, Total Coliforms, E. Coli = all pathogens
- 5 (2 group) Radionuclide MCLs + Uranium = All radionuclides
- Lead and Copper corrosion control: Treatment Requirements
- Acrylamide and Epichlorohydrin: Treatment Technique as product quality.

The coverage is actually far greater than the numbers imply. Essentially all microbial pathogens are covered by the MCL and treatment requirements. All radionuclides are covered by those rules, and treatment requirements such as surface water filtration and disinfection address numerous contaminants simultaneously. Disinfection byproducts

(DBP) indicator MCLs are intended to trigger techniques that result in across the board reductions of many unmeasured DBPs.

The existing regulations are very comprehensive as they cover almost all of the categories of potential drinking water contaminants including: microbial contamination in great detail, natural precursor products, inorganic chemicals, disinfection byproducts indicators, radionuclides, corrosion products, volatile and other synthetic organics, and pesticides. The potential for microbial contamination has been and will always be the greatest threat to health from drinking water. Although some outbreaks still occur, public water suppliers with Safe Drinking Water Act mandates have very successfully dealt with microbial threats, and no regulatory action should ever jeopardize our continued control over that threat.

As they should be, the regulations are designed to be protective, and they are produced with very conservative health assessments that are generally designed to overestimate potential risks. They utilize conservative default assumptions in the absence of detailed data, e.g. on margins of safety for toxicity, linear non threshold extrapolation models, and on occurrence and exposure and relative source contributions. I look at conservative risk assessments and regulations as a sort of insurance policy that we pay for to assure that there are not now and will not be meaningful risks from drinking water. However, conservative assumptions must be rational and carry mainstream scientific credibility, because, in a way they can convert risk assessors into pseudo regulators. The issue is ultimately how large should the safety margins be, and how much insurance cost is appropriate. There is a price, and over regulation can also have negative consequences, such as by unnecessarily increasing costs to consumers, and by limiting use of some beneficial technologies. Also, excessively dwelling on hypothetical and negligible risk concerns by regulators and the press also drives some people to mistrust their public drinking water supply and pay the extra (perhaps 1000x) cost of bottled water.

- **Examples of Some Pending Issues**

When producing a national regulation, EPA must, by law as well as common sense, determine that the contaminant is of national significance, is a risk to health, and also

demonstrate that the regulation will achieve meaningful health risk reduction. Here are several examples of current issues that are being debated and considered for regulation by EPA, including perchlorate, pharmaceuticals and nitrosamines. It is useful to put them into perspective relative to the context of the SDWA mandates.

- **Perchlorate**

Perchlorate in the environment, diet, and drinking water at low parts per billion levels, is potentially both of natural and anthropogenic origin. Perchlorate (as well as many other common anions) competes with iodine uptake by the thyroid and under some condition and dose could cause adverse consequences especially in infants. There has been much debate in the US, and some states have set standards or action levels at very low parts per billion (ppb) levels. EPA produced a guideline at 15 µg /L (15 ppb) in drinking water, and is now engaging in a regulatory development process. On the other hand in 2011, JECFA, the Joint Expert Committee on Food Additives, an independent multinational external toxicology/health science advisory committee of the UN Food and Agriculture Organization and World Health Organization released their analysis of the level of concern for perchlorate in Report 959. After reviewing the toxicology, epidemiological and clinical evidence, the NAS report from which EPA derived its current value, and dietary and water concentrations including much US data, they calculated a provisional maximum tolerable daily intake (PMTDI) of 10 µg/kg bw/day and drew the following conclusion:

“The estimated dietary exposures of 0.7 µg/kg bw/day (highest) and the 0.1 µg/kg bw/day (mean), including both food and drinking water, are well below the PMTDI. The committee considered that these estimated dietary exposures were not of health concern.”

- **Pharmaceuticals**

In recent years there have been reports of detections of several pharmaceuticals in some drinking waters mostly at parts per trillion levels. Pharmaceuticals can reach drinking water from upstream wastewater discharges and runoff from some animal feed lots. They are attenuated to some degree partly by the wastewater treatment process, environmental passage (biodegradation, decomposition and dilution), and drinking water treatment. Most of the entry of pharmaceuticals into wastewater comes from human excretion of

pharmaceuticals and metabolites after therapeutic uses; some fairly small portion derives from improper disposal of unused drugs. One week ago the World Health Organization issued a report that included contributions from a 10 member Working Group on Pharmaceuticals in Drinking Water, of which I was a member, and which reviewed much US and other data. WHO concluded:

“Trace quantities of pharmaceuticals in drinking water are very unlikely to pose risks to human health because of the substantial margin of exposure or margin of safety between the concentrations detected and the concentrations likely to evoke a pharmacological effect.” (*i.e. the therapeutic dose*)

“The current levels of exposure to pharmaceuticals in drinking water also suggest that the development of formal guideline levels for pharmaceuticals in the WHO *Guidelines for Drinking Water Quality* is unwarranted.”

Furthermore, WHO went on to say that routine monitoring and installation of specialized drinking water treatment was not deemed necessary.

- Nitrosamines

Nitrosamines are formed in some industrial processes, ubiquitous in foods, generated during cooking of proteins, and produced by humans endogenously from ingestion of precursor substances and oxynitrogen compounds. They are also found in some drinking waters at parts per trillion levels, especially those with upstream wastewater discharges, and also in some cases from disinfection with chloramine and from some polymers used as part of water treatment. Almost all nitrosamines are considered to be carcinogens. EPA has listed several nitrosamines in its Contaminant Candidate List (CCL 3) and in unregulated contaminant monitoring lists.

The regulatory challenge is that the portion of daily exposure to nitrosamines due to drinking water in those locations is likely less than 1% of all the other sources. The monitoring costs are substantial, and water treatment possibilities are not completely defined. Because the relative source contribution from drinking water sources is so minimal, a low Maximum Contaminant Level that would impact some number of those water supplies that contain some nitrosamine would have a negligible, if any, impact on risk and public health.

- **Unregulated Contaminants**

In theory, addressing unregulated contaminants in a formal way is a reasonable concept to determine which substances may warrant further assessment and possible regulation because of exposure from water and potential health risk. However, my sense is that EPA's approach to date has not been very efficient or effective. The process has been operating for more than 10 years and a huge amount of preparative and assessment work has been done, but there have not been any new regulations developed to date. In fact, that points to the obvious conclusion that there are not very many contaminants that demand national regulation to protect public health beyond those already on the books. On the other hand, I think EPA could have arrived at the same conclusion and identified perhaps a few candidates for regulatory consideration by a much more direct and efficient process. It should be said in EPA's defense that they were partly driven to that process by advice from a National Academy of Sciences report and from their statutory National Drinking Water Advisory Council.

- **Recommendations**

Overall public drinking water quality in the US is very good and the drinking water is safe, and undoubtedly safer than it has ever been since the introduction of centralized water supplies more than 200 years ago, and introduction of collected wastewater discharges. The potential for microbial contamination has and will always be the greatest threat. Public water suppliers with Safe Drinking Water Act mandates have very successfully dealt with microbial threats, and no action should ever jeopardize our continued control over that threat.

However, concerns are commonly raised because current and rapidly developing analytical technologies continually produce new detections at parts per billion, parts per trillion and even lower levels, and this trend will continue and expand, because analytical science becomes more sensitive. Those exposures are essentially always extremely unlikely, if not implausible, to have any meaningful risk. These amounts are many orders of magnitude below levels that can show a detectable effect from even high dose testing.

The number of substances in the water environment can be large, but the amounts are very small, and the likelihood for requiring national drinking water regulations to protect public health for many of them present at minute trace levels is not great. As a practical matter, it is simply physically and economically impossible, and also unnecessary to have a long list of regulated substances in drinking water. The resources and time required to produce regulations are great and the process is not responsive to the needs of water suppliers and public health officials to have access to a scientifically credible basis for rapid decision making when a substance is detected. That is precisely why the EPA Office of Drinking Water initiated the Health Advisory program in ~ 1980, and about 200 Health Advisories currently exist.

Risk assessments always utilize conservative default assumptions when detailed information is not available. Scientific knowledge progresses constantly and sometimes the risks may turn out to be less than previously estimated or assumed, so it is essential for credibility to always allow or require EPA to utilize the best mainstream scientific information when it is making regulatory decisions. It might be necessary to amend the “anti backsliding “ provision in the SDWA to allow that to occur.

- **Suggested Drinking Water Act Implementation Strategy**

We have accumulated a significant history of drinking water composition and quality in the US and causes of contamination have decreased, so it would be logical and appropriate to utilize that knowledge to revise our approach to assuring the safety of public water supplies. Following is a suggested more efficient strategy to cope with the realities of safe drinking water provision and assurance of continued safe and safer drinking water.

1. Eliminate regulations that do not meet significant risk, national significance and meaningful risk reduction tests. Many regulations on the books have negligible occurrence near levels of concerns demonstrated by many years of compliance monitoring. Convert them into Health Advisories (see # 7). This might require legislation.

2. There needs to be application of rational and faster prescreening and prioritization methodologies such as the Threshold of Toxicological Concern (TTC) that has been used for years by the FDA and other organizations to screen food additives.

3. Add probably a small number of regulations that would meet the 1996 SDWA tests (national prevalence, health risk and meaningful risk reduction), and periodically update as needed.

- 4. When regulating, utilize individual MCLs, Treatment Technologies, or groupings as justified and technically appropriate. These have been traditionally utilized in implementation of the Safe Drinking Water Act, to date.**
- 5. Always utilize the best available mainstream science when performing risk assessments and making regulatory decisions.**
- 6. Emphasize addressing ageing distribution system infrastructure, because it is the likely greatest current and future drinking water health risk concern that requires correction.**
- 7. Periodically carry out national surveys of source and finished drinking water composition so as to be up to date on what is present and might warrant regulation.**
- 8. Greatly expand the number of peer reviewed Drinking Water Health Advisories (DWHAs) on substances that have been or would probably be in drinking waters. This is very cost effective and it would provide a compendium of substances in drinking water with authoritative guidance on health significance. It is responsive to the needs of water suppliers and public health officials for making rapid judgments in the event of a detection of a new substance.
e.g. DWHAs for most pesticides and pharmaceuticals can be readily produced from existing very robust registration and drug approval data bases.**
- 9. EPA should provide guidance and assistance to states to help them develop local need regulations-health advisory assessments, technology performance and cost, and analytical methods.**
- 10. EPA should facilitate applications of needed and new technologies developed by others, e.g. provide technical assistance to states and water suppliers by technology demonstrations, and via Technology Verification programs.**
- 11. More aggressively use Clean Water Act, Toxic Substances Control Act, and Pesticide authorities to reduce contaminant introduction and burdens on Public Water Supplies.**
- 12. Focus on preventing environmental and drinking water contamination. Industrial discharge controls have been successful. Manage pharmaceuticals by improved sewage treatment and controls on disposal, and pesticides by water basin management controls on applications.**
- 13. Focus CCLs and UCMRs on most likely candidates rather than as shopping lists containing only a few candidates of likely concern.**
- 14. Partner with states for sharing validated water monitoring data in a usable common electronic format so that information on national circumstances and trends is always readily available.**

This proposed strategy is:

- **Comprehensive and forward looking, anticipatory and sustainable.**
- **Provides coverage of many more contaminants, essential benchmarks, and nationally consistent advice.**
- **Consistent with the SDWA mandate to protect public health.**
- **Much more efficient and cost effective for EPA, the states and water suppliers.**
- **Reduces wasteful compliance monitoring for public water suppliers**
- **Further reduces source contamination.**
- **Reduces uncertainties for water and state and local regulatory officials and the public.**
- **An opportunity to get ahead of the curve on interpretations of significance of trace contaminant detections using margins of safety and margins of exposure (MOE) to provide officials and the public a better perspective on DW quality and “risk” e.g. pharmaceuticals.**
- **It provides timely leadership and national consistency on water health related issues, (applications in Hazardous Waste Sites, Superfund...)**

Downsides—not many.

- **States might not always regulate their local need contaminants- EPA has supervisory oversight authorities under the SDWA implementation.**
- **State regulations will not always be uniform---they aren’t always now.**

The bottom line is that this approach is responsive to the need, sustainable, credible, and efficient, and it provides more public health protection and much more bang for the buck!

Thank you for the opportunity to present these comments and suggestions.