Testimony: Michael Traynor Speaks to the Next Generation

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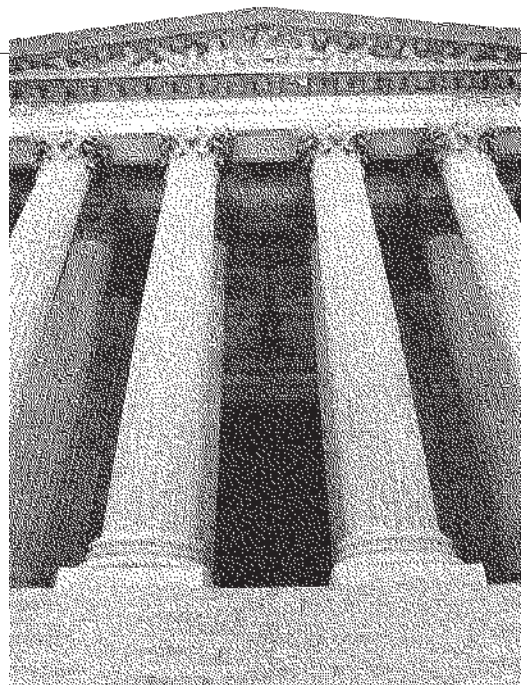

THE FORUM

The Perchlorate Debate: Is the Chemical Worth Regulating?

Perchlorate is a chemical that occurs naturally in the environment and as an industrial contaminant, chiefly from rocket fuel, fertilizer, and bleach. It can have an adverse effect on the ability of humans to uptake iodine into the thyroid, and fetuses and young children are especially sensitive. The science on perchlorate's occurrence and potential human health effects is relatively robust but is complicated by several other naturally occurring substances in food with the same effects.

In 2008, the Environmental Protection Agency looked at the available data and concluded that regulating perchlorate under the Safe Drinking Water Act would not present a meaningful opportunity for health risk reduction. The agency is charged with regulating five new pollutants a year under the act, and the Obama EPA has pledged to add 16 chemicals to the list. Last February, the agency looked at the same data and concluded that regulating perchlorate as a drinking water contaminant would indeed lead to meaningful health risk reduction. The next step is to set a Maximum Contaminant Level that will be permitted in drinking water systems.

Clearly, the science and policy surrounding perchlorate regulation is complex, with several different plausible interpretations. In this issue we present a number of views on how EPA might chart a path forward, and the many obstacles to success, as it seeks to establish a perchlorate drinking water standard.

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Gail Charnley Elliott
President
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Assistant General Counsel
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"EPA's inspector general has determined that perchlorate is only a minor contributor to thyroid iodine deficiency."

George Gray
Director, Center for Risk Science and Public Health
George Washington University School of Public Health

"EPA's determination to regulate is not supported by science and is contrary to the requirements of the statute."

Tom Roberts
Member
Van Ness Feldman, P.C.

"EPA determined that the chemical may have an adverse effect on the health of persons by inhibiting the transport of iodide."

Nancy Stoner
Assistant Administrator, Office of Water
Environmental Protection Agency

Not an Efficient Way to Protect Public Health

GAIL CHARNLEY ELLIOTT

Regulating perchlorate as a drinking water contaminant is not an efficient way to safeguard public health. There have been no actual reports indicating that perchlorate exposure has harmed public health or interfered with fetal or infant development. That possibility has been hypothesized because perchlorate, like many other substances, competes for the uptake of iodine by the thyroid gland. The weight of scientific evidence indicates that current environmental perchlorate levels are highly unlikely to pose developmental or other health risks for pregnant women and infants with adequate dietary iodine.

Iodine is required to maintain healthy thyroid hormone levels, which help regulate normal development. Perchlorate and other naturally occurring substances that compete with iodine to potentially affect the production of thyroid hormones are easily counteracted by adequate dietary iodine. Homeostasis assures that levels of thyroid hormones sufficient for the body's needs are maintained, even in situations with reduced levels of available iodine. According to a National Academy of Sciences report on perchlorate, "Compensation for iodide deficiency or other perturbations in thyroid hormone production . . . is the rule." The report concluded that long-term, sustained exposure to more than 30 milligrams of perchlorate per day — 600 times EPA's safety limit — would be required to produce adverse thyroid effects in healthy adults. The average daily intake of perchlorate in the United States is 10,000 times lower than that, although some people — especially pregnant women — may consume ten times more than the average amount. It is not "healthy adults" who are of concern, however. The people of concern, and the target of perchlorate regulation, are iodine-insufficient pregnant women and infants.

Since the 1970s it has been standard practice throughout the world to screen babies at birth to determine whether their thyroid glands are functioning as they should. Such testing assures prompt intervention should an infant lack adequate thyroid hormone levels and is aimed at avoiding developmental problems attributable to inadequate thyroid function. In addition, although iodine is not a required component of prenatal vitamins, most do include it. Centers for Disease Control data indicate that about seven percent of pregnant women in the United States are iodine deficient; however the same data also show no differences in thyroid hormone levels when iodine deficient women are compared to iodine-sufficient women.

EPA concluded in 2008 that regulating perchlorate as a drinking water contaminant did not present a meaningful opportunity for public health protection because fewer than one million people were likely to be exposed to perchlorate in their drinking water above the level of concern and, of those, only about 30,000 are likely to be pregnant at any given time. In contrast, the 2011 decision to regulate perchlorate as a drinking water contaminant was based on the conclusion that almost 17 million people are potentially exposed to perchlorate levels in water above the level of concern.

The difference is attributable to the use of different methods and assumptions. The earlier decision used different quantitative methods to estimate the effects of various perchlorate exposures than did the later decision, different assumptions about how much pregnant women and children eat and drink, and different levels of concern. Neither decision explicitly considered iodine status and, interestingly, recent studies have found no effect of perchlorate on thyroid hormone levels even in pregnant and non-pregnant women with low iodine status.

Meanwhile, complicating attempts to regulate perchlorate is the fact that perchlorate exposure does not occur in isolation from exposure to other substances that also compete with iodine, particularly nitrate and thiocyanate. Such substances are ubiquitous in the diet and occur in such quantities and with such potencies that determining the additional contribution to risk made by small exposures to environmental perchlorate is potentially impossible. Perchlorate itself has been detected in all foods tested. The question then becomes one of whether regulating perchlorate as a drinking water contaminant — while ignoring perchlorate, nitrate, and thiocyanate exposure from food and other sources — is likely to protect pregnant women and infants with inadequate dietary iodine.

The answer is no. Regulating perchlorate in drinking water will not have a detectable impact on public health. Public health measures aimed at ensuring adequate dietary iodine and thyroid hormone function during pregnancy and childhood might have a detectable impact on public health, for reasons that go way beyond perchlorate exposure. Such measures are, sadly, not within EPA's regulatory purview. When EPA is the hammer, every chemical looks like a nail, because that is the only tool EPA has available to fulfill its statutory mandates to safeguard public health.

Gail Charnley Elliott is President of HealthRisk Strategies.

Hardly Rocket Science: The Case for Regulating

THOMAS E. CLUDERAY

The Environmental Protection Agency has spent more than a decade reviewing the safety of perchlorate, a common ingredient in rocket fuel and persistent drinking water contaminant. By now, the record offers compelling evidence that perchlorate is a thyroid toxin linked to a host of potential adverse health effects.

On the question of whether that makes perchlorate "worthy of further regulation," the answer must be a resounding yes. The EPA has decided to revisit a 2008 decision under the Bush administration not to regulate this contaminant, and should now act expeditiously to develop a national drinking water standard for perchlorate. Doing so will go a long way toward protecting public health, particularly of vulnerable populations.

We understand perchlorate's health effects far better today than in the late 1990s, when EPA began reviewing the chemical under the Safe Drinking Water Act. Perchlorate can alter levels of thyroid hormones that are essential to proper development of fetuses and infants and to good health in adults. A groundbreaking study by the Centers for Disease Control and Prevention showed that even low doses of perchlorate — 3 parts per billion in drinking water — may interfere with normal thyroid functioning. Other studies show that fetuses and young children are particularly susceptible to the chemical and that thyroid hormone disruption can lower IQ levels and impede motor skills. In view of this, only a cynic would deny perchlorate's potential to harm public health.

We are exposed to perchlorate through food — certainly a source of concern — and also through drinking water, a significant source of exposure. Recent tests indicate that between 5 million and 17 million people in the United States are served by public water systems with perchlorate contamination. Several states have taken important steps toward addressing this problem. In 2006, Massachusetts set a robust drinking water standard for perchlorate of 2 ppb. And just this year, California proposed to lower its public health goal for perchlorate from 6 ppb to 1 ppb to account for new data showing increased risk. However, the chemical's widespread presence in drinking water means that only a national standard will ensure that all segments of the population are protected.

Fortunately, the Safe Water Drinking Act provides a vehicle for closing those gaps. For more than 30 years, the act has given EPA the authority to safeguard U.S. drinking water — something Congress has long deemed "essential to the protection of public health." So far, the agency has used the law to promulgate standards for more than 90 contaminants. Perchlorate must be next. Like the pollutants already subject to national standards, perchlorate poses significant health risks and is common in drinking water at levels of concern. That is why I was delighted to hear EPA Administrator Lisa Jackson voice her commitment to reevaluating perchlorate in early February. As the agency pushes ahead, I urge it to follow California's lead and set a standard that is feasible and provides adequate health protection — such as 1 part per billion.

Some of those who favor perchlorate regulation have proposed that policymakers focus on exposures through food before tackling the issue of drinking water. I recognize that policy solutions often have to address multiple fronts to generate meaningful results. In my view, however, setting a drinking water standard is the most feasible first step in regulating perchlorate to protect public health.

The Safe Water Drinking Act created a national framework that has been tested over time to deal with contaminants of rising concern. Public water systems already must follow federal standards for dozens of other contaminants, and they are in the best position to reduce perchlorate exposures in an effective, uniform manner. In contrast, addressing perchlorate exposure via food would necessarily involve a number of additional, much more complicated considerations, including how to treat soil contamination, irrigation water, and fertilizer, which all contribute perchlorate to our food diet.

When it comes to perchlorate, we are no longer at the frontiers of regulatory science. That is why I join my colleagues at Environmental Working Group in applauding Administrator Jackson for assessing again whether to set a national drinking water standard for perchlorate. Establishing such a standard would result in meaningful health protection and would hardly require the resources it took to send rockets to the moon.

Thomas E. Cluderay is Assistant General Counsel of the Environmental Working Group in Washington, D.C.

Newer Science Serves as a Guide to Maximum Levels

MICHAEL DOURSON

As analytical chemistry has improved, perchlorate from human and natural sources has been increasingly found in drinking water and other environmental media. The Department of Defense and others have invested a significant amount of time and treasure into understanding this exposure and perchlorate's health effects. Now that EPA has decided to regulate perchlorate in drinking water, EPA's choice of a regulatory Maximum Contaminant Level, or safe concentration of perchlorate in drinking water, is likely to be controversial.

But this does not have to be so.

The level at which the MCL is set depends on a number of factors, chief among which is often the amount of perchlorate that EPA thinks can be safely consumed daily for a lifetime, even by particularly sensitive people; this amount is known as a "reference dose." The choice of perchlorate reference dose hinges on the studies most relevant to protecting public health, particularly the health of people identified as those most likely to be sensitive to its effects. The National Academy of Sciences has identified pregnant women and newborns as those potentially most sensitive. EPA's current reference dose is based on the academy's calculations, which relied on a study performed in healthy adults, adjusted mathematically to account for the fact that the people of greatest concern are not necessarily the "healthy adults" upon whom the data were derived. That reference dose is six years old.

Fortunately, newer studies now exist that provide better information from which to derive a reference dose. One of these newer studies, performed in Chile, gives definitive information on perchlorate's likely critical effect (or its absence) in numerous pregnant women and newborns.

Specifically, Tellez and coworkers performed a prospective epidemiologic study among pregnant women from three cities in northern Chile with high, medium, or low levels of perchlorate in their public drinking water. Those investigators tested the hypothesis that long-term exposure to perchlorate may cause iodine deficiency in either the mother during gestation or the baby at birth. Iodine is critical to normal thyroid gland function, which in turn is critical for normal fetal and infant development.

The study found no changes in thyroid-related hormones due to perchlorate in drinking water. Birth measurements, such as weight, length, and head circumference, were not different among the three cities and were consistent with current U.S. norms. All of the women's iodine levels were intermediate between values reported for pregnant women in the United States, and within current World Health Organization recommendations. Moreover, breast milk iodine was not decreased among women with detectable perchlorate exposure.

Because this study measured perchlorate levels and potential effects in individual subjects in a prospective manner, it can be reliably concluded that perchlorate in drinking water up to the highest levels studied of 114 micrograms per liter — many times higher than several U.S. state standards and over four times higher than EPA's reference dose — does not change human maternal thyroid function nor important birth parameters in their babies.

Other newer studies may be useful. In fact, studies performed evaluating perchlorate exposure during pregnancy and thyroid hormone levels in newborns have demonstrated no relationship between perchlorate exposure and thyroid hormone levels. For example, a study of pregnant women participating in the National Health and Nutrition Examination Survey showed no relationship between thyroid hormone levels and urinary perchlorate, even in the low-iodine women.

A study in Israel of hormone levels in babies born to mothers exposed to very high levels of perchlorate in their drinking water (95 to 340 micrograms per liter) during pregnancy found no differences when compared with women consuming drinking water with low perchlorate levels. A study in Nevada found no difference in thyroid hormone levels when newborns in Las Vegas, where perchlorate was detected in drinking water up to 15 micrograms per liter, were compared to those from Reno, with no detectable perchlorate. A study of women in Wales and Italy evaluated thyroid hormone levels in low-iodine-status pregnant women during the first trimester, when the fetus is thought to be most influenced by thyroid hormones, and found no effect of ubiquitous perchlorate exposure.

Thus, a substantial body of data now exists showing no effect of perchlorate exposure on maternal or neonatal hormone levels or on indices of fetal growth, with some studies measuring even over 100 micrograms of perchlorate per liter of drinking water. Also, data now exist showing no effect of perchlorate on thyroid hormone levels in pregnant and non-pregnant women with low iodine status. As EPA and others debate the value of the national MCL for perchlorate in drinking water, a reference dose based on studies of potential effects in pregnant women and children — not on studies of adult men and non-pregnant women — is now possible.

And it should be demanded.

Michael Dourson is the President of Toxicology Excellence for Risk Assessment, an independent and nonprofit risk assessment research and development corporation.

The Challenge of Cumulative Risk Assessments

GEORGE GRAY

Is regulating perchlorate in drinking water a good way to improve public health? A cumulative risk assessment — which combines multiple factors that may lead to an adverse health outcomes — can help answer that question, but it can also raise many more.

Researchers and legislators are eager to see EPA use this tool. Two National Research Council reports have given advice to EPA on conducting cumulative risk assessments. Language requiring it has appeared in TSCA reauthorization bills. The agency's Children's Health Protection Advisory Committee "recommends that EPA consider cumulative exposures and stressors such as socioeconomic and nutritional status."

Ideally, cumulative risk assessments will help answer questions about combined effects of diverse chemical agents, as well as combined effects of chemical and nonchemical stressors like stress, diet, or noise. It will also address concerns about disproportional risk burdens in disadvantaged populations. And it will provide community-based evaluations of pollution impacts. The question that has not been confronted is how these analyses are to be used. Can they be used in the regulatory arena or are they really public health tools that help us identify the key sources of risk and most effective interventions for a population?

The outcome of a cumulative risk assessment conducted for perchlorate is instructive. The potential risk from perchlorate comes from its ability to block the uptake of iodine into the thyroid gland. Iodine is used by the thyroid to make a number of hormones, and sufficient iodine levels are essential for fetal brain development. Low dietary intake of iodine has long been known to be a risk factor for thyroid dysfunction (that's why we iodize our salt), and the compounds thiocyanate, nitrate, and perchlorate can all block iodine uptake. Thiocyanate and nitrate are naturally found in foods like green leafy vegetables, and cigarette smoking leads to thiocyanate exposure.

Last year, EPA's Office of Inspector General released a report that included a cumulative risk assessment for stressors that reduce thyroid gland iodine levels and potentially put developing babies at risk. The study combined estimates of exposure to thiocyanate, nitrate, and perchlorate as well as iodine intake to identify the key contributors to the risk of low thyroid iodine levels and its sequelae.

The study found that perchlorate in drinking water was only a very minor contributor to the risk of thyroid iodine deficiency. Instead, insufficient iodine in the diet was determined to be the "dominant and principal" contributor to this public health concern. Consumption of thiocyanate and nitrate in food and water were of some concern, especially in populations with low iodine intake. Ultimately, EPA's inspector general opined, "Potentially lowering the perchlorate drinking water limit from 24.5 ppb to 6 ppb does not provide a meaningful opportunity to lower the public's risk." This directly addresses a key decision EPA must make under the Safe Drinking Water Act.

So how should this information be used? If cumulative risk assessment tells us about key contributors to risk and the benefits that could come from addressing them, it would appear from the IG report that little gain would come from perchlorate regulation. Other public health interventions, primarily increasing iodine intake by pregnant women, were identified as doing much more to ensure healthy levels of iodine in the thyroid and healthy babies. Yet many of these actions fall outside of EPA's regulatory mandate. Should they be considered? Should EPA act on a very small part of the problem because that is where it has authority? Should other agencies be expected to rely on EPA analyses and act (and vice versa)? It is clear that when properly done cumulative risk analyses will reveal multiple factors influencing health outcomes that cross traditional boundaries of agencies and agency offices – if they fall within the regulatory system at all. Little thought has been given to ways to decide which, if any, are appropriate targets for action.

It is clearer how cumulative risk assessment can be used in public health applications. Knowing how various factors — including chemical exposures, lifestyle choices, diet, and psychosocial stressors — interact to cause specific diseases can help us identify the interventions that provide the greatest public health gains for out investments. The solutions may be regulatory but are more likely to involve other public-health tools, such as social marketing campaigns, technology dissemination, and community outreach.

The example of perchlorate shows that those researchers and legislators eager to see it put to use need to think not only about how to do cumulative risk assessment, but also how to use it.

George Gray is at a professor in the Department of Environmental and Occupational Health and Director of the Center for Risk Science and Public Health at the George Washington University School of Public Health and Health Services.

Ignoring Authoritative Science

TOM ROBERTS

EPA's Regulatory Determination on Perchlorate, issued last February, concluding that perchlorate should be regulated under the Safe Drinking Water Act is not supported by well-established science and is contrary to the explicit requirements of the statute.

In 2005, the National Academy of Sciences determined that perchlorate has no measurable effect on the adult human body at a level equivalent to 245 parts per billion (ppb) in drinking water. The NAS further determined that 24.5 ppb perchlorate in drinking water — a 10-fold safety factor from the no observed effect level — would be safe for even the most sensitive populations. Subsequent studies have confirmed the NAS conclusions, specifically with respect to developing fetuses and newborns.

Perchlorate — a naturally occurring and man-made salt used in military, aerospace, and industrial settings — is one of the most studied chemicals under regulatory review. It has been the subject of more than 60 years of research, beginning with its worldwide use as a prescribed drug to treat Graves' disease. It is precisely because perchlorate has been so extensively studied that its lack of health effects at environmental levels is so well understood.

Perchlorate is known to inhibit iodide uptake, an effect which NAS scientists have concluded is non-adverse.Perchlorate is one of three common compounds known to have this non-adverse effect.The other two, nitrate and thiocyanate, each occur naturally in many of the foods we eat. Together these two compounds account for more than 95 percent of the iodide uptake inhibition (IUI) that commonly takes place in the body. Even at the highest environmental doses detected in drinking water, some studies have reported that perchlorate accounts for less than one percent of IUI. In light of this knowledge and the 2005 NAS study, the EPA inspector general concluded in 2010 that there was no basis for regulating perchlorate as an individual substance.

Under the SDWA, EPA is required to make three specific findings in order to determine that a compound should be regulated:

First, the compound may have an adverse effect on the health of persons. Second, the compound is known to occur or there is a substantial likelihood that it will occur in drinking water systems with a frequency and at levels of public health concern. Third, regulation of the compound, in the sole judgment of the EPA administrator, presents a meaningful opportunity for health risk reduction.

In 2008 EPA, relying on all of the available scientific data, published a preliminary determination finding that the second and third tests were not met and that there was no basis to regulate perchlorate under the SDWA. In its 2011 Regulatory Determination EPA, relying on broad generalizations, concluded that perchlorate met all three of the SDWA tests. With respect to the first test, however, EPA did not cite any new scientific data that disproves or even raises questions about the conclusions reached by the NAS and the other existing studies. Quite simply, EPA is not able to point to scientific evidence that perchlorate, at environmental levels, may have an adverse effect on human health.

With respect to the second test, EPA relied upon an unrepresentative set of data that is eight to ten years old. Since those data were collected, levels of perchlorate in the Colorado River (by far the largest water source that contains perchlorate) have decreased by 80 percent due to cleanup activities. Actions by several states have also resulted in significant decreases in the frequency and levels of perchlorate. EPA chose to ignore this more recent data.

While the third test is solely within the discretion of the administrator, there has to be some rationality to his or her judgment. Where all of the available scientific data demonstrate that perchlorate has no measurable, let alone adverse, effect on humans, including the most sensitive subpopulation, the pregnant woman, it is hardly rational to conclude that regulation of perchlorate presents a meaningful opportunity for health risk reduction.

In recent testimony before the House Subcommittee on Oversight and Investigations, Administrator Lisa Jackson stated: "It is a priority of the EPA and of this administration, to ensure that our regulatory system is guided by science and that it protects human health and the environment in a pragmatic and cost effective manner." Unfortunately, EPA's actions with respect to perchlorate do not meet this standard.

As the nation faces unprecedented pressure on public sector budgets, it makes absolutely no sense to expend limited federal funds to develop a regulation that will force local drinking water providers to invest scarce resources treating a chemical that poses no adverse health effects.

Tom Roberts is a member of the firm at Van Ness Feldman, P.C.

Agency to Regulate Perchlorate

NANCY STONER

Last February, EPA Administrator Lisa Jackson announced the agency's decision to regulate perchlorate in drinking water to better protect public health for millions of Americans. Perchlorate is a naturally occurring and man-made chemical that is used to produce rocket fuel, fireworks, flares, and explosives. Perchlorate can also be present in bleach and in some fertilizers. Research indicates perchlorate may disrupt the thyroid's ability to produce hormones that are critical to developing fetuses and infants.

The administrator's decision is based on an extensive review of the best available science. The Safe Drinking Water Act requires EPA to promulgate a drinking water regulation, if EPA determines that a contaminant meets three criteria. First, the contaminant may have an adverse effect on the health of persons. Second, the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern. Third, in the sole judgment of the administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

Based on evaluation of the available peer reviewed science on perchlorate health effects, EPA determined that the chemical may have an adverse effect on the health of persons by inhibiting the transport of iodide into the thyroid, resulting in a deficiency of iodide. Thyroid hormones play an important role in the regulation of metabolic processes throughout the body and are also critical to developing fetuses and infants, especially with respect to brain development. Because the developing fetus depends on an adequate supply of maternal thyroid hormone for its central nervous system development during the first and second trimester of pregnancy, iodide uptake inhibition from low-level perchlorate exposure has been identified as a concern in connection with increasing risk of neurodevelopmental impairment in fetuses of hypothyroid mothers. Poor iodide uptake and subsequent impairment of the thyroid function in pregnant and lactating women have been linked to delayed development and decreased learning capability in their infants and children.

EPA collected monitoring data on perchlorate from 3,865 public water systems from 2001 to 2005 under the agency's Unregulated Contaminant Monitoring Regulation, or UCMR. EPA found that 160 (approximately 4.1 percent) of the public water systems reported at least 1 detection of perchlorate at or above the minimum reporting level of 4 micrograms per liter. To determine if perchlorate was occurring at levels of public health concern in these water systems, EPA compared the reported drinking water concentrations to Health Reference Levels for perchlorate.

EPA calculated HRLs based upon the perchlorate Reference Dose recommended by the National Research Council and adopted by EPA in 2005. (The RfD is an estimate of a daily oral exposure that is likely to be without an appreciable risk of adverse health effects.) EPA accounted for the differences in body weight, drinking water consumption, and the amount of perchlorate in the diet at 14 different stages of life to calculate the HRLs that range from 1 microgram per liter to 47 micrograms per liter.

These HRLs are concentrations of perchlorate in drinking water that may result in total perchlorate exposures (from food and water) greater than the RfD for individuals at each life stage. Given the range of potential alternative HRLs and the occurrence of perchlorate in water systems above these levels, EPA determined that perchlorate is known to occur or there is a substantial likelihood that it will occur with a frequency and at levels of public health concern.

EPA estimated the population served by public water systems (PWSs) monitored under UCMR for which the highest reported perchlorate concentration was greater than thresholds ranging from 4 to 23 micrograms per liter. For example, EPA estimated that 5.1-16.6 million people are served by PWSs that are above the Minimal Risk Level of 4 micrograms per liter. EPA determined that a National Primary Drinking Water Regulation for perchlorate could reduce exposures for these populations to levels below the range of thresholds and that such exposure reductions present a meaningful opportunity for the reduction of health risks for persons served by PWSs.

EPA's decision initiated development of a drinking water standard for perchlorate which will be proposed for public review and comment by no later than February 2013. EPA will continue to evaluate the science as we develop the proposed rule which must be promulgated within 18 months of the proposal. For more detailed information about EPA's decision, see http://water.epa.gov/drink/contaminants/unregulated/perchlorate.cfm.

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