Perchlorate Information Bureau

Perchlorate Factbook

Why EPA's 2022 Determination Ensures Public Health is Protected, Is Justified by the Science, & Complies with Federal Law

The Perchlorate Information Bureau is supported by Aerojet Rocketdyne, American Pacific Corporation, and Lockheed Martin. These companies have worked cooperatively with the U.S. Environmental Protection Agency and other jurisdictions to increase scientific and medical understanding of perchlorate's risk to human health.

July 2022

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Introduction

On March 31, 2022, the United States Environmental Protection Agency (U.S. EPA) announced it would not be moving forward to regulate perchlorate in drinking water, after nearly two decades of review and study and recommendations from six independent peer review panels convened over that time, including the National Academy of Sciences.

EPA's decision in this matter ensures the protection of public health and the environment, is based on the best available science, and complies with federal law as well as the Biden Administration's pledge to scientific integrity.

Specifically, EPA's decision is supported by 70 years of scientific research—perchlorate is one of the most well-studied environmental chemicals EPA has ever evaluated. The agency has spent decades generating and collecting valuable information to support the robust scientific database on how perchlorate acts in the human body. In 2020, EPA scientists came to the conclusion that the levels of perchlorate found in drinking water pose no threat of adverse effects to human health, even for the most sensitive populations.

Recent research and testing have also provided nationwide evidence that perchlorate levels are decreasing, with many systems that detected perchlorate 20 years ago now having no detections at all - further emphasizing that federal action is not needed.

These established facts on health and occurrence also underscore that EPA's decision complies with Federal law – specifically the requirements of the Safe Water Drinking Act (SDWA).

EPA's Action Ensures Public Health is Protected

Adverse effects from perchlorate exposure have been theorized, but never demonstrated in humans of any age.

The scientific database on perchlorate dates back to its use as a medicine in the 1950's, and includes nearly *70 years* of scientific study. EPA's modeling, which represents the best available science today, demonstrates that levels of perchlorate found in drinking water have no effects on either the typical U.S. consumer or the most sensitive subpopulations.

The science is abundantly and overwhelmingly clear: perchlorate detections in drinking water, in the few places where it is found, do not pose a public health concern. *No cases of adverse effects* from exposure to perchlorate at levels found in drinking water *have ever been documented*.

EPA has conducted extensive modeling on perchlorate. Claims that perchlorate causes thyroid problems, birth defects or other serious health problems are simply inaccurate – *no published research on perchlorate exposure in humans exists to support them*.

After reviewing the entire body of perchlorate research, the National Research Council of the National Academy of Sciences (NAS) determined in 2005 that levels of perchlorate below 245 parts per billion (ppb)[1] have no measurable effect on human health.

NAS emphasized that the only documented effect of perchlorate exposure in humans above 245 ppb is Iodine Uptake Inhibition (IUI). NAS has stated very clearly that "*inhibition of iodide uptake by the thyroid clearly is not an adverse effect . . .*".[2] IUI occurs regularly in all humans as a result of diet and other factors.

NAS further said that any adverse effects from perchlorate are "only proposed" and have not been demonstrated in humans.[3]

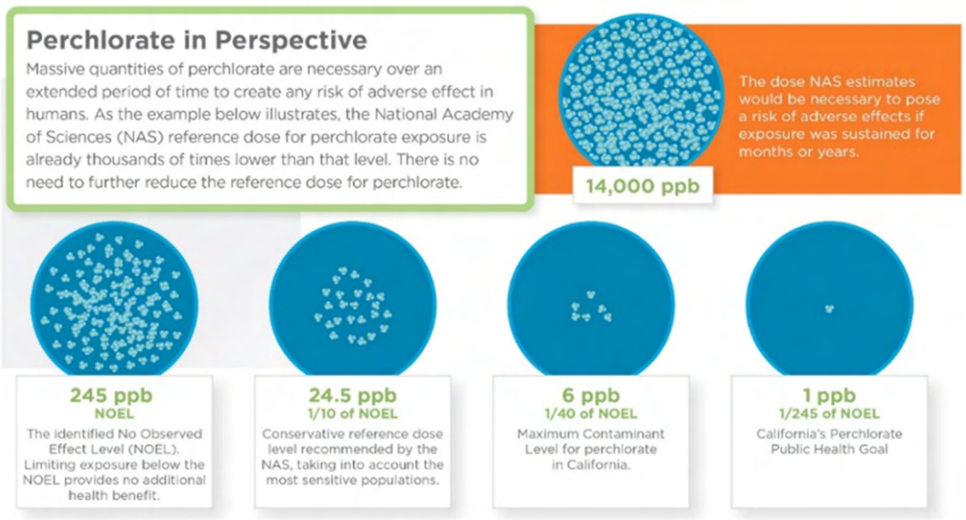
Levels of Perchlorate that "may" lead to possible adverse effects are thousands of times higher than what's been found in any public drinking water system.

The NAS has identified a "No Observed Adverse Effect Level" (NOAEL) for perchlorate (basically the threshold above which adverse effects "may" occur) at about 0.4 mg/kg-d[4] (equivalent to approximately 14,000 parts per billion (ppb) in water for a 70 kg adult drinking two liters of water per day).

NAS also determined the No Observed Effect Level (NOEL) for perchlorate to be about 245 ppb in water. Considering that in 99 percent of the water systems where perchlorate has been found, levels detected are below 10 ppb,[5] *and declining*, it is unlikely anyone is drinking water containing perchlorate at levels above the NOEL, and extremely unlikely anyone is drinking water with perchlorate levels anywhere close to the NOAEL identified by the NAS.

To put the NOAEL into sharper context, if perchlorate was found in drinking water at a level of 20 ppb, *you would have to drink 370 gallons*[6] *of that water, every day,* for months or years to be considered at-risk of theoretical adverse effects. That's enough to fill two hot tubs, or nine bathtubs.

According to NAS, perchlorate doses as high as 1,000 mg per day (roughly equivalent to 100,000 ppb[7] were once given to pregnant mothers to treat hyperthyroidism, with no adverse effects on either the mothers or their babies.[8]



Key Questions on Adverse Effects

Q **Why, in 2011, did EPA say that Perchlorate has been linked to mild, and in some cases severe, and irreversible neurological outcomes in infants?**

A EPA's 2011 finding on this topic states: "perchlorate exposure has been identified as a concern in connection with increasing risk of neurodevelopmental impairment in fetuses of hypothyroid mothers." However, (1) "identifying" perchlorate (2) as a "concern" (3) "in connection with" (4) "increasing risk," falls well short of finding that perchlorate may cause such an effect. In 2019, in its proposed rule on perchlorate, EPA describes a biological chain of events and then states that "decreased maternal thyroid hormone levels during pregnancy have been linked to decrements in neurocognitive function in offspring." However, there is no additional finding that perchlorate at concentrations found in drinking water will cause decreased maternal thyroid hormone levels, or the postulated decrements.

Q **Can perchlorate cause cancer in humans?**

A No. The National Academy of Sciences has confirmed perchlorate is not likely to cause cancer and numerous other credible studies have shown no evidence that perchlorate causes cancer in humans, even when consumed at levels far higher than any found in drinking water.

Q **Is perchlorate present in food at levels high enough to potentially pose a risk of adverse health effects?**

A According to research from the U.S. Food and Drug Administration, the answer is no. The FDA study, "Dietary Intake of Perchlorate and Iodine" did not find evidence that anyone, adult or child, is exposed to unsafe perchlorate levels from food.

Is Perchlorate Toxic?

The mere presence of perchlorate does not constitute a health concern; it's the amount of a substance that determines whether there is an adverse effect. Calcium or Vitamin C can be toxic, for example, if consumed in excessively high doses.

Perchlorate was widely used as a medicine in the mid-20th century to treat overactive thyroids, and prescribed for treatment at doses hundreds of thousands of times higher than any amounts found in drinking water.

Describing perchlorate as "toxic" mischaracterizes the facts. After nearly 70 years of clinical research, there are no known "unsafe" levels of perchlorate, only theoretical estimates of adverse effects that might occur at extremely high doses. It is unlikely, and there is no evidence, that anyone in the US is being exposed to these high levels.

The real science on perchlorate is this: there is not a single study in nearly seven decades of scientific research that concludes that low levels of perchlorate found in drinking water are a threat to humans of any age or in any potentially sensitive subpopulation.


Paracelsus

Paracelsus, the father of toxicology famously observed in 1493:

"*All things are poison and nothing is without poison; the dosage alone makes . . . a poison.*"

How does Perchlorate Affect the Body?

Thanks to nearly 70 years of clinical research, and perchlorate's use as a medicine, we have a very thorough understanding of how perchlorate acts in the body.

Perchlorate's "mechanism of action" (MOA, how it acts in the body) has been known for decades and is undisputed by scientists. The first measurable effect is Iodide Uptake Inhibition (IUI). Basically, perchlorate competes with iodine for absorption by the thyroid gland, which uses iodine to make hormones.

In its landmark 2005 report, *Health Implications of Perchlorate Ingestion* the NAS was very clear on this subject. NAS emphasized that IUI is the only documented effect of perchlorate exposure, and that, "Inhibition of iodide uptake by the thyroid clearly is not an adverse effect…" adding that if IUI does not occur, there cannot be a progression to any hypothesized adverse effects (pp 166-167).

IUI occurs regularly in every human being, regardless of perchlorate exposure, due to diet and other factors.

Perchlorate is not the only chemical with this MOA; other chemicals, such as nitrate and thiocyanate, also occur naturally in drinking water and many of the foods we eat[9] and together these latter two compounds account for more than 99 percent of the iodine uptake inhibition (IUI) that regularly takes place in the body.[10] *Even at doses higher than reported from drinking water, perchlorate accounts for less than one percent of IUI.*[11]

The amount of nitrate currently allowed in drinking water has the same effect as 300 ppb of perchlorate.[12]

Key Questions on Perchlorate and Toxicity

Q **Has any credible science emerged since the NAS report that shows perchlorate has other effects on human health, or acts in the body differently than what was previously known?**

A There is no known research, data, published paper or other science that changes our understanding of how perchlorate acts in the body, or shows perchlorate causes an adverse health effect at levels found in drinking water. The NAS reviewed 50 years of perchlorate science and concluded that IUI is the only documented effect of perchlorate exposure in humans, and that IUI is a non-adverse effect. The body of perchlorate research published since the NAS review confirms these findings.

Q **What would be considered a "high level" of perchlorate exposure, high enough to potentially pose a risk of adverse health effects?**

A NAS identified the "No Observed Effect Level" for perchlorate at 245 ppb in water, and the "No Observed Adverse Effect Level" at an amount equal to about 14,000 ppb. We know how much perchlorate it takes to have an effect on human health, and according to national water sampling surveys conducted by EPA, perchlorate—when it is found—is present at less than ten percent of the recognized "No Observed Effect Level."

Q **With so many things that can cause IUI, isn't exposure to them a concern for people with low iodine intake in their diet?**

A It is correct that the effect of perchlorate exposure on thyroid function depends on an individual's iodine status and low iodine could be an issue, but only if exposure is above the No Observed Effect Level of (245 ppb). Considering that in 99 percent of the water systems where perchlorate has been found, levels detected are below 10 ppb[13], and *declining*, it is unlikely anyone is being exposed to perchlorate at levels above the NOEL. Moreover, according to the National Institutes of Health, the U.S. population diet is generally iodine sufficient, making perchlorate exposure much less of a public health issue.[14]

Perchlorate in Drinking Water and IQ: Is There A Connection?

Perchlorate exposure levels that "may" lead to any IQ impacts are substantially higher than any amounts detected in drinking water.

In nearly 70 years of research, no science has emerged demonstrating that levels of perchlorate detected in U.S. drinking water supplies have any adverse effects on human health.

Theoretical claims of an adverse impact on human IQ or brain development overlook the fact that perchlorate has a well-documented, scientifically-established "No Observed Effect Level" (NOEL) of 245 ppb and only one public water system in the U.S. has ever measured perchlorate in excess of that level.[15]

It is scientifically-accepted that no adverse health effects will occur when humans are exposed to levels below the NOEL of any compound. If no one is being exposed to levels above the perchlorate NOEL, then theoretical changes in thyroid hormones or subsequent effects on neurodevelopment and IQ would not occur.

EPA's Biologically Based Dose Response (BBDR) model for perchlorate is a method that uses mathematical modeling to predict a possible effect where no data from actual human studies exist.

EPA's model is fit for purpose in assessing risk and evaluating whether a regulatory standard is needed, and represents the best available science. It should also be recognized that EPA's model is very conservative and likely over predicts the effects of perchlorate.

Is Anyone Actually at Risk?

Exposure levels below 245 ppb have no observable effect on humans of any age or demographic, and it's highly unlikely anyone is being exposed to these levels.

In 99 percent of the water systems where perchlorate was initially detected in 2001-2003, the levels detected were below 10 ppb[16], and have been declining ever since. Based on other research from the FDA[17] and the EPA[18], it is unlikely anyone is being exposed to perchlorate at levels above the "No Observed Effect Level" of 245 ppb.

We know that the only documented effect of perchlorate if exposure exceeds 245 ppb is Iodine Uptake Inhibition (IUI). We also know that IUI is reversible, is not an adverse effect, and occurs regularly in humans as a result of diet and other factors.

Perchlorate is not the only chemical with this MOA; other chemicals, such as nitrate and thiocyanate, also occur naturally in drinking water and many of the foods we eat[19] and together these latter two compounds account for more than 99 percent of the iodine uptake inhibition (IUI) that regularly takes place in the body.[20] *Even at doses higher than reported from drinking water, perchlorate accounts for less than one percent of IUI.*[21]

In 2005, the NAS concluded that a reference dose for perchlorate of 0.0007 milligrams per kilogram of body weight per day — roughly equal to 24.5 parts per billion (ppb) in drinking water — would be safe for even the most sensitive populations.

NAS ensured the protection of even the most sensitive populations when it took the unprecedented conservative step of proposing a Reference Dose based on applying a 10-fold safety factor to the recognized "no observed effect level." This is substantially more protective than usual EPA practice, which sets standards based on adverse effect levels.

With a reference dose in place to protect the most sensitive population, and perchlorate detections below that reference dose, one can reasonably conclude that all segments of the U.S. population are protected.

What's Being Done About Perchlorate Exposures Now, and in the Future?

Lack of a federal regulation drinking water regulation does not mean nothing is being done about perchlorate exposure. States where perchlorate occurrence has been most prevalent have already taken regulatory action, further emphasizing that additional federal regulation is not needed.

Cleanup agreements and operations are in effect in several areas where perchlorate has been detected. Both private industry and the Department of Defense have been engaged in an ongoing program of investigation and remediation of perchlorate-affected sites.

Perchlorate detections in water have actually been decreasing for more than a decade. Importantly, these decreases are occurring in the absence of federal regulation under the Safe Drinking Water Act.

EPA is pursuing multiple integrated actions to address perchlorate in the nation's waters. Cleaning up existing contamination and protecting drinking water sources from future contamination are central to the agency's approach to addressing perchlorate in drinking water.

The success of ongoing public and private efforts in the absence of federal regulation is reflected in the dramatic declines in perchlorate occurrence, confirmed in the EPA report, Reductions of Perchlorate in Drinking Water (May 2020). These gains are clear evidence that a national drinking water standard is not necessary to protect public health or the environment.

EPA's Plan to Address Perchlorate Contamination: (March 31, 2022)

EPA is providing more than $15 billion in grant funding to address emerging contaminants. This funding is part of the single-largest investment in U.S. water infrastructure and can be used to address perchlorate and other drinking water needs.

EPA plans to establish a web-based toolkit (to be online in 2022) with information to assist drinking water systems and communities concerned about perchlorate.

EPA is working with states to address perchlorate contamination under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), also known as the Superfund program. The agency will also consider proposed revisions to Resource Conservation and Recovery Act (RCRA) standards to reduce impacts of perchlorate to human health and the environment.

EPA will also continue to consider new information on the health effects and occurrence of perchlorate.

EPA's Action is Justified by Science

The Scientific Record on Perchlorate

Perchlorate is one of the most studied compounds in EPA history, with nearly 70 years of human and animal research available, dating back to its use as a medicine to treat thyroid disorders.

In the 1950s, perchlorate was approved by the FDA as a safe and effective medication to treat people with overactive thyroid glands. It has been replaced in the U.S. with newer medications, partly because enormous doses were required to have any effect, and because it had to be re-administered frequently since it is rapidly eliminated from the body. It's still used as a thyroid medication in some parts of the world.

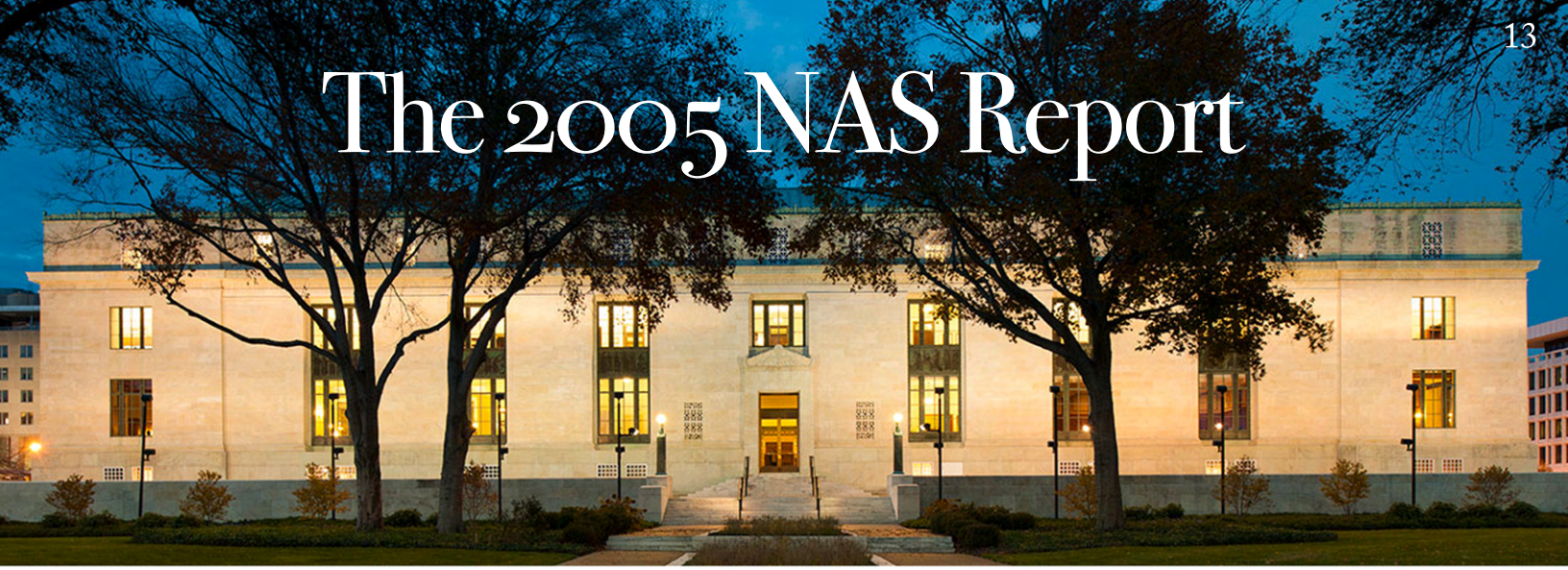
The scientific literature regarding the health effects of perchlorate is robust. It encompasses nearly 70 years of studies with a wide dose-response range spanning low, daily amounts detected in some drinking water samples, up to high, therapeutic doses given intentionally for years at a time. Rarely does a chemical of environmental concern have such robust data on which to base a toxicological assessment.

Perchlorate is one of the few compounds for which there is a recognized No Observed Effect Level (NOEL), as established by the NAS in its landmark report, "Health Implications of Perchlorate Ingestion."

As encouraged by the NAS, scientific research on perchlorate has been ongoing since the NAS issued its 2005 report, predominantly validating its conclusions. No credible, peer-reviewed studies have found an adverse health effect caused by levels of perchlorate found in drinking water.

Perchlorate is one of the most well-studied environmental chemicals EPA has ever evaluated since its founding in 1970. The agency has spent decades generating and collecting valuable information to support the robust scientific database on how perchlorate acts in the human body.

The 2005 NAS Report



In 2005, at the request of EPA and the Department of Defense (DOD), the National Academy of Sciences (NAS) was asked to review the data on the health effects of perchlorate.

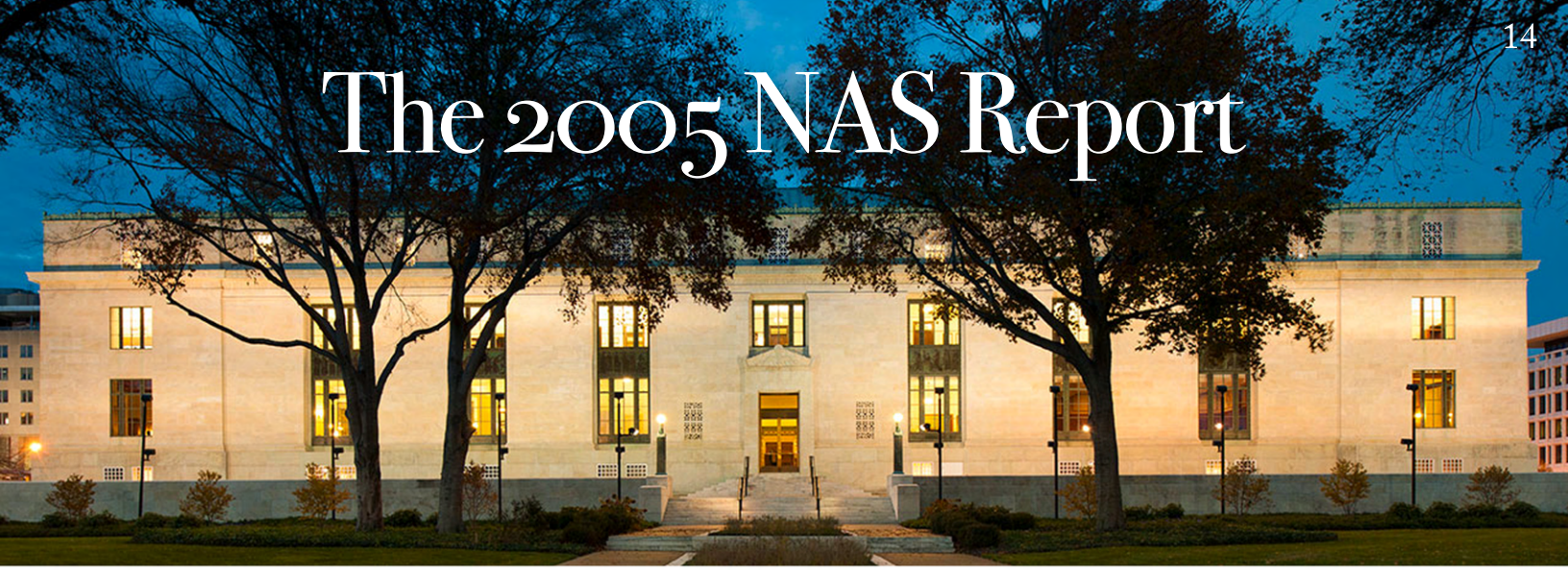
The NAS determined that:

1) there are no measurable health effects of perchlorate exposure below 245 ppb

2) the only known effect of perchlorate above that level is Inhibition of Iodine Uptake – a non-adverse effect

3) a perchlorate Reference Dose of 24.5 parts per billion would be safe for even the most vulnerable populations over a lifetime

The 2005 NAS Report



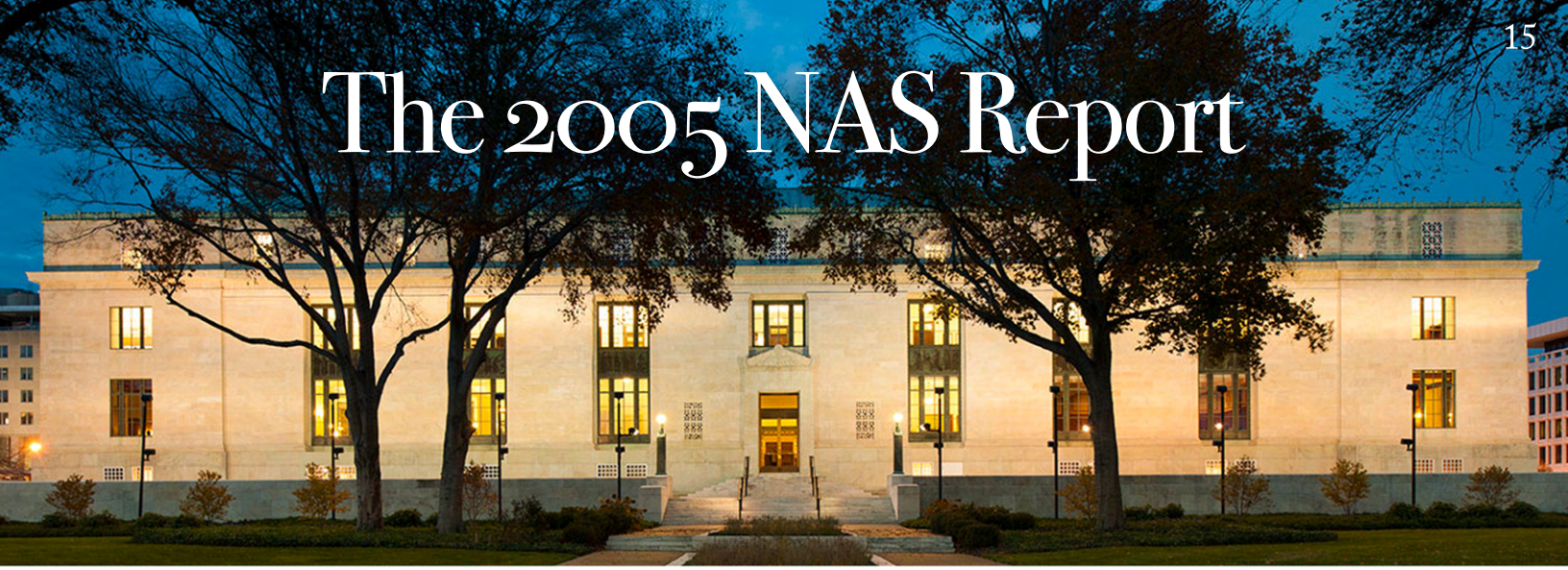
NAS is Trusted for its Independence.

NAS is the gold standard of scientific inquiry. Its findings merit the utmost respect because of the eminence of its panels, the transparency of its procedures, and its history of independence.

The NAS select panel on perchlorate comprised fifteen world-renowned experts in toxicology, thyroid health and other areas of science directly related to perchlorate. The NAS also implemented a very public and transparent process with public meetings and comment periods, in conducting its review.

Scientific studies must pass muster within well-established review procedures, including external peer review. NAS exclusively examined peer-reviewed published research and came to its own conclusions about the quality of that research.

The 2005 NAS Report



After examining 50 years of perchlorate literature, NAS published its landmark 2005 report, Health Implications of Perchlorate Ingestion, concluding:

At doses above levels found in drinking water but below therapeutic doses, Inhibition of Iodine Uptake (IUI) is the only consistently documented effect of perchlorate exposure in humans.

IUI is observed only at doses greater than 0.007 milligrams (mg) per kg-d (equivalent to 245 ppb in drinking water). IUI is a reversible biochemical phenomenon and is not an adverse effect. The No Observed Effect Level (NOEL) for IUI was recognized at 245 ppb for perchlorate.

Human and animal data demonstrate no adverse effect can occur if no IUI occurs.

A Reference Dose (RfD) for perchlorate equivalent to 24.5 ppb in drinking water would be safe for all populations, including the most sensitive.

Basing the RfD on a on a dose at which no effect, including a non-adverse effect, occurs is conservative and health protective compared to standard EPA practice, which involves setting an RfD based on the dose at which adverse effects occur.

EPA's Science Advisory Board and Perchlorate Model

EPA's 2022 perchlorate determination reflects substantial work by independent scientific experts and rests securely on the recommendations of six independent peer review panels, including the National Academy of Sciences.

While perchlorate's MOA has been known for decades, in the past ten years EPA has developed modeling tools that allow simulations of the effects of perchlorate in humans at levels found in drinking water and the environment.

EPA's science experts on the Science Advisory Board (SAB) directed EPA to take a rigorous scientific approach to perchlorate and construct a physiologically-based pharmacokinetic (PBPK) model. Thereafter, EPA did so and found no risk of adverse health effects at the low levels found in a small number of public drinking water systems.

This sophisticated scientific analysis provides an even better understanding of the health effects of perchlorate at levels found in drinking water and now constitutes the best available science on perchlorate's effects at varying exposure levels.

The two-step model approach recommended by the SAB was reviewed twice during its development by independent peer review panels and was declared "fit for purpose" in helping EPA determine whether to regulate perchlorate.

The model shows consistent results across a wide range of conditions of initial thyroid hormone levels, iodine consumption, and other physical parameters—perchlorate at levels found in drinking water has an extremely small effect that is likely beyond the range of accuracy and precision of the model and underlying data. Simply put: concentrations of perchlorate found in drinking water have no effect on even the most sensitive population.

EPA's modeling leads to the conclusion that there is no meaningful opportunity for risk reduction through promulgation of a national drinking water standard. Since this approach relies on the totality of the scientific information available, focuses on a proposed adverse health effect (neurodevelopment) and the most sensitive subpopulation (fetuses of pregnant women), the use of the present modeling represents the best available science.

What Others Say

EPA's determination not to regulate perchlorate, based on the lack of adverse effects and very low occurrence, is consistent with findings and statements from other scientific and regulatory authorities.

EPA's Office of the Inspector General (OIG): In April 2010 OIG stated, among other conclusions that "EPA's perchlorate reference dose (24.5 ppb) is conservative and protective of public health, and further reducing perchlorate exposure below the reference dose does not effectively lower risk." The OIG concluded that iodide deficiency "is the dominant stressor in this public health issue." Stated differently, whether an individual has adequate iodide is determined more by the amount of iodide in their diet than by exposure to any of the other stressors (e.g., thiocyanate, nitrate, or perchlorate). Of note, the U.S Centers for Disease Control and the Food and Drug Administration both emphasize that the U.S. diet is iodine sufficient.

U.S. Food and Drug Administration (FDA): FDA has examined the concentration of perchlorate in the U.S. diet through several nationally-representative surveys of perchlorate in food. After analyzing this food and the expected consumption data, the FDA has concluded that exposures to perchlorate through food are lower than EPA's RfD and are unlikely to cause any health effects with daily exposure over a lifetime.[22] Since dietary exposure is significantly larger than drinking water exposure for most Americans, FDA's judgment regarding total dietary exposure through food is relevant to EPA's drinking water determination.

U.S. Agency for Toxic Substances and Disease Registry (ATSDR): ATSDR's toxicological profile on perchlorate confirms that adverse effects have never been demonstrated in humans.[23]

EPA's Determination Complies with Federal Law

The Safe Drinking Water Act Requirements

The Safe Drinking Water Act (SDWA) requires three criteria be met before a compound can be regulated:

(1) it may have an adverse effect on human health

(2) it occurs in public drinking water systems at a frequency and at levels of public health concern

(3) federal regulation of the substance presents a meaningful opportunity for health risk reduction[24]

EPA *must find that the compound satisfies all three statutory criteria for regulation*.[25] If even one of the criteria is not met, then that compound cannot be regulated under the SDWA.

Perchlorate does not meet even one of the statutory requirements. Based on the evidence and federal law, the only conclusion EPA could have reached was that perchlorate does not "present a meaningful opportunity for health risk reduction".

Because EPA's determination is based on 70 years of peer-reviewed scientific research, it is consistent with both Federal Law and the Biden Administration's pledge to scientific integrity.

EPA must give proper weight to the overwhelming scientific evidence that there is no credible scientific rationale, nor any public health benefit to be achieved, by federal regulation of perchlorate. EPA's resources are better spent on addressing real environmental risks.

A comparison of perchlorate and other SDWA contaminants, specifically sodium, manganese, sulfate, and boron, shows that a decision to withdraw the perchlorate determination is consistent with past EPA decisions not to regulate.

Key Questions on Perchlorate and Federal Law

Q **Some have claimed that EPA's decision appears to defy a court order that required the agency to establish a drinking water standard. Is that true?**

A Following a deadline lawsuit, EPA agreed to issue a final decision under the SDWA on perchlorate by a date certain, and the 2022 determination is the fulfillment of that agreement.

EPA did not agree to limit its options or inherent authority under the SDWA as part of the agreement, nor could it ever legally do so.

Q **But EPA did make a determination to regulate perchlorate in 2011, didn't it?**

A EPA's 2011 action was a preliminary decision to pursue the detailed scientific work necessary to determine whether perchlorate should be regulated under the SDWA and, if so, at what levels. At the time of the 2011 determination, EPA had not developed the scientific evidence needed to fully evaluate perchlorate. At the time, EPA's entire rationale was reflected in a single declarative sentence, which simply stated that setting a standard would reduce exposures to levels below that standard.

In addition, little of the exhaustive scientific, occurrence and cost-benefit analysis required by the SDWA had been completed by 2011

The First Requirement: Can Perchlorate Have an Adverse Effect?

No adverse health effects from perchlorate exposure have been documented in humans in nearly 70 years of scientific study, dating back to perchlorate's use as a medicine.

At levels below 245 ppb, perchlorate has no observable health effect at all.

NAS concluded that perchlorate may have an adverse effect at therapeutic doses (14,000 ppb) if that level of exposure is sustained for months or years, but emphasized "The continuum of possible effects of iodine uptake inhibition caused by perchlorate (a non-adverse effect, and the only known effect of perchlorate exposure) is only proposed and has not been demonstrated in humans…"[26]

Per the NAS conclusion, while it is technically correct to say that perchlorate "may" have an adverse effect on human health, the relevant question is whether levels of perchlorate *found in the environment* (i.e., in drinking water) may have an adverse effect on human health. The overwhelming weight of the scientific evidence says it does not.

To put the potential adverse effect level into sharper context, if perchlorate was found in drinking water at a level of 20 ppb, a person would have to *drink 370 gallons of that water, every day,* for months or years to be considered at-risk of theoretical adverse effects. That's the equivalent of drinking nine bathtubs of water every day.

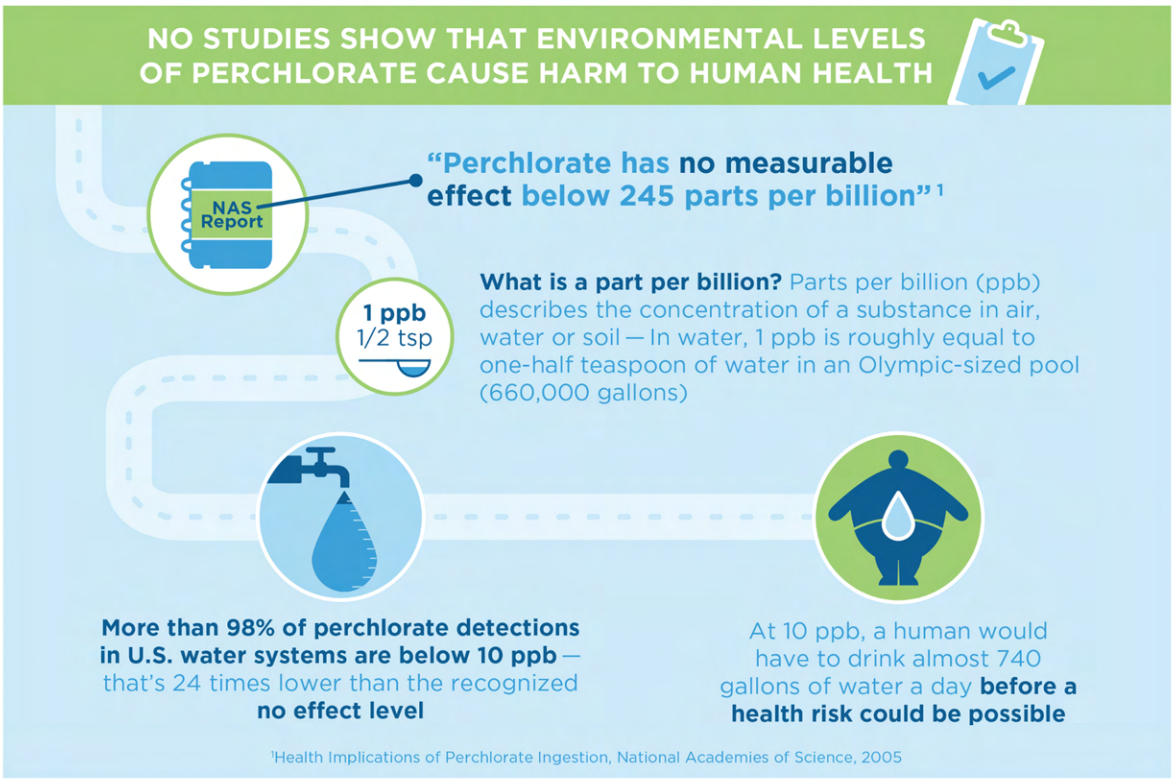
In the context of the Safe Drinking Water Act, and the three required criteria for a compound to be regulated, the first criteria concerning the risk of adverse effects is not met, and that alone justifies EPA's 2022 determination.

The Second Requirement:
Does Perchlorate Occur in Public Drinking Water at a Frequency and Levels of Public Health Concern?

There are no known unsafe levels of perchlorate in public drinking water systems; it is unlikely anyone in the US is being exposed to levels that have any effect.

EPA's most recent analysis of the best public health information demonstrates that perchlorate is not known to occur, nor is there a substantial likelihood that it will ever occur, in public water systems with a frequency and at levels of public health concern.

EPA data collected from 2001 to 2003 showed that where perchlorate was detected, it was found at less than 10 parts per billion (ppb) in 99% of samples tested.[27] For context, The National Research Council of the National Academy of Sciences (NAS) determined in 2005 that levels of perchlorate below 245 ppb have no measurable effects of any kind in humans.



The Second Requirement:
Does Perchlorate Occur in Public Drinking Water at a Frequency and Levels of Public Health Concern?

EPA's 2022 determination not to regulate perchlorate is supported by nationwide evidence that perchlorate levels are decreasing, further emphasizing that federal action is not needed.

Research published in the past five years has demonstrated that perchlorate detections in drinking water have decreased substantially since 2001, as EPA itself documented in 2020.

A study by Corey et al. (2017) reported that total exposure of perchlorate from food and water sources has decreased since 2005, and confirmed that perchlorate contributes less than 1 percent of total daily Iodine Uptake Inhibition when a person eats a normal and healthy diet.

The Colorado River provides water to millions of people in several western states[28] and is by far the largest single source of U.S. drinking water impacted by perchlorate. The 1997 discovery of perchlorate in the Colorado River prompted the Nevada Division of Environmental Protection (NDEP) and others to initiate the Southern Nevada Perchlorate Cleanup Project. As a result, concentrations in the river have been declining for over two decades.[29] According to NDEP, concentrations in the Las Vegas Wash, which is down gradient of source areas, have declined by more than 94%.[30]

An April 2019 study by Luis et al.[31] gathered and assessed updated data from 94 of the 152 large water systems (62%) that had had at least one detection under EPA's Unregulated Contaminant Monitoring Rule (UCMR) 1[32] between 2001 and 2005. In the new analysis, 63 systems reported no detections, and another 17 reported concentrations below 4 ppb. Altogether, updated perchlorate concentrations were lower than the UCMR 1 concentrations in 90 out of the 94 PWSs for which information was available.

Other recent and reliable data from SDWA Consumer Confidence Reports further indicates very low occurrence of perchlorate in public water systems.

Key Questions on Perchlorate Occurence

Q **There are claims that as many as 16 million American's are being exposed to unsafe levels of perchlorate – is that accurate?**

A Setting aside for the moment that there are no scientifically-established unsafe levels of perchlorate, the allegation that 16 million people might be exposed to unsafe levels of perchlorate is based on out of date and flawed information.

The 16 million number is based on the results of EPA's UCMR 1 data collection effort, conducted between 2001 and 2003. The UCMR 1 data showed that water systems serving a total of 16 million people had one or more detections of perchlorate above 4 ppb.

However, perchlorate concentrations have been declining for decades. The data from UCMR 1 is badly outdated.

A study from 2019[33] gathered and assessed updated data from the water systems that detected perchlorate in UMCR 1. Essentially all of the systems for which more recent data was available had lower perchlorate concentrations and most reported that no perchlorate was detected in their water.[34]

Multiple studies have also concluded that EPA's UCMR 1 data were flawed – largely because they were collected from source water and not drinking water that was actually served to consumers. The result was the samples overstated the presence of perchlorate in drinking water and were not representative of conditions at the time.

Key Questions on Perchlorate Occurence

Q **Is EPA is allowing for too much exposure to one chemical – perchlorate - in the face of a host of other chemicals in water, including other chemicals that cause IUI?**

A EPA's Office of the Inspector General (OIG) considered the issue of multiple contaminants in water as far back as 2010. Concerning perchlorate, OIG wrote: "EPA's perchlorate Reference Dose (approximately 24.5 parts per billion in water) is conservative and protective of human health and further reducing exposure below the RfD does not effectively lower risk."

Q **Did EPA also account for possible exposure to perchlorate from food?**

A Yes. EPA did develop a relative source contribution (RSC) estimate to account for exposure to perchlorate from drinking water and other sources, including food. Notably, there has never been a health concern about perchlorate in food. The FDA has examined the issue of perchlorate in food and determined the average dietary intake of perchlorate from foods—where it occurs—is less than the EPA reference dose. FDA further announced that it would recommend no changes in diets for infants or children due to perchlorate exposure.[35]

The Third Requirement:
Does Federal Regulation Present a Meaningful Opportunity for Health Risk Reduction?

Multiple lines of evidence concerning the science on adverse effects and the occurrence of perchlorate in drinking water all point to the conclusion that additional regulation of perchlorate does not present a meaningful opportunity for health risk reduction.

The actual text in this section of the Safe Drinking Water Act reads: "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."[36] While this does give the EPA Administrator discretion, the Administrator's decision must be based on the evidence.

Because perchlorate does not meet the first two SDWA criteria, it cannot meet the third, and it would be an abuse of the Administrator's discretion to make a judgment finding that perchlorate should be regulated.

EPA's determination not to regulate perchlorate is directly in line with past EPA determinations on other chemicals of concern

Withdrawal of the 2011 Determination for perchlorate is consistent with EPA's past determinations that a meaningful opportunity to regulate health risk does not exist.

A comparison of occurrence data for perchlorate and relevant compounds from EPA's Contaminant Candidate List (CCL) 1 and CCL 2 regulatory determinations reveals that perchlorate presents a smaller opportunity for risk reduction than sodium, manganese, sulfate, and boron, all of four of which EPA has made determinations not to regulate.

Perchlorate is well within the range of values of occurrence and health benchmark levels that EPA has previously determined do not merit regulation.[37]

	Percent of Public Water Systems with detects	Percent of Population Served Above ½ HRL	Population Served Above ½ HRL (millions)
Sodium	100	18.5	15.9
Manganese	68	4.6	3.9
Sulfate	88.1	10.2	21.8
Boron	81.9	2.9	2.5
Perchlorate (2019)	0.05	0.02	0.06

Notes

1. One ppb is roughly equal to a half teaspoon of material diluted in an Olympic-sized pool.

2. National Research Council: Health Implications of Perchlorate Ingestion. National Academy Press, 2005. http://books.nap.edu/catalog.php?record_id=11202 See page 166 (emphasis in original).

3. Ibid at 165.

4. National Research Council: Health Implications of Perchlorate Ingestion. National Academy Press, 2005. http://books.nap.edu/catalog.php?record_id=11202 P 171

5. See EPA UCMR-1 Data (2001-2003): of 34,193 water samples EPA tested from US public water systems, only 637 samples (1.86%) had perchlorate levels above 4 ppb. Half of those 637 samples (i.e., 319) were in the range of 4 ppb to 6.4 ppb. Thus, perchlorate levels were less than 6.4 ppb in more than 99% of water samples.

6. NOAEL (µg/kg-d) / Concentration in water (µg/L) * body weight (kg) * Conversion factor (gal/L) = gallons/d;
NOAEL is 400 µg/kg-d (0.4 mg/kg-d)
Concentration in water is 20 µg/L (20 ppb)
Default body weight is 70 kg
There is 1 liter per 0.264 gal (0.264 gal/L)
400 µg/kg-d / 20 µg/L * 70 kg * 0.264 gal/L = 370 gallons/d

7. 1000 mg/d * 1000 µg/mg / 2 L/d= 500,000 µg/L (or ppb)

8. National Research Council: Health Implications of Perchlorate Ingestion. National Academy Press, 2005. http://books.nap.edu/catalog.php?record_id=11202 PP 6-7

9. Belzer et al., Using Comparative Exposure Analysis to Validate Low-dose Human Health Risk Assessment: the Case of Perchlorate, in Comparative Risk Assessment and Environmental Decision Making (I. Linkov & A. Ramadan ed. 2004).

10. Tonacchera et al., Relative Potencies and Additivity of Perchlorate, Thiocyanate, Nitrate, and Iodide on the Inhibition of Radioactive Iodide Uptake by the Human Sodium Iodide Symporter, 14 Thyroid 1012, 1016 (2004).

11. EPA Office of Inspector General, Scientific Analysis of Perchlorate, Report No. 10-P-0101 (Apr. 19, 2010). See also Wyngaarden et al., The Effect of Certain Anions upon the Accumulation and Retention of Iodide by the Thyroid Gland, 50 Endocrinology 537 (1952), Wyngaarden et al., The Effects of Iodide, Perchlorate, Thiocyanate, and Nitrate Administration upon the Iodide Concentration Mechanism of the Rat Thyroid, 52 Endocrinology 568 (1953)

12. De Groef, et al, 2006, European Journal of Endocrinology.

13. See EPA UCMR-1 Data (2001-2003): of 34,193 water samples EPA tested from US public water systems, only 637 samples (1.86%) had perchlorate levels above 4 ppb. Half of those 637 samples (i.e., 319) were in the range of 4 ppb to 6.4 ppb. Thus, perchlorate levels were less than 6.4 ppb in more than 99% of water samples.

14.(https://ods.od.nih.gov/factsheets/Iodine-HealthProfessional/#:~:text=Since%20the%20inception%20of%20the,U.S.%20population%20is%20iodine%20sufficient)

15. US EPA Perchlorate Occurrence and Exposure (Updated UCMR 1 Data Set). The only water system above 90 ppb was in Puerto Rico with a value of 420 ppb at the time. EPA stated: EPA contacted the Puerto Rico Aqueduct and Sewer Authority (PRASA) in January 2019. PRASA personnel indicated that no updated monitoring data for perchlorate is available. PRASA personnel stated that the Utuado water system was significantly impacted by hurricane Maria and monitoring records from years prior to 2017 were lost.

Notes

16. See EPA UCMR-1 Data (2001-2003): of 34,193 water samples EPA tested from US public water systems, only 637 samples (1.86%) had perchlorate levels above 4 ppb. Half of those 637 samples (i.e., 319) were in the range of 4 ppb to 6.4 ppb. Thus, perchlorate levels were less than 6.4 ppb in more than 99% of water samples.

17. CW Murray et al: US Food and Drug Administration's Total Diet Study: Dietary intake of perchlorate and iodine. J Expo Sci Environ Epidemiol, 2008. (http://www.nature.com/jes/journal/vaop/ncurrent/pdf/7500648a.pdf)

18. Office of Water: The Analysis of Occurrence Data from the First Unregulated Contaminant Monitoring Regulation (UCMR1) in support of Regulatory Determinations for the Second Drinking Water Contaminant Candidate List (EPA 815-D-06-008); EPA, 2006.

19. Belzer et al., Using Comparative Exposure Analysis to Validate Low-dose Human Health Risk Assessment: the Case of Perchlorate, in Comparative Risk Assessment and Environmental Decision Making (I. Linkov & A. Ramadan ed. 2004).

20. Tonacchera et al., Relative Potencies and Additivity of Perchlorate, Thiocyanate, Nitrate, and Iodide on the Inhibition of Radioactive Iodide Uptake by the Human Sodium Iodide Symporter, 14 Thyroid 1012, 1016 (2004).

21. EPA Office of Inspector General, Scientific Analysis of Perchlorate, Report No. 10-P-0101 (Apr. 19, 2010). See also Wyngaarden et al., The Effect of Certain Anions upon the Accumulation and Retention of Iodide by the Thyroid Gland, 50 Endocrinology 537 (1952), Wyngaarden et al., The Effects of Iodide, Perchlorate, Thiocyanate, and Nitrate Administration upon the Iodide Concentration Mechanism of the Rat Thyroid, 52 Endocrinology 568 (1953).

22. 1000 mg/d * 1000 µg/mg / 2 L/d= 500,000 µg/L (or ppb)

23. 111 Murray et al., US Food and Drug Administration's Total Diet Study: Dietary intake of perchlorate and iodine, 18 J. of Exposure Sci. & Envtl. Epidemiology 571 (2008); Abt et al., Update on dietary intake of perchlorate and iodine from U.S. food and drug administration's total diet study: 2008-2012, 28 J. of Exposure Sci. & Envtl. Epidemiology 21 (2018).
See ATSDR's Tox profile for perchlorate, specifically section 1.5 and 1.6 (pp 7-10) at:
(https://www.atsdr.cdc.gov/toxprofiles/tp162.pdf)

24. https://www.epa.gov/laws-regulations/summary-safe-drinking-water-act

25. SDWA § 1412(b)(1)(A); 42 U.S.C. § 300g-1(b)(1)(A).

26. National Research Council: Health Implications of Perchlorate Ingestion. National Academy Press, 2005. http://books.nap.edu/catalog.php?record_id=11202 See page 165 (parentheses added)

27. U.S. EPA, Unregulated Contaminant Monitoring Rule 1 (UCMR 1).

28. U.S. Bureau of Reclamation, Colorado River Basin Water Supply and Demand Study at 3 (Dec. 2012), available at https://www.usbr.gov/watersmart/bsp/docs/finalreport/ColoradoRiver/CRBS_Executive_Summary_FINAL.pdf

29. Nevada Division of Environmental Protection, Environmental Cleanup, http://ndep.nv.gov/environmental-cleanup (last visited Aug. 7, 2019).

30. Nevada Division of Environmental Protection, Environmental Cleanup, http://ndep.nv.gov/environmental-cleanup

Notes

31. 19 Water Supply 681 (2019) (2019 Occurrence Study).

32. Id. at 682.

33. Id. at 690

34. Belzer et al., Using Comparative Exposure Analysis to Validate Low-dose Human Health Risk Assessment: the Case of Perchlorate, in Comparative Risk Assessment and Environmental Decision Making (I. Linkov & A. Ramadan ed. 2004).

35. Murray et al., US Food and Drug Administration's Total Diet Study: Dietary intake of perchlorate and iodine, 18 J. of Exposure Sci. & Envtl. Epidemiology 571 (2008); Abt et al., Update on dietary intake of perchlorate and iodine from U.S. food and drug administration's total diet study: 2008-2012, 28 J. of Exposure Sci. & Envtl. Epidemiology 21 (2018).

36. 42 USC 300g-1(b)(1)(B)(ii) & (b)(1)(A)

37. Health Reference Level (HRL) is defined as a lifetime exposure concentration (of a contaminant) protective of adverse, non-cancer health effects, that assumes all the exposure to a contaminant is from drinking water (normal exposure to a particular contaminant is due to drinking water, food ingested, and air breathed where applicable)