Calendar No. 1055

110TH CONGRESS
2d Session

SENATE

REPORT
110–484

PROTECTING PREGNANT WOMEN AND CHILDREN FROM PERCHLORATE ACT OF 2008

SEPTEMBER 24 (legislative day, SEPTEMBER 17), 2008.—Ordered to be printed

Mrs. BOXER, from the Committee on Environment and Public Works, submitted the following

R E P O R T

[To accompany S. 150]

together with

MINORITY VIEWS

[Including cost estimate of the Congressional Budget Office]

The Committee on Environment and Public Works, to which was referred the bill (S. 150) to amend the Safe Drinking Water Act to protect the health of pregnant women, fetuses, infants, and children by requiring a health advisory and drinking water standard for perchlorate, reports favorably thereon with an amendment and recommends the bill (as amended) do pass.

PURPOSE AND SUMMARY OF THE LEGISLATION

The purpose of S. 150, the Protecting Pregnant Women and Children from Perchlorate Act of 2008 is to require a health advisory and national primary drinking water regulation for perchlorate. The bill would also require EPA to create a public health advisory for perchlorate that is fully protective, with an adequate margin of safety, of the health of vulnerable persons, including pregnant women, infants, and children, taking into consideration body weight, exposure patterns and all routes of exposure. S. 150 as amended would also require the EPA to propose a national primary drinking water regulation for perchlorate within 9 months of the date of enactment of S. 150, and to finalize a national primary

drinking water standard for perchlorate within 18 months of the date of enactment.

BACKGROUND AND NEED FOR THE LEGISLATION

BACKGROUND

Perchlorate is a salt used to create flares, fireworks, and other items. It also occurs naturally in some areas, including in fertilizers imported from Chile. Once released into the environment, perchlorate can move through soil, into water, and then into food. People's health may be harmed by exposure to perchlorate, through eating food or drinking water contaminated with this toxic substance. According to the National Academy of Sciences (NAS), certain exposure levels of perchlorate can affect "thyroid hormone production by inhibiting the uptake of iodine . . . ." [1] Also, according to the NAS: "Thyroid hormones are critical for normal growth and development of the central nervous system of fetuses and infants." Vulnerable persons, including pregnant women, infants, and children are especially vulnerable to perchlorate's impact on iodine uptake in the body.

In 2005, the Government Accountability Office (GAO) found 395 sites in 35 states with more than 4 parts per billion (ppb) of perchlorate. The Environmental Protection Agency (EPA) knows of 160 drinking water systems, serving almost 17 million people in 26 states, with perchlorate levels of at least 4 ppb. The State of California knows of perchlorate contamination in 274 active or standby water wells at levels of at least 4 ppb.

In 2005, the National Academy of Sciences (NAS) report found that low levels of perchlorate may pose health risks and recommended a safe level of exposure to perchlorate from all sources—contaminated drinking water and food.[2]

Since 2005, several studies show widespread perchlorate exposure. In October 2006, researchers at the federal Centers for Disease Control (CDC) found detectable levels of perchlorate in all urine samples taken during the 2001–2002 National Health and Nutrition Examination Survey (NHANES) of U.S. residents age six and older, with significantly higher levels found in children than in adults.[3] In December 2006, researchers at the CDC published a follow-up study that showed that there was a "significant" relationship between the amount of urinary perchlorate and two different thyroid hormones in women. It was the first study to show a correlation.[4]

A 2007 study in the Proceedings of the National Academy of Sciences found that perchlorate concentrates in breast milk. A January 2008 broad study by the U.S. Food and Drug Administration found perchlorate in 74% of all foods tested, including baby food, and the study found: "Infants and children demonstrated the highest estimated intakes of perchlorate on a body weight basis."

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[1] National Research Council, National Academy of Sciences, Health Implications of Perchlorate Ingestion (2005), available online at *http://www.nap.edu/catalog.php?record__id=11202.*

[2] Ibid.

[3] Blount, et al.; Perchlorate Exposure of the U.S. Population, 2001–2002; Journal of Exposure Science and Environmental Epidemiology (2007) 17, 400–407; doi:10.1038/sj.jes.7500535; published online 18 October 2006.

[4] Blount, et al.; Urinary Perchlorate and Thyroid Hormone Levels in Adolescent and Adult Men and Women Living in the United States; Environmental Health Perspectives Volume 114, Number 12, December 2006.

While science increasingly raises health concerns about perchlorate, EPA has not issued a drinking water standard for perchlorate and has ended monitoring requirements for perchlorate in drinking water, stating that the agency believed that it had adequate monitoring data. In February 2005, EPA issued perchlorate drinking water guidance of 24.5 parts per billion that failed to account for perchlorate exposures from food and water combined, and the guidance failed to lower levels of allowed exposure to account for childhood exposures or non-drinking water exposures. In August 2006, EPA issued perchlorate cleanup guidance, which EPA's Children's Health Protection Advisory Committee stated "is not protective of children's health."

In 2007, EPA decided not to begin the process to regulate perchlorate in public drinking water, and said it would review new scientific information and make a final determination at a later date. The Agency said that it expected to make an initial determination of whether to regulate perchlorate in drinking water in 2008.

NEED FOR LEGISLATION

EPA has known about perchlorate's health risks since before 2002. Scientific studies since that time have demonstrated that perchlorate contamination of drinking water and food sources is widespread, and that current levels of exposure in some areas are sufficient to affect the hormone system of vulnerable persons.

In the face of this scientific information, states have taken action, including California and Massachusetts, to create perchlorate drinking water standards; EPA has not taken action and has eliminated its perchlorate monitoring requirements.

S. 150 will help to protect vulnerable persons, including pregnant women, infants, children, and others in our country from dangerous perchlorate exposures. It will also ensure that the public is fully informed about perchlorate exposures and the potential health effects from such exposures. These are common sense and long-overdue actions needed to protect public health.

SUMMARY OF MAJOR PROVISIONS OF THE BILL

The purpose of S. 150, the Protecting Pregnant Women and Children from Perchlorate Act of 2008, is to require a health advisory and national primary drinking water regulation for perchlorate. The bill would also require EPA to create a public health advisory for perchlorate that is fully protective, with an adequate margin of safety, of the health of vulnerable persons, including pregnant women, infants, and children, taking into consideration body weight, exposure patterns and all routes of exposure.

S. 150 would also require the EPA to propose a national primary drinking water regulation for perchlorate within 9 months of the date of enactment of S. 150, and to finalize a national primary drinking water standard for perchlorate within 18 months of the date of enactment. The proposed and final standards must be protective, with an adequate margin of safety, of the health of vulnerable persons, including pregnant women, infants, and children, taking into consideration body weight, exposure patterns and all routes of exposure. The standard must establish a maximum contaminant level which is as close to the maximum contaminant goal

for perchlorate, and as protective of vulnerable persons, as is feasible. Regulation of perchlorate under the Safe Drinking Water Act would also apply all of the Act's other safeguards, including monitoring and public right-to-know protections, to drinking water supplies.

SECTION-BY-SECTION ANALYSIS

Section 1. Short title

Section 1 establishes the short title of the Act as the "Protecting Pregnant Women and Children from Perchlorate Act of 2008".

Section 2. Findings

This section contains findings related to perchlorate contamination and health effects.

Section 3. Monitoring and health advisory for perchlorate

Section 3 amends section 1412 of the Safe Drinking Water Act by requiring EPA to create a health advisory and national primary drinking water regulation for perchlorate, a health advisory for perchlorate that is fully protective, with an adequate margin of safety, of the health of vulnerable persons, including pregnant women, infants, and children, taking into consideration body weight, exposure patterns and all routes of exposure.

The section requires that EPA propose a national primary drinking water regulation for perchlorate within 9 months of the date of enactment of S. 150, and finalizes a national primary drinking water standard for perchlorate within 18 months of the date of enactment.

LEGISLATIVE HISTORY AND VOTES

VOTES

On July 31, 2008, the Committee on Environment and Public Works held a business meeting to consider Chairman Boxer's amendment in the nature of a substitute to S. 150. The Committee favorably adopted the Boxer substitute by voice vote, with Senators Inhofe, Craig, and Alexander going on record as opposing passage of the bill.

On May 6, 2008, the Committee held a legislative hearing titled, "Perchlorate and TCE in Drinking Water". On April 29, 2008 the Committee held a hearing titled, "Oversight on EPA Toxic Chemicals Policies." On February 6, 2007, the Committee held a hearing titled, "Oversight on Recent EPA Decisions," at which perchlorate was discussed.

REGULATORY IMPACT STATEMENT

In compliance with section 11(b) of rule XXVI of the Standing Rules of the Senate, the committee notes that the Congressional Budget Office has found that it "cannot determine the nature or extent of possible regulations that would result from this bill, and consequently cannot determine whether the costs of the mandate in the bill would exceed the intergovernmental threshold established in UMRA. . . ." In addition, CBO found that "because most of the water systems owned by private entities are small, CBO esti-

mates that in any one year the costs to comply with the mandate would fall below the threshold established for private-sector entities ($136 million in 2008, adjusted annually for inflation).''

MANDATES ASSESSMENT

In compliance with the Unfunded Mandates Reform Act of 1995 (Public Law 104–4), the Committee notes that the Congressional Budget Office has said that it ''cannot determine the nature or extent of possible regulations that would result from this bill and consequently cannot determine whether the costs of the mandate in the bill would exceed the intergovernmental threshold established in UMRA ($68 million in 2008, adjusted annually for inflation). Because most of the water systems owned by private entities are small, CBO estimates that in any one year the costs to comply with the mandate would fall below the threshold established for private-sector entities ($136 million in 2008, adjusted annually for inflation).''

S. 150—Protecting Pregnant Women and Children from Perchlorate Act of 2008

S. 150 would require the Environmental Protection Agency (EPA), no later than 90 days after the bill's enactment, to issue a health advisory for perchlorate in drinking water that fully protects susceptible populations, including pregnant women, infants, and children. (Perchlorate is a chemical used in rocket fuel.) EPA also would be required under this legislation to establish a final regulation governing the amount of perchlorate that is permissible in drinking water.

Based on information from EPA, CBO estimates that enacting S. 150 would cost about $4 million over the 2009–2011 period, subject to the availability of appropriations. That funding would be used to support about 10 additional personnel as well as contractor costs to meet the requirements of this legislation.

Enacting the legislation would not affect direct spending or revenues.

By requiring EPA to establish and enforce a drinking water regulation for perchlorate, S. 150 would impose an intergovernmental and private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA). The mandate would require operators of public water systems to monitor for the presence of perchlorate and to decrease its presence in water supplies. CBO cannot determine the nature or extent of possible regulations that would result from this bill and consequently cannot determine whether the costs of the mandate in the bill would exceed the intergovernmental threshold established in UMRA ($68 million in 2008, adjusted annually for inflation). Because most of the water systems owned by private entities are small, CBO estimates that in any one year the costs to comply with the mandate would fall below the threshold established for private-sector entities ($136 million in 2008, adjusted annually for inflation).

The total cost of the intergovernmental mandate would depend on the level of perchlorate allowed by the regulation, which would affect the number of water systems that need to comply and the resulting monitoring and construction costs faced by operators of those systems. Over 40,000 public systems would be subject to new

monitoring requirements once EPA establishes a regulation. Those monitoring costs could total about $5 million annually in the first three years the regulation would be effective, but those costs could decrease significantly in subsequent years.

Total construction costs to install equipment or build new treatment facilities could be significant but would vary substantially depending on the number and size of water systems that would need to treat for perchlorate. Annual costs for construction also would depend on how long EPA allows for such activities. Based on discussions with industry sources and information from states and EPA officials, CBO expects that total construction costs could range from less than $30 million to more than $80 million annually over a 3–5-year period once the regulation is effective. The annual costs would depend in part on how long operators would be given to complete construction.

The CBO staff contacts for this estimate are Susanne S. Mehlman (for federal costs), Burke Doherty (for the state and local impact), and Amy Petz (for the private-sector impact). This estimate was approved by Theresa Gullo, Deputy Assistant Director for Budget Analysis.

MINORITY VIEWS

Safe and affordable drinking water is a critical component for healthy and economically prosperous communities. The Safe Drinking Water Act is the legal authority for the Environmental Protection Agency (EPA) to ensure that Americans continue to receive the safest water in the world for consumption and also adequately address new drinking water contaminants and concerns. The Safe Drinking Water Act provides significant opportunity for transparent scientific review and processes for regulatory determinations. S. 150, the Protecting Pregnant Women and Children from Perchlorate Act of 2007, disregards scientific review, critical drinking water act processes, and is misleading in the bill's findings. For these reasons, we oppose this legislation.

The bill's findings are disingenuous and ignore several important facts. The findings strongly suggest the Department of Defense (DOD) and industry are responsible for any perchlorate found in water. Research by the Center for Disease Control (CDC) and others indicates that perchlorate is found as a naturally occurring substance and shows up in many areas around the country, even where there is no, and never has been, a DOD or industrial presence. Further, a recent collaborative effort in California found that 100% of DOD sites pose "No Threat" to drinking water.

Naturally occurring perchlorate has been found in large quantities in West Texas and from unknown sources in Hills, Iowa. Perchlorate doesn't only appear in water, but is also commonly found in the food supply. A recent Food and Drug Administration (FDA) study found that when people with diets high in perchlorate were tested, the sensitive subpopulations were below the reference dose established by the National Academies of Science (NAS). The study included sampling populations that had high levels of perchlorate in their drinking water.

The Environmental Protection Agency (EPA) knows of 160 drinking water systems in 26 states with perchlorate levels of at least 4 ppb. EPA states: "There are approximately 156,000 public drinking water systems," and "perchlorate was detected at levels above the minimum reporting level of 4 parts per billion (ppb) in approximately 2 percent of the more than 34,000 samples analyzed." Those numbers are very similar to the findings in a 2005 GAO report.

The findings dismiss the National Academy of Sciences' recommended daily dosage of perchlorate. The NAS reference dose of 24.5 parts per billion (ppb) is fully protective of the most sensitive subpopulations and is very conservative as it uses a precursor to an adverse health effect as a jumping off point. In 2005, a panel of the National Academy of Sciences (NAS) concluded that perchlorate caused no observable health effects, adverse or otherwise, at levels as high as 0.007 mg/kg/day, equivalent to drinking water levels of 245 parts per billion (ppb). To ensure an adequate margin

of safety for even potentially vulnerable subpopulations (e.g., pregnant and nursing mothers and their children) the NAS panel applied a ten-fold safety factor, resulting in a perchlorate Reference Dose of 0.0007 mg/kg/day, equivalent to a drinking water level of 24.5 ppb.

The CDC does not suggest that people in the United States are suffering health consequences at doses lower than the current EPA reference dose of 24.5 ppb. The underlying bill's findings do not take into account new and ongoing studies of perchlorate. Additional work is needed to determine whether some unknown factor associated with perchlorate exposure might be the cause of the observed changes in thyroid function. In addition, the EPA's Children's Health Protection Advisory Committee's (CHPAC) August 2006 statement referenced in the committee report is not fully inclusive of all current scientific findings available. For instance, the CHPAC statement was unable to consider the 2007 findings of a study that measured perchlorate and iodine levels in the milk of 57 lactating Boston-area women. No correlation was found between breast milk perchlorate and iodine levels. Additionally, the lack of correlation between breast milk perchlorate and iodine levels seemingly corroborates the Chilean findings which were unfortunately discounted in the CHPAC letter.

According to Jonathan Borak (MD, FACP, FACOEM) Clinical Professor of Epidemiology and Public Health at Yale School of Medicine, "The ongoing public debate about environmental perchlorate exposure has led to misstatements and misinterpretations of the relevant scientific findings. The current state of knowledge should be clear. There is no evidence of excessive perchlorate in the U.S. diet and little likelihood that routine perchlorate ingestion would exceed the EPA and NAS Reference Dose. There is no evidence that perchlorate is a human carcinogen. There is evidence that the U.S. diet contains sufficient iodine, and sufficient iodine intake is protective against effects that might result from perchlorate excess."

The Environmental Protection Agency has the legal authority to regulate perchlorate in public water systems if " . . . the contaminant may have an adverse effect on the health of persons; 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; and 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 [Section 1412(b)(1)(A)(i)–(iii) of the Safe Drinking Water Act]." Currently, EPA is weighing the various scientific studies that have been released as late as January of this year in accordance with the Safe Drinking Water Act requirements to determine whether regulating perchlorate in drinking water is warranted. Congress should not undermine the sanctity of the Safe Drinking Water Act by politicizing and predetermining outcomes prior to the completion of the scientific review process. The Safe Drinking Water Act procedures were enacted to discontinue this type of Congressional intervention and require EPA to base rules and regulations on science, not individual members' political gains.

LARRY E. CRAIG.
JAMES M. INHOFE.

CHANGES IN EXISTING LAW

In compliance with section 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by the bill as reported are shown as follows: Existing law proposed to be omitted is enclosed in **[**black brackets**]**, new matter is printed in italic, existing law in which no change is proposed is shown in roman:

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SAFETY OF PUBLIC WATER SYSTEMS (SAFE DRINKING WATER ACT)

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SEC. 1400. This title may be cited as the "Safe Drinking Water Act".

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SEC. 1412. (a)(1) Effective on the enactment of the Safe Drinking Water Act Amendments of 1986, each national interim or revised primary drinking water regulation promulgated under this section before such enactment shall be deemed to be a national primary drinking water regulation under subsection (b). No such regulation shall be required to comply with the standards set forth in subsection (b)(4) unless such regulation is amended to establish a different maximum contaminant level after the enactment of such amendments.

(2) * * *

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(b) STANDARDS.—

(1) IDENTIFICATION OF CONTAMINANTS FOR LISTING.—

(A) GENERAL AUTHORITY.—* * *

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(12) CERTAIN CONTAMINANTS.—

(A) ARSENIC.—

(i) SCHEDULE AND STANDARD.—* * *

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(C) PERCHLORATE.—

(i) HEALTH ADVISORY.—Notwithstanding any other provision of this section, not later than 90 days after the date of enactment of this subparagraph, the Administrator shall publish a health advisory for perchlorate that is fully protective, with an adequate margin of safety, of the health of vulnerable persons (including pregnant women, infants, and children), taking into consideration body weight, exposure patterns, and all routes of exposure.

(ii) PROPOSED REGULATIONS.—Notwithstanding any other provision of this section, the Administrator shall propose (within 9 months of the date of enactment of this subparagraph) and shall finalize (within 18 months of the date of enactment) a national primary drinking water regulation for perchlorate—

(I) that based on the factors in clause (i) and other relevant data, is protective, with an adequate margin of safety, of vulnerable persons (including pregnant women, infants, and children); and

(II) the maximum contaminant level of which is as close to the maximum contaminant level goal for perchlorate, and as protective of vulnerable persons, as is feasible.

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