

(2) A quorum consists of five members.

* * * * *

Dated: February 2, 2011.

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Dated: January 18, 2011.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[EPA–HQ–OW–2008–0692, EPA–HQ–OW–2009–0297; FRL–9262–8]

RIN 2040–AF08

Drinking Water: Regulatory Determination on Perchlorate

AGENCY: Environmental Protection Agency (EPA).

ACTION: Regulatory determination.

SUMMARY: This action presents EPA's (or the Agency's) regulatory determination for perchlorate in accordance with the Safe Drinking Water Act (SDWA). Specifically, EPA has determined that perchlorate meets SDWA's criteria for regulating a contaminant—that is, perchlorate may have an adverse effect on the health of persons; perchlorate is known to occur or there is a substantial likelihood that perchlorate 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 perchlorate in drinking water systems presents a meaningful opportunity for health risk reduction for persons served by public water systems. Therefore, EPA will initiate the process of proposing a national primary drinking water regulation (NPDWR) for perchlorate.

DATES: For purposes of judicial review, the regulatory determination is issued as of February 11, 2011, as provided in 40 CFR 23.7.

ADDRESSES: EPA has established dockets for this action under Docket ID numbers EPA–HQ–OW–2008–0692 and EPA–HQ–OW–2009–0297. All documents in these dockets are listed on the <http://www.regulations.gov> Web site. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material,

is not placed on the Internet, but will be publicly available in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the Water Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–2426.

FOR FURTHER INFORMATION CONTACT: Eric Burneson, Office of Ground Water and Drinking Water, Standards and Risk Management Division, at (202) 564–5250 or e-mail burneson.eric@epa.gov. For general information contact the EPA Safe Drinking Water Hotline at (800) 426–4791 or e-mail: hotline-sdwa@epa.gov.

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Abbreviations and Acronyms

CBI—confidential business information
 CCL—Contaminant Candidate List
 EPA—U.S. Environmental Protection Agency
 FR—Federal Register
 HRL—health reference level
 kg—kilogram
 L—liter
 MCL—maximum contaminant level
 MRL—Minimum Reporting Limit

NOEL—no observed effect level
 NPDWR—National Primary Drinking Water Regulation
 NRC—National Research Council
 PBPK—Physiologically-Based Pharmacokinetic
 PWS—public water system
 RfD—reference dose
 SDWA—Safe Drinking Water Act
 UCMR—Unregulated Contaminant Monitoring Rule
 µg—microgram (one-millionth of a gram)
 U.S.—United States

I. General Information

Does this action impose any requirements on my public water system?

Today's action notifies interested parties of EPA's determination to regulate perchlorate, but imposes no requirements on public water systems (PWSs). However, this action also initiates the process to develop a national primary drinking water regulation (NPDWR) for perchlorate. At such time as the Agency establishes an NPDWR, certain PWSs will be required to take action to comply with the regulation in accordance with the schedule specified in the regulation.

II. Background

A. What is the purpose of this action?

The purpose of today's action is to present EPA's final determination to regulate perchlorate in drinking water, the rationale EPA used to make this regulatory determination, and EPA's response to certain key issues raised by commenters on previous **Federal Register** (FR) notices on the drinking water regulatory determination for perchlorate. (All comments are addressed in a Response to Comments document that is available in EPA's docket ID No. EPA–HQ–OW–2009–0297 for this regulatory determination.)

B. Background on Perchlorate Regulatory Determinations

The statutory and regulatory background for this action is described in detail in the October 10, 2008, FR notice discussing EPA's preliminary regulatory determination for perchlorate (73 FR 60262; USEPA 2008a). Briefly, SDWA section 1412(b)(1)(A), as amended in 1996, requires EPA to make a determination whether to regulate at least five contaminants from its Contaminant Candidate List (CCL) every five years. To regulate a contaminant in drinking water, EPA must determine that it meets three criteria: (1) The contaminant may have an adverse effect on the health of persons; (2) 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 (3) 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. Once EPA makes a determination to regulate a contaminant in drinking water, SDWA requires that EPA issue a proposed NPDWR within 24 months and a final NPDWR within 18 months of proposal.

EPA included perchlorate on the first, second, and third CCLs that were published in the **Federal Register** on March 2, 1998 (63 FR 10273; USEPA 1998), February 24, 2005 (70 FR 9071; USEPA 2005a), and October 8, 2009 (74 FR 51850; USEPA 2009a), respectively. On May 1, 2007, EPA published an update on the Agency's evaluation of perchlorate as part of the preliminary regulatory determination for 11 other CCL 2 contaminants (72 FR 24016; USEPA 2007). The Agency did not make a preliminary determination for perchlorate as part of this regulatory determination, but requested public comment on the options that the Agency was evaluating for perchlorate and requested information that could assist the Agency in its regulatory determination. EPA received eight comment letters in response to the May 2007 document (72 FR 24016; USEPA 2007) that addressed perchlorate. Public comments on the May 2007 document can be found online at <http://www.regulations.gov> (Docket ID No. EPA-HQ-OW-2007-0068).

On October 10, 2008, EPA published a preliminary regulatory determination for perchlorate (73 FR 60262; USEPA 2008a), requesting public comment on its determination that perchlorate did not occur with a frequency and at levels of public health concern and regulation of perchlorate did not present a meaningful opportunity for health risk reduction for persons served by public water systems (the second and third criteria for regulating a contaminant under SDWA). The October 2008 notice describes in detail EPA's basis for its preliminary determination not to develop an NPDWR for perchlorate (73 FR 60262; USEPA 2008a). The Agency received nearly 33,000 comment letters on the October 2008 notice. Public comments on the October 2008 notice and supporting materials are available electronically at <http://www.regulations.gov> (Docket ID No. EPA-HQ-OW-2008-0692).

On August 19, 2009, EPA published the *Perchlorate Supplemental Request for Comments* (74 FR 41883; USEPA 2009b) requesting comment on

additional approaches to analyzing data related to EPA's perchlorate regulatory determination. These additional comments were sought in an effort to ensure consideration of all potential options for evaluating whether there is a meaningful opportunity for human health risk reduction of perchlorate through a NPDWR. EPA stated that the alternative analyses presented in this notice could lead the Agency to make a determination to regulate perchlorate. EPA received over 6,000 comments on the August 2009 notice.

EPA has evaluated the approximately 39,000 public comments received on the May 2007 document, the October 2008 notice, and August 2009 notice. EPA has prepared a response to comment document that addresses the comments related to the perchlorate regulatory determination (USEPA, 2010a). This response to public comment document, the public comments on the August 2009 notice, and supporting materials are available electronically at <http://www.regulations.gov> (Docket ID No. EPA-HQ-OW-2009-0297).

C. What is EPA's final regulatory determination on perchlorate and what happens next?

After careful review and consideration of public comments on the May 2007, October 2008, and August 2009 notices, the Agency has made a determination to regulate perchlorate in drinking water. EPA has found that perchlorate may have an adverse effect on human health. EPA has reversed its October 2008 preliminary determination not to develop an NPDWR for perchlorate and now concludes, based on the analysis presented in this regulatory determination, that there is a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern. Finally, EPA has determined that regulation of perchlorate presents a meaningful opportunity to reduce health risk for persons served by public water systems.

EPA is initiating the development of a proposed NPDWR for perchlorate. EPA intends to publish a proposed regulation and analyses required by SDWA for public review and comment within 24 months of this regulatory determination. EPA will consider the public comments and expects to promulgate a final regulation within 18 months of the proposal.

III. Final Regulatory Determination for Perchlorate

In making final regulatory determinations, EPA uses the criteria

mandated by the 1996 SDWA Amendments. Specifically, EPA has found that perchlorate may have an adverse effect on the health of persons, that perchlorate occurs or there is a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern, and that regulation of perchlorate in drinking water systems presents a meaningful opportunity for health risk reduction for persons served by public water systems.

A. May perchlorate have an adverse effect on the health of persons?

Yes. The perchlorate anion is biologically significant specifically with respect to the functioning of the thyroid gland. Perchlorate can interfere with the normal functioning of the thyroid gland by inhibiting the transport of iodide into the thyroid, resulting in a deficiency of iodide in the thyroid. Perchlorate inhibits (or blocks) iodide transport into the thyroid by chemically competing with iodide, which has a similar shape and electric charge. The transfer of iodide from the blood into the thyroid is an essential step in the synthesis of thyroid hormones. The 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 (NRC, 2005). Additionally, deficiency during childhood reduces child growth and cognitive motor function (Zimmerman, 2009). Therefore, EPA finds that perchlorate may have an adverse effect on the health of persons.

B. Is perchlorate known to occur or is there a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern?

Yes. EPA has determined that perchlorate occurs or there is a substantial likelihood that perchlorate will occur with a frequency and at

levels of health concern in public water systems. EPA has made this determination by comparing the best available data on the occurrence of perchlorate in PWSs to potential health reference levels (HRLs) for perchlorate. HRLs are not final determinations about the level of a contaminant in drinking water that is necessary to protect any particular population. Rather they are benchmarks against which EPA compares the concentration of a contaminant found in public water systems to determine if it is at levels of public health concern.

In January 2005, the National Research Council (NRC) published "Health Implications of Perchlorate Ingestion," a review of the state of the science regarding potential adverse health effects of perchlorate exposure and mode of action for perchlorate toxicity (NRC, 2005). The NRC recommended that EPA use data from the Greer *et al.* (2002) human clinical study as the basis for deriving a reference dose for perchlorate (NRC, 2005). Although the NRC committee concluded that hypothyroidism is the first adverse effect in the continuum of effects of perchlorate exposure, NRC recommended that "the most health-protective and scientifically valid approach" was to base the perchlorate RfD on the inhibition of iodide uptake by the thyroid, which the NRC considered a non-adverse effect (NRC, 2005). The NRC recommended that EPA apply an intraspecies uncertainty factor of 10 to the no observed effect level (NOEL),¹ to account for differences in sensitivity between the healthy adults in the Greer *et al.*, (2002) study and the most sensitive population, fetuses of pregnant women who might have hypothyroidism or iodide deficiency.

They viewed this as conservative and protective of health given that the NOEL is based on a non-adverse effect (iodide uptake inhibition), which precedes the adverse effect in a continuum of possible effects of perchlorate exposure. The NRC also noted that "any decrease (in thyroid hormone) is potentially more likely to have adverse effects in sensitive populations (people with thyroid disorders, pregnant women, fetuses, and infants). EPA's Integrated Risk Information System (IRIS) adopted the NRC's recommendations resulting in an RfD of 0.7 µg/kg/day (USEPA, 2005b).

In the October 2008 preliminary regulatory determination, EPA had derived a single HRL of 15 µg/L based upon the RfD, an estimate of perchlorate exposure from food for pregnant women, and traditional adult body weight (70 kg) and drinking water consumption (2 L/day) values. This single HRL was derived to reflect exposure to a pregnant woman and her fetus, which the NRC identified as "the most sensitive population."

Since the NRC also identified infants and developing children as additional life stages, EPA derived potential alternative HRLs for 14 life stages (age groups) using the RfD and life stage-specific exposure information in the August 9, 2009, notice (74 FR 41883; USEPA 2009b). These levels range from 1 µg/L to 47 µg/L and are the 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. These HRLs are calculated based on individuals who consume an average amount of perchlorate from food (except for pregnant women where EPA used a

90th percentile dietary intake estimate), but who consume equal or more water on a per body weight basis than 90 percent of their cohorts. EPA is evaluating these potential alternative HRLs and considers them to be levels of public health concern for purposes of this determination. EPA has compared these values to the data provided by PWSs subject to the first Unregulated Contaminant Monitoring Rule (UCMR 1). EPA collected and analyzed drinking water occurrence data for perchlorate from 3,865 PWSs between 2001 and 2005 under the UCMR 1. The minimum reporting level (MRL) for perchlorate under the UCMR 1 was 4 µg/L.

EPA found that 160 (approximately 4.1 percent) of the 3,865 PWSs that sampled and reported had at least 1 analytical detection of perchlorate (in at least 1 sampling point) at levels greater than or equal to the MRL of 4 µg/L. These 160 PWSs are located in 26 States and 2 territories. Of these 160 PWSs, 8 are systems serving 10,000 or fewer people and 152 are systems serving more than 10,000 people. These 160 systems reported 637 detections of perchlorate at levels greater than or equal to 4 µg/L, which is approximately 11.3 percent of the 5,629 samples collected by these 160 PWSs and approximately 1.9 percent of the 34,331 samples collected by all 3,865 PWSs. The average concentration of perchlorate for those samples with positive detections for perchlorate was 9.85 µg/L and the median concentration was 6.40 µg/L.

Table 1 presents the number and percentage of PWSs that reported perchlorate at levels exceeding various threshold concentrations. Note that the MRL for perchlorate under the UCMR 1 was 4 µg/L.

TABLE 1—PERCENT PUBLIC WATER SYSTEM ESTIMATES FOR PERCHLORATE ABOVE THRESHOLDS OF INTEREST

Threshold concentration ^a	PWSs with at least 1 detection > threshold of interest	PWS entry or sample points with at least 1 detection > threshold of interest ^b
4 µg/L	4.0% (155 of 3,865)	2.5% (371 of 14,987)
6 µg/L	2.5% (97 of 3,865)	1.5% (219 of 14,987)
9 µg/L	1.5% (56 of 3,865)	0.77% (115 of 14,987)
13 µg/L	0.93% (36 of 3,865)	0.37% (56 of 14,987)
14 µg/L	0.85% (33 of 3,865)	0.32% (48 of 14,987)
19 µg/L	0.62% (24 of 3,865)	0.20% (30 of 14,987)

¹ No observed effect level (NOEL)—an exposure level at which there are no statistically or

biologically significant increases in the frequency or

severity of any effect between the exposed population and its appropriate control.

TABLE 1—PERCENT PUBLIC WATER SYSTEM ESTIMATES FOR PERCHLORATE ABOVE THRESHOLDS OF INTEREST—
Continued

Threshold concentration ^a	PWSs with at least 1 detection > threshold of interest	PWS entry or sample points with at least 1 detection > threshold of interest ^b
23 µg/L	0.39% (15 of 3,865)	0.13% (19 of 14,987)

^aAll occurrence measures in this table were conducted on a basis reflecting values greater than the listed thresholds. Five systems detected perchlorate levels equal to 4 µg/L and are therefore not presented in this table.

Given the range of potential alternative HRLs, EPA has reversed its October 2008 preliminary determination not to regulate perchlorate in drinking water. Based on the data in Table 1 and the range of potential alternative HRLs, EPA has 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.

C. Is there a meaningful opportunity for the reduction of health risks from perchlorate for persons served by public water systems?

Yes. EPA has made this determination based on a consideration of the best available peer reviewed science and data collected in accordance with accepted methods related to perchlorate occurrence in drinking water, the presence of perchlorate in foods, and the potential health effects of exposure to perchlorate.

Table 2 presents EPA's estimates of the population served by PWSs that were monitored under UCMR 1 for which the highest reported perchlorate concentration was greater than the thresholds identified in Table 1. EPA has determined that a NPDWR for perchlorate could reduce perchlorate exposures for these populations to levels below the potential alternative HRLs that EPA has identified as levels of public health concerns for purposes of this determination, and that such exposure reductions present a meaningful opportunity for the reduction of health risks for persons served by PWSs.

Specifically, Table 2 presents EPA's estimates of the population served by PWSs that were monitored under UCMR 1 for which the highest reported perchlorate concentration was greater than the thresholds identified in Table 1. The second column of Table 2 presents a range of estimates of the population served by PWSs that had at least one sample with perchlorate concentrations greater than the threshold. The population range represents both a high end estimate, as well as a central value estimate. These

population estimates were derived using the UCMR 1 monitoring data. The high end estimate of the population served drinking water above a threshold is derived by adding the entire system population of all PWSs in which at least one sample was found to contain perchlorate above the threshold. EPA considers this a high end estimate because it is based on the assumption that the entire system population is served water from the entry point that had the highest reported perchlorate concentration. In fact, many PWSs have multiple entry points into which treated water is pumped for distribution to their consumers. For the PWSs with multiple entry points, it is unlikely that the entire service population receives water from the one entry point with the highest single concentration. Therefore, EPA also provides a central value estimate of the population served water with perchlorate above a threshold in the second column in Table 2. EPA developed this central value estimate by assuming the population was equally distributed among all entry points and added only the proportion of the total population served by those entry points in a PWS that had at least one sample with perchlorate concentrations greater than the threshold. For example, if a PWS with 10 entry points serving 200,000 people had a sample from a single entry point with a concentration at or above a given threshold, EPA assumed that the entry point served one-tenth of the PWS population, and added 20,000 people to the total when deriving the central value population estimate. In contrast, for the high end estimate using the example above, EPA added the entire PWS population of 200,000 to the total population. The latter is likely an overestimate. The UCMR 1 population estimates in Table 2 are for people at all life stages.

TABLE 2—POPULATION ESTIMATES FOR PWSs THAT DETECTED PERCHLORATE ABOVE VARIOUS THRESHOLDS

Threshold ^a	Range of population served by PWSs with at least 1 detection > threshold ^b (million)
4 µg/L	5.1–16.6
6 µg/L	3.0–11.8
9 µg/L	1.6–5.2
14 µg/L	0.9–2.1
19 µg/L	0.7–1.6
23 µg/L	0.4–1.0

^aAll occurrence measures in this table were conducted on a basis reflecting values greater than the listed thresholds. All population estimates in this table are rounded.

^bPopulation estimates are derived from UCMR 1 data.

D. Regulatory Determination

EPA has determined that perchlorate meets the criteria for regulating a contaminant in Section 1412(b)(1)(A) of SDWA. As previously discussed in this regulatory determination, perchlorate may have an adverse effect on the health of persons and perchlorate is known to occur or there is a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern. Moreover, in light of the discussion in this regulatory determination and the information available at this time, the Administrator finds that regulation of perchlorate in drinking water systems presents a meaningful opportunity for health risk reduction for persons served by public water systems. Therefore, EPA will initiate the process of proposing a NPDWR for perchlorate.

E. Key Commenter Issues

EPA received a total of approximately 39,000 comments from individuals or organizations on the May 2007 document, and the October 2008, and August 2009 **Federal Register** notices regarding the perchlorate regulatory determination. This section briefly discusses a number of the key issues raised by commenters and EPA's response to these concerns. Responses

to all of the comments received are available in the "Comment Response Document for the Final Regulatory Determination on Perchlorate" (USEPA, 2010a) available at <http://www.regulations.gov> (Docket ID No. EPA-HQ-OW-2009-0297).

1. Health Implications of Perchlorate Exposure Above the RfD

EPA received comments indicating that the levels of perchlorate in drinking water that result in exposures greater than the RfD are not levels of public health concern because the RfD is based on a precursor to an adverse effect. EPA believes the NRC appropriately based the RfD on iodide uptake inhibition to the thyroid, for the reasons discussed in its report. EPA also received a substantial number of comments supporting the Agency's current view. EPA notes that the data underlying the definition of iodide uptake inhibition as a precursor effect and the relationship of iodide uptake inhibition to the continuum of adverse outcomes reflects an understanding of effects in adults; it may not reflect the relationship of the precursor event to adverse outcomes in neonates and infants, who may not have iodide stores sufficient to offset the effects of reduced iodide uptake. The less resilient neonatal and infant system makes the exposure gap between a precursor event (iodide uptake inhibition due to perchlorate) and reduced T3/T4 levels likely to be narrower than for adults, and in fact, the distinction between the two may be blurred for the very young (Greer *et al.*, 2002; Savin *et al.*, 2003; van den Hove *et al.*, 1999). The NRC noted that, "[T]he minimal prolonged decrease in thyroid hormone production that would be associated with adverse health effects is not known; any decrease is potentially more likely to have adverse effects in sensitive populations (people with thyroid disorders, pregnant women, fetuses, and infants) but data are not available to determine the magnitude of the decrease needed to cause adverse effects in those populations."

2. Other Thyroid Inhibiting Chemicals

EPA received a number of comments that the Agency should consider the comparative effect on iodine uptake of perchlorate exposure in drinking water to nitrate and thiocyanate exposure in drinking water in determining whether there is a meaningful opportunity for risk reduction. Other commenters, including EPA's Office of Inspector General (USEPA, 2008c), believe that a NPDWR for a group of chemicals may be appropriate based on a yet-to-be-conducted cumulative risk assessment

that assesses and characterizes the combined human health risk from perchlorate, nitrate, and thiocyanate.

While EPA acknowledges that nitrate and thiocyanate have the same mode of action as perchlorate, and that the effects of combined exposure to perchlorate, nitrate, and thiocyanate are additive, EPA does not believe there are sufficient scientific data currently available to assess and characterize the combined risk of these contaminants. EPA has committed to a drinking water strategy that outlines four principles to expand public health protection for drinking water (USEPA, 2010b). One of these principles is to address contaminants as groups. However, EPA does not believe that regulatory action to address perchlorate should be further delayed. Therefore, EPA intends to develop a proposed rule for perchlorate. At such time as a NPDWR is promulgated, EPA is required to review and revise, as appropriate, its drinking water standards at least every six years. Any revision must at least maintain or improve public health protection. When there are sufficient scientific data to assess the cumulative risks of perchlorate and other contaminants, EPA will review this information to evaluate whether any revisions of NPDWRs are appropriate.

3. Perchlorate in Food

A commenter wrote that a drinking water regulation for perchlorate does not present a meaningful opportunity for health risk reduction because perchlorate contamination in food is widespread. Other commenters indicated that EPA should regulate perchlorate in drinking water to reduce the public's overall exposure to perchlorate. EPA agrees that perchlorate contamination is more widespread in foods than in PWSs; however, EPA does not believe that the widespread presence of perchlorate in food overrides the need for public health risk reduction for persons served by PWSs with perchlorate contamination. The Agency presented an extensive evaluation of dietary exposure to perchlorate in the October 2008 and August 2009 notices (73 FR 60262; USEPA 2008a and 74 FR 41883; USEPA 2009b). EPA has used this dietary exposure data to account for the relative source contribution (RSC) of perchlorate from food to estimate the range of levels of public health concern. EPA recognizes that a drinking water regulation would not eliminate total perchlorate exposure, but believes that the reduction in perchlorate exposure in drinking water presents a meaningful opportunity for health risk reduction for

persons served by PWSs contaminated by perchlorate.

4. Iodide Nutritional Status

Some commenters stated that public health concerns over iodide uptake inhibition could be addressed more efficiently through promotion of iodide nutrition than through regulation of perchlorate. EPA agrees that promoting iodide nutrition is good public health policy and may have a positive influence in reducing the iodide uptake inhibition effects associated with exposure to perchlorate. However, the Agency does not think it is appropriate to rely on the promotion of iodide nutrition in this case, especially since these activities are outside of EPA's SDWA authority. As a result, while the health concerns associated with perchlorate may be addressed through other means, it is the Administrator's judgment that a standard limiting perchlorate in drinking water can reduce health risk, particularly to fetuses, infants and children.

5. Physiologically-Based Pharmacokinetic (PBPK) Modeling

EPA reviewed, modified, and applied the perchlorate PBPK models, which were originally developed by Merrill *et al.* (2005) for adults and Clewell *et al.* (2007) for other life stages, to estimate the iodide uptake inhibition in the thyroid for each life-stage (73 FR 60262; USEPA 2008a). Estimated ingestion rates were then used to estimate the internal dose and resulting iodide uptake inhibition for several life stages, including susceptible populations (*e.g.*, pregnant women and their fetuses, as well as breast-fed and bottle-fed infants).

In the August 2009 notice, EPA stated that it was re-evaluating how best to incorporate the PBPK modeling analysis into its evaluation of perchlorate—if at all. The Agency sought comments on ways to use the PBPK modeling analysis to inform the regulatory determination.

Several commenters supported the use of the PBPK model to inform the regulatory determination only if the significant limitations of the current model are addressed. For example, the inability of the model to reflect iodide nutritional status was cited by commenters and three of four peer reviewers as an important limitation (USEPA, 2008d). Also, several commenters stated that the risks to breast-fed infants and young children are not adequately addressed by the model. They challenged that the modeling analysis is based on average weight infants and healthy adults, while the sensitive life stages for perchlorate

include premature infants and hypothyroid women.

After further consideration of the peer review and public comments, EPA concludes that the PBPK modeling analysis, in the context of the perchlorate regulatory determination, is useful in examining which life stages are most susceptible to the effects of perchlorate. For example, the model indicates that a fetus may be seven times more sensitive to the effects of perchlorate than a pregnant woman. The model also allows for the estimation of the concentration of perchlorate in breast milk (thus breast-fed infant exposure) at various maternal perchlorate exposure levels. However, because of the stated limitations, EPA has decided the model does not directly bear on the current decision regarding the need for a NPDWR for perchlorate. EPA is continuing to evaluate whether the model could be used in setting a NPDWR for perchlorate.

F. Next Steps

EPA is initiating the development of a proposed NPDWR for perchlorate. However, this is not the end of a decision process but a middle step in a process that leads to a final drinking water standard. Based on this decision, EPA intends to publish a proposed NPDWR for public review and comment within 24 months of this regulatory determination.² EPA will continue to evaluate the science as we develop the proposed NPDWR. EPA will, as part of the proposed NPDWR, present a health risk reduction and cost analyses, an analysis of feasible treatment methods, and an analysis of small system compliance technologies. EPA will also consult with the National Drinking Water Advisory Council, the Science Advisory Board, and the Secretary of Health and Human Services, as required under SDWA.

IV. References

Clewell, R.A., E.A. Merrill, J.M. Gearhart, P.J. Robinson, T.R. Sterner, D.R. Mattie, and H.J. Clewell, III. 2007. Perchlorate and radioiodide kinetics across life stages in the human: Using PBPK models to predict dosimetry and thyroid inhibition and sensitive subpopulations based on developmental stage. *Journal of*

²On January 8, 2009, EPA issued an interim health advisory to provide guidance to State and local officials in their efforts to address perchlorate contamination. The interim health advisory (USEPA, 2008e) can be found at: http://www.epa.gov/safewater/contaminants/unregulated/pdfs/healthadvisory_perchlorate_interim.pdf and in EPA's docket ID No. EPA-HQ-OW-2009-0297 for this notice. EPA expects to make a final decision on the interim health advisory at such time as a definitive decision has been made with respect to the promulgation of a final perchlorate regulation.

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Lisa P. Jackson,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 144 and 147

[CMS–9981–P]

RIN 0950–AA20

Student Health Insurance Coverage

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This document contains a proposed regulation that would establish rules for student health insurance coverage under the Public Health Service Act and the Affordable Care Act. The proposed rule would define “student health insurance