

GAO

Testimony

Before the Committee on Environment
and Public Works, U.S. Senate

For Release on Delivery
Expected at 10:00 a.m. EDT
Tuesday, July 12, 2011

SAFE DRINKING WATER ACT

Improvements in Implementation Are Needed to Better Assure the Public of Safe Drinking Water

Statement of David C. Trimble, Director
Natural Resources and Environment

U.S. Government Accountability Office

GAO 90

YEARS

1921-2011

ACCOUNTABILITY ★ INTEGRITY ★ RELIABILITY

Madam Chairman Boxer, Ranking Member Inhofe, and Members of the Committee:

I am pleased to be here today to discuss highlights of GAO's report on the Environmental Protection Agency's (EPA) implementation of requirements for determining whether additional drinking water contaminants warrant regulation. As you know, the number of potential drinking water contaminants is vast—as many as tens of thousands of chemicals may be used across the country, and EPA has identified more than 6,000 chemicals that it considers to be the most likely source of human or environmental exposure. The potential health effects of exposure to most of these chemicals, and the extent of their occurrence in drinking water, are unknown. Under 1996 amendments to the Safe Drinking Water Act, every 5 years EPA is to determine for at least five contaminants whether regulation is warranted, considering those that present the greatest public health concern. EPA issued final regulatory determinations in 2003 and 2008 on a total of 20 contaminants, deciding in each case not to regulate. In fact, EPA did not recommend any new contaminants for regulation until February 2011, when it reversed its controversial 2008 preliminary decision to not regulate perchlorate, an ingredient in rocket fuel and other products.

This statement summarizes our report being released today that (1) evaluates the extent to which EPA's implementation of the 1996 amendments has helped assure the public of safe drinking water and (2) reviews the process and scientific analyses EPA used to develop the 2008 preliminary decision to not regulate perchlorate.¹ In preparing this testimony, we relied on our work supporting the accompanying report, which contains a detailed description of our scope and methodology. All of the work for this report was performed in accordance with generally accepted government auditing standards.

¹GAO, *Safe Drinking Water Act: EPA Should Improve Implementation of Requirements on Whether to Regulate Additional Contaminants*, [GAO-11-254](#) (Washington, D.C.: May 27, 2011).

**Systemic Limitations
in EPA’s
Implementation of
Requirements for
Determining Whether
to Regulate Additional
Contaminants Have
Impeded Progress in
Helping Assure the
Public of Safe
Drinking Water**

As detailed in our report, we found the following concerning the extent to which EPA’s implementation of the 1996 amendments has helped assure the public of safe drinking water.

**EPA Has Neither Identified
the Drinking Water
Contaminants of Greatest
Public Health Concern Nor
Fully Used Its Authority to
Obtain Data for Making
Regulatory Determinations**

EPA has not effectively implemented the 1996 amendments’ requirement to consider, for regulatory determinations, contaminants that present the greatest public health concern. The contaminant candidate list² that the amendments require EPA to develop every 5 years represents one level of prioritization as EPA selects from a larger universe those contaminants the agency believes warrant consideration for regulation. However, EPA officials told us that its Office of Water, which has primary responsibility for implementing the requirements of the Safe Drinking Water Act, has not (1) further ranked or otherwise prioritized the contaminants on the list on the basis of public health concern or (2) prioritized contaminants on the basis of public health concern when selecting them for regulatory determinations. In fact, for 16 of the 20 regulatory determinations made through January 2011, EPA based its decisions to not regulate on its assessment that public exposure to these drinking water contaminants was minimal—that is, there was limited or no occurrence of them in public drinking water systems. An EPA official described these determinations as addressing the “low hanging fruit”—rather than the contaminants of greatest public health concern. Overall, data availability—not

²The 1996 amendments require that EPA identify and publish a list every 5 years of unregulated contaminants that may require regulation; the list is called the contaminant candidate list.

consideration of greatest public health concern—has been the primary driver of EPA’s selection of contaminants for regulatory determinations.

To assess unregulated contaminants against the statutory criteria, EPA needs sufficient information on both (1) the occurrence of these contaminants in drinking water—called occurrence data—to assess the population potentially being exposed and the levels of that exposure and (2) the human health effects that may result from exposure to the contaminants in drinking water. EPA has made some progress in developing the occurrence and health effects data it needs, but for many contaminants EPA lacks sufficient occurrence and health effects data to support regulatory determinations, which continues to limit its ability to make these decisions. Specifically, in finalizing its current candidate list comprising 116 contaminants, EPA indicated that the agency lacked sufficient occurrence or health effects data, or both, for making regulatory determinations for at least 100 of the contaminants. Moreover, in 2009 EPA’s Science Advisory Board recommended that the agency further prioritize among the contaminants on the candidate list because the list was too large, noting that prioritizing the contaminants on the list would help the agency meet its goal of selecting contaminants for regulatory determinations that “have the greatest opportunity to improve the safety of drinking water and protect public health.”

In addition, in its testing program for unregulated contaminants—which can provide key occurrence data to inform regulatory determinations—EPA has fallen short in both the number of contaminants tested and the utility of the data provided because of management decisions and program delays. For example, despite having the authority to require testing for up to 30 drinking water contaminants in each 5-year cycle, in implementing the first two cycles of the testing program, EPA required that only 51 contaminants be tested—thereby not availing itself of its authority to obtain occurrence data for 9 additional contaminants. Moreover, in some cases, the occurrence data EPA used to support its regulatory determinations were based on testing (analytic) methods that were not sufficiently sensitive to identify the presence of contaminants at EPA’s health reference level—the level that EPA uses in assessing whether to regulate specific contaminants.³ For 9 of the 20 contaminants

³The health reference level is the estimated level of exposure to a contaminant in drinking water below which adverse health effects are not likely.

for which EPA made regulatory determinations in 2003 and 2008, the minimum reporting level—the lowest level of a contaminant at which detections can be reported under testing protocols—exceeded EPA’s health reference level. For example, for dieldrin—an insecticide banned by EPA for all uses in 1987 because of concerns about harm to human health and its ability to persist in the environment for decades—the agency relied on testing data obtained using minimum reporting levels ranging from 10 to 2,200 times higher than EPA’s health reference level.⁴ EPA reported in its regulatory determination documents for dieldrin that it was detected in 0.06 percent of samples.⁵ However, in subsequent testing of source water for drinking water wells using more sensitive tests with minimum reporting levels near and below EPA’s health reference level, the U.S. Geological Survey (USGS) detected dieldrin in 3.1 percent of public well samples. Importantly, nearly all of USGS’s detections were at levels above EPA’s health reference level. USGS was able to detect dieldrin—and determine its presence above EPA’s level of public health concern—in these groundwater well samples because it used a lower minimum reporting level for its testing than EPA used for its regulatory determinations. This is significant because, as USGS has reported, when a reporting level exceeds a health benchmark, a contaminant may be present at a concentration greater than the health benchmark but remain undetected, resulting in greater uncertainty in evaluating the contaminant concentration in the context of public health. EPA’s testing program obtains data using minimum reporting levels that are often higher than those used by the USGS in its National Water Quality Assessment Program—ranging from 2 to more than 600 times higher.

In addition, the lack of timely health assessment data on drinking water contaminants continues to limit EPA’s ability to make regulatory determinations. As a result of long-standing productivity problems in EPA’s Integrated Risk Information System (IRIS) program—managed by the Office of Research and Development—EPA has not been able to keep its existing chemical toxicity assessments current or to complete

⁴EPA did not disclose that the data presented were not sufficiently sensitive to detect occurrence at the agency’s health reference level.

⁵In this testimony, as in our report, we refer to *Federal Register* notices regarding EPA’s regulatory determinations (notices) and EPA’s regulatory determination support documents individually and collectively, as appropriate. When referring to these documents collectively, we use the term “regulatory determination documents.”

assessments of the most important chemicals of concern.^{6, 7} For example, from 1998 through 2008, the Office of Water lacked current IRIS assessments⁸ or other sufficient health information for 24 chemical contaminants on the candidate lists, and the Office of Research and Development completed assessments for only 2 of the 24. Moreover, the Office of Water's current needs for health effects information for contaminants on the current candidate list have roughly doubled—when publishing the third candidate list in 2009, EPA identified health effects information gaps for 44 of the 104 chemicals on the list. Importantly, most of these contaminants with information gaps (1) are not on the IRIS agenda (i.e., assessments are neither under way nor planned) and (2) have not been identified by the Office of Water as priorities for IRIS assessments.

EPA Lacks Policies or Guidance on Applying the Broad Statutory Criteria for Selecting Contaminants for Regulatory Determinations and Making the Determinations

The Safe Drinking Water Act requires EPA to select contaminants for regulatory determinations that present the greatest public health concern. However, EPA has not defined the characteristics of contaminants of greatest public health concern or developed a process for prioritizing the contaminants on its candidate list for regulatory determination on this basis. As a result, EPA lacks criteria and a process for identifying those contaminants on its candidate list that pose the greatest public health concern.

Moreover, under the act, in selecting contaminants that present the greatest public health concern, EPA is to consider the effect of these contaminants on subpopulations at greater risk of adverse health effects from exposure to drinking water contaminants. In addition, EPA has

⁶See GAO, *Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System*, [GAO-08-440](#) (Washington, D.C.: Mar. 7, 2008).

⁷In January 2009 we added transforming EPA's processes for assessing and controlling toxic chemicals as a high-risk area in our report—updated in February 2011—on governmentwide high-risk areas requiring increased attention by executive agencies and Congress. See GAO, *High-Risk Series: An Update*, [GAO-09-271](#) (Washington, D.C.: January 2009); and *High Risk Series: An Update*, [GAO-11-278](#) (Washington, D.C.: February 2011).

⁸IRIS assessments provide EPA's toxicity assessments of contaminants that may cause cancer and those that may cause neurological or other noncancer effects, or both. EPA uses IRIS or comparable toxicity assessments to develop health reference levels for the drinking water contaminants.

stated that in making regulatory determinations, the act requires the agency to consider the effects the contaminants have on sensitive subpopulations, such as infants, children, those with kidney or liver diseases or weakened immune systems, and the elderly. Children, for example, represent a sensitive subpopulation because they may be more highly exposed to toxic substances in drinking water and at greater risk of adverse health effects than adults as a result of consuming more water per unit of body weight than adults. Children may also have increased susceptibility following exposure to drinking water contaminants because they continue to develop both behaviorally and physiologically throughout childhood. Furthermore, in 1995, EPA published its *Policy on Evaluating Health Risks to Children*, which states that the agency will “consider the risks to infants and children consistently and explicitly as a part of risk assessments generated during its decision making process,” and to “the degree permitted by available data in each case, the Agency will develop a separate assessment of risks to infants and children or state clearly why this is not done.” In 2006, EPA developed a general guidance document for all EPA program offices on implementing its 1995 children’s health policy, as well as several technical guidance documents that could help the Office of Water develop its own guidance specific to assessing the sensitivity of children to drinking water contaminants.

Notwithstanding the requirements of the Safe Drinking Water Act and EPA’s 1995 children’s health policy, the Office of Water did not implement a specific approach for considering children’s health in developing its 2003 and 2008 regulatory determinations. In addition, the Office of Water has not developed guidance for its staff on when and how to analyze the effects of drinking water contaminants on children—or other sensitive subpopulations—for the purposes of identifying the drinking water contaminants of greatest concern on which to make regulatory determinations and to ensure it consistently and explicitly considers risks to children in making these determinations, such as by developing separate health reference levels for children. While EPA identified children as a sensitive population in 11 of the 20 regulatory determinations it completed in 2003 and 2008, Office of Water officials confirmed that for these 20 determinations, EPA did not develop separate health reference levels for children or make adjustments to its health assessments.

The 1996 amendments also provide three broad criteria for EPA to use in making regulatory determinations, all of which must be met for EPA to determine that regulation is warranted. Notably, two of the criteria are so broadly stated that they could potentially be interpreted so as to lead to

regulating all of the contaminants on candidate lists, some of them, or none of them. Specifically, the second statutory criterion—that a 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”—is susceptible to varying interpretations. For example, different people may reasonably have differing views on the frequency and levels of occurrence that represent a public health concern. The third criterion—that regulation of the contaminant presents “in the sole judgment of the Administrator . . . a meaningful opportunity for health risk reduction”—is expressly discretionary, and similarly open to differing interpretations.

Importantly, the Office of Water has not developed policies or guidance to help EPA staff apply these broad criteria. Guidance that might help EPA staff apply the criteria transparently and consistently could, among other things, (1) define or set thresholds or parameters for assessing whether a contaminant occurs, or is substantially likely to occur, in public water systems with a frequency and at levels of public health concern and (2) provide factors or characteristics of situations that would present meaningful opportunities for health risk reduction. We note that such guidance could also serve as the basis for an internal review mechanism to help EPA ensure consistent implementation of the statutory criteria. Office of Water officials could not describe examples of what would meet the three criteria beyond stating that “there are no bright lines” and that they would “know it when we see it.” Without clarifying guidance, EPA’s regulatory determinations lack transparency, and EPA is at risk of making inconsistent determinations, undermining the program’s credibility and the agency’s ability to assure the public of safe drinking water.

In the absence of regulations or guidance for applying the broad statutory criteria, EPA appears to apply an informal policy that contaminants warranting regulation should occur in public water systems on a “national” scale. For example, documents supporting EPA’s 2003 regulatory determinations state that the consideration of geographic distribution “is important because the agency is charged with developing national regulations, and it may not be appropriate to develop [national primary drinking water regulations] for regional or local contamination problems.” In addition, some EPA officials serving on regulatory determination work groups told us that a contaminant must occur “nationally” to warrant a determination to regulate. Notably, however, the Safe Drinking Water Act does not require that contaminants be found in public water systems on a national basis for an Administrator to find a meaningful opportunity for health risk reduction. In fact, other parts of the statute provide for relief

from monitoring and flexibilities for instances in which a contaminant occurs in certain areas but not in others. Moreover, there is nothing in the act's committee reports suggesting that a contaminant need occur nationally to support a decision to regulate. Without EPA guidance providing a definition or parameters, an informal "national occurrence" standard is open to shifting interpretations, potentially affecting the consistency and credibility of EPA's decision making. To the extent EPA is informally applying an unspecified national occurrence requirement for contaminants to be evaluated as occurring "with a frequency and at levels of public health concern," EPA is implementing a critical policy and interpretation of the Safe Drinking Water Act that has neither been defined nor subjected to public review.

Further, regarding the third statutory criterion, EPA has not articulated guidelines or thresholds for how it is to assess whether regulating a specific contaminant would provide a meaningful opportunity for health risk reduction. The absence of guidelines on what scenario or scenarios might illustrate "a meaningful opportunity for health risk reduction" increases the potential for inconsistent decision making and reduces the decisions' transparency.

In addition, EPA has not developed any guidance on the circumstances that would trigger a re-evaluation of a prior decision to not regulate or the process the agency would use in conducting a re-evaluation. In at least one instance—1,1,2,2-tetrachloroethane—an updated IRIS assessment became available after EPA's determination to not regulate, but the agency has not announced whether it will reconsider the determination. In addition, as discussed in the following section, the credibility of some of EPA's regulatory determinations was limited. As we reported, we believe EPA should consider whether it needs to re-evaluate any of its past determinations to not regulate in light of the systemic and individual shortcomings we identified. In the absence of policies or guidance that identifies the circumstances that would trigger such re-evaluations and the process the agency would use in conducting them, it is not clear how and when such re-evaluations would occur.

The Credibility of Some of EPA's Regulatory Determinations As Presented in *Federal Register* Notices and Support Documents Is Limited by a Lack of Transparency, Clarity, and Consistency

The Safe Drinking Water Act requires EPA to ensure that, in its regulatory determinations, among other things, the presentation of information on public health effects is comprehensive, informative, and understandable. In addition, to the extent that EPA's regulatory determination notices and key support documents are transparent, clear, and consistent regarding the occurrence and health effects data the agency relied on, the credibility of the determinations is enhanced. However, for the regulatory determinations that EPA has made to date, some of the notices and support documents lack these key qualities. For example, as reflected in the following excerpts from EPA's regulatory determination documents for manganese and boron, EPA's presentation of health effects information on some contaminants lacked clarity, consistency, and transparency.

- EPA's 2003 regulatory determination support document for manganese states unequivocally that there are "no data to indicate children are more sensitive to manganese than adults." However, EPA's 2003 health effects support document for manganese discusses studies that identify an association between exposure to manganese in drinking water and learning disabilities in children and concludes that additional studies are needed to investigate the possibility that children are more sensitive than adults.
- EPA's regulatory determination support document for manganese notes that infants and newborns may be potentially susceptible to manganese toxicity, but this key document does not disclose that newborns may be exposed to high levels of manganese from infant formula or that these high levels of manganese in formula can be magnified when it is reconstituted with manganese-contaminated water.
- In its regulatory support document for boron, the Office of Water (1) identified the primary adverse effects identified from studies of animals after chronic exposure to low doses of boron as generally involving the testes and the developing fetus and (2) stated that animal studies identify the developing fetus as "potentially sensitive to boron" and concluded that boron concentrations greater than the health reference level "might" have an effect on prenatal development. In contrast, the Office of Water's May 2008 *Drinking Water Health Advisory for Boron*—developed in conjunction with the regulatory determination and published just 2 months before the regulatory determination was issued—states that there are "compelling lines of evidence to suggest that the testicular morphological effects" reported in studies of animals are applicable to children. Also, the Office of

Water's health advisory was not limited to prenatal exposure as it concluded that exposure to boron between birth and puberty may result in adverse cellular effects that would "affect testicular function."

- EPA's *Summary Document from the Health Advisory for Boron and Compounds* provides an important warning regarding infants' exposure to boron in drinking water that is not included in either EPA's drinking water advisory for boron or its regulatory determination support document discussed above. Specifically, the summary document states that water containing boron "at levels above the HA [health advisory]" should not be used to prepare food or formula for infants. EPA does not identify which of the exposure duration health advisories it is referring to in this warning.

In addition, EPA's regulatory determination documents lack transparency and clarity regarding how EPA determined its health reference levels were protective of children. In addressing seven of the contaminants in its 2003 regulatory determination notice for which EPA identified children as a sensitive subpopulation, EPA did not explain the potential effect of not developing separate health reference levels for children (or not making adjustments to its health assessments to reflect increased sensitivity) on its ability to ensure that the health reference levels used in the regulatory determinations were protective of children. Instead, EPA stated that the agency had not yet determined a protocol for making a regulatory determination for a chemical for which body weight and drinking water intake of infants or a particular childhood age group would be the basis of a regulatory action. As discussed earlier, health assessments based on adult weight and drinking water intake may not fully account for the risks to children of exposure to drinking water because they consume more water per unit of body weight and may have other susceptibilities, as well. Regarding its 2008 notice that included four contaminants for which children were identified as a sensitive subpopulation, Office of Water officials told us they would have developed separate assessments for children if they had determined children were "particularly sensitive" to the adverse health effects of contaminants being considered for regulation. However, EPA did not explain in its regulatory determination notices or support documents the basis for its determinations that children were not particularly sensitive to the adverse health effects of the contaminants considered for regulation—even for those contaminants, such as manganese and boron, for which EPA had determined children were a sensitive subpopulation. EPA also did not explain how the sensitivity of children can be evaluated in the absence of a separate assessment based on the weight and drinking water intake of children.

Also, EPA's regulatory determination notices lack transparency and clarity regarding the limitations of new or updated health advisories the agency issued in conjunction with 9 decisions to not regulate. According to EPA, the advisories are to provide, for example, "guidance to communities that might be exposed to elevated concentrations." However, the regulatory determination notices do not acknowledge that when EPA determines regulation is not warranted but a health advisory is needed, it will generally be up to states, localities, and consumers to determine whether such contaminant levels are found in public water systems in their jurisdiction. Importantly, because public water systems are not typically required to test for the presence of unregulated contaminants, information on the levels of the contaminants in individual public water systems may be outdated or unavailable. While some states—such as California and Massachusetts—can promulgate their own drinking water regulations, others are statutorily prohibited from, or otherwise constrained in, enacting more stringent regulations than EPA has promulgated or promulgating their own drinking water regulations for contaminants that EPA does not regulate. In addition, individuals may have to have their water tested by a laboratory to determine how much of these unregulated contaminants are present in their drinking water to heed, for example, EPA's warning in some cases to not use drinking water with contaminants in excess of certain levels to prepare infant food or formula. Moreover, EPA releases its drinking water advisories by posting them on its Web site and does not issue public notification of them, such as a press release, which potentially limits awareness of the health advisories.

Our report provides information on the following limitations that also reduce the credibility of EPA's completed regulatory determinations: (1) EPA's explanations of the occurrence data EPA relied on to assess known and likely occurrence of contaminants in drinking water lack transparency, clarity, and consistency; (2) EPA's regulatory determinations lack clarity regarding its reliance on outdated and limited occurrence data to support some determinations; (3) the regulatory determination documents lack transparency and clarity regarding EPA's reliance on minimum reporting levels greater than its health reference levels; and (4) EPA lacked consistency and clarity in making determinations when IRIS assessments were either in process or needed to be updated.

The Process and Analyses EPA Relied on to Support Its Preliminary Determination on Perchlorate Were Atypical, Lacked Transparency, and Limited the Agency's Independence in Developing and Communicating Its Scientific Findings

As detailed in our report, we found the following concerning the process and scientific analyses EPA used to develop its 2008 preliminary determination to not regulate perchlorate.

EPA Used a Less Inclusive, Less Transparent, and More Directive Process in Developing Its Preliminary Regulatory Determination on Perchlorate Than Its Usual Process

In contrast to EPA's usual regulatory determination process, which is managed by a work group of professional staff with relevant expertise from across the agency, EPA officials decided that the agency's continuing deliberations on perchlorate would be managed by a less inclusive, small group of high-level officials, such as the Deputy Administrator and several Assistant Administrators. Notably, EPA did not include the Office of Children's Health Protection in its small group despite EPA's and the National Academies' conclusion that iodide uptake inhibition from perchlorate exposure had been identified as a concern in connection with increasing the risk of neurodevelopmental impairment in fetuses of pregnant women with iodine deficiency and to developmental delays and decreased learning capability in infants and children. This group of high-level officials managed the regulatory determination process for perchlorate both within EPA and externally with the

Perchlorate Interagency Working Group,⁹ whose work was coordinated by the Council on Environmental Quality.¹⁰ According to an EPA briefing document, the Perchlorate Interagency Working Group was established in 2002 “to identify and help resolve perchlorate science and science policy issues.”

In contrast to the usual process EPA used for its regulatory determinations, in which EPA staff with relevant expertise develop and submit options to the Assistant Administrator for the Office of Water for review and selection, the Assistant Administrator directed the Office of Water staff in developing the preliminary determination for perchlorate to draft a preliminary determination that reflected the agency’s decision to not regulate perchlorate and to support it with a detailed and specific rationale that EPA and other members of the Perchlorate Interagency Working Group had agreed to, under the leadership and coordination of the Council on Environmental Quality.¹¹ EPA Office of Water officials told us that they believed this agreement—which is not part of the record for the preliminary regulatory determination—was developed by senior officials from the Council on Environmental Quality, the Department of Health and Human Services (HHS), EPA, the Office of Management and Budget (OMB), and the U.S. Department of Agriculture. The agreement focused on how EPA should address the key science issues concerning perchlorate in its preliminary regulatory determination and specified (1) a health reference level of 15 parts per billion of perchlorate in drinking water and (2) the rationale for EPA to support the conclusion that this health reference level would be protective of pregnant women and their fetuses as well as of infants and children.

⁹The Perchlorate Interagency Working Group includes officials from the Office of Management and Budget (OMB) and the Office of Science and Technology Policy, both part of the Executive Office of the President; Department of Defense; National Aeronautics and Space Administration; Department of Energy; the Department of Health and Human Services’ Food and Drug Administration and the Agency for Toxic Substances and Disease Registry; Department of Agriculture; and Department of the Interior.

¹⁰The Council on Environmental Quality, which is part of the Executive Office of the President, coordinates federal environmental efforts in the development of environmental policies and initiatives.

¹¹According to an EPA official, the agreement was documented in an unattributed two-page white paper and faxed to EPA from the Council on Environmental Quality in early August 2008; EPA made some editorial changes to the document but did not alter the substance of the agreement.

EPA Established a Reference Dose for Perchlorate but Subjected It to a More Limited Review Than the Agency's Standard IRIS Assessment Review Process

In developing an IRIS assessment of perchlorate, EPA established a reference dose¹² on the basis of the National Academies' recommendations, but subjected it to a more limited review than the agency's standard IRIS assessment review process.¹³ EPA's 2002 draft IRIS assessment of perchlorate—from which EPA derived a drinking water equivalent level of 1 part per billion¹⁴—drew significant attention—including from such federal agencies as the Department of Defense, the Department of Energy, and the National Aeronautics and Space Administration, because of the implications such a level could have on their operations if EPA were to develop a drinking water regulation for perchlorate. According to a senior EPA official, the controversy that arose over the draft IRIS assessment of perchlorate “was like nothing I had ever seen or have seen since.” As a result of the divergent views between EPA and the other federal agencies, the Administrator of OMB's Office of Information and Regulatory Affairs urged the four interested agencies to convene a National Academies panel to review the draft IRIS assessment. Convened in October 2003, the panel conducted this review and issued its report in January 2005.¹⁵

The National Academies 2005 perchlorate report made several key recommendations to EPA on the basis of a different study from those on which EPA had based its 2002 draft IRIS assessment on perchlorate. The National Academies' recommended reference dose was more than 20 times higher than the one proposed in EPA's draft IRIS assessment. EPA's final internal review of the revised IRIS assessment for perchlorate—termed a consensus review—differed from the agency's

¹²A reference dose is an estimate of the total daily oral exposure to a contaminant—for example, from food and water—that is not likely to cause “appreciable risk of deleterious effects during a lifetime.” A reference dose is a key component of the calculation EPA uses to derive a health reference level for drinking water contaminants.

¹³The National Academies consists of four private, nonprofit organizations that advise the federal government on scientific and technical matters: the National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and National Research Council.

¹⁴A drinking water equivalent level represents the estimated exposure to a contaminant that is assumed to be protective for noncarcinogenic health effects during a lifetime of exposure. EPA calculated this drinking water equivalent level using the reference dose that EPA proposed in its 2002 draft IRIS assessment and the agency's default assumptions for adult weight and daily drinking water intake.

¹⁵National Academies, *Health Implications of Perchlorate Ingestion* (Washington, D.C., 2005).

usual consensus review process. For example, the scope of the internal review was limited in that the IRIS program did not seek input from consensus reviewers on the *scientific basis* for the assessment as it typically does; rather, it sought input only on the extent to which the science in the IRIS Summary was not inconsistent with the major conclusions of the National Academies' report. At least two EPA offices essentially opted out of the consensus review process because of this limitation, which was a significant departure from the usual IRIS consensus practice.

EPA Relied on an Estimate of the Relative Exposure to Perchlorate from Drinking Water and Food That It Derived from a Novel Analysis and Used a Nontraditional Method to Calculate the Relative Source Contribution

In developing its regulatory determination on perchlorate, EPA conducted a novel analysis to develop estimates of exposure to perchlorate for various subpopulations, which the agency subsequently used to calculate the relative source contribution—the allocated exposure to perchlorate from drinking water alone.¹⁶ Independent scientists who reviewed EPA's analysis noted that it had several limitations—in particular, uncertainties specific to the exposure estimate for pregnant women. Nonetheless, EPA relied on the exposure estimate for pregnant women to calculate the relative source contribution, stating that the National Academies had identified pregnant women and their fetuses as the most sensitive subpopulation.¹⁷

In calculating the relative source contribution, EPA used a nontraditional method—called the subtraction method¹⁸—that was less conservative than the approach it had used for its other completed regulatory

¹⁶The relative source contribution is an allocation of the estimated oral exposure to the contaminant from drinking water alone; it has a significant impact on the health reference level that the agency derives for contaminants with noncancer adverse health effects.

¹⁷The 2005 National Academies report on perchlorate contained varying characterizations of sensitive subpopulations, sometimes referring to pregnant women and their fetuses alone as *the most sensitive subpopulation* and other times including infants in this designation. In addition, the National Academies identified developing children as a sensitive population and people with compromised thyroid function and people who are iodide-deficient as potentially sensitive populations.

¹⁸The subtraction method allocates the entire reference dose to the known sources of exposure by subtracting the known nontarget sources of exposure and allocating the remainder of the reference dose to the target—in this case, drinking water—even in cases where the total estimated exposure is less than the reference dose. This method has the effect of removing any cushion between the existing exposure levels and the reference dose.

determinations. While EPA identified some of the limitations of the exposure analysis in its preliminary regulatory determination notice for perchlorate, it did not discuss the effects of the limitations on EPA's exposure analysis. Although the agency's guidance for calculating the relative source contribution cautions against using the subtraction method in the absence of adequate data representative of at-risk populations—and EPA lacked data to estimate exposure to perchlorate for certain populations—the agency did not explain that the method it used to calculate the relative source contribution for perchlorate was the subtraction method or its reasoning for selecting this method.

According to Key EPA Scientists, the Agency Mischaracterized Important Scientific Findings That Emerged from Its Novel Analysis of the Sensitivity of Various Age Groups to Perchlorate in Drinking Water

In early 2008, EPA used a physiologically based pharmacokinetic (PBPK) model¹⁹ to (1) evaluate the relative sensitivity of sensitive subpopulations to the health reference level the agency had developed based on pregnant women and their fetuses and (2) address concerns that some sensitive subpopulations, such as infants, exposed at the health reference level may receive concentrations of perchlorate above the reference dose. For its preliminary regulatory determination, the agency used the model in a novel way and, according to some key EPA scientists, mischaracterized the findings of the modeling analyses by selecting and presenting information in such a way as to support the agreed-upon conclusion that a health reference level of 15 parts per billion was protective of *all* sensitive subpopulations, including infants.

While EPA's Office of Research and Development conducted numerous sensitivity analyses with the PBPK model, EPA presented the results of a PBPK analysis in its October 2008 preliminary regulatory determination for perchlorate to support its conclusion that a health reference level of 15 parts per billion was protective of all sensitive subpopulations, including infants, and stated that using the model in this way could reduce some of the uncertainty regarding the sensitivities of subpopulations other than pregnant women. However, Office of Research and Development officials disagreed with the way EPA presented the information in its preliminary regulatory determination notice, saying the agency did not sufficiently explain the uncertainties and limitations of the analysis, presenting the information more conclusively than was appropriate.

¹⁹PBPK models are complex and involve numerous underlying assumptions that are imbedded in mathematical representations of the processes associated with how a contaminant behaves within, and is eliminated from, the body.

Further, the table EPA published in the preliminary regulatory determination notice presenting the results of the PBPK analysis included data that may not be consistent with EPA's conclusion that a health reference level of 15 parts per billion was protective of all subpopulations. That is, the table provided sufficient data for informed readers of the preliminary determination to calculate that infants and young children could be exposed to doses of perchlorate at levels as high as 5.5 times greater than the reference dose, supporting the concern that infants and young children may, in fact, be more vulnerable to perchlorate exposure. While EPA's regulatory determination notice stated that the modeled exposure exceeds the reference dose for some subpopulations, the agency was not explicit about the extent to which the reference dose is exceeded—as calculated above—and did not explain the implications of this result on its conclusion that the health reference level of 15 parts per billion is protective of all subpopulations. In providing comments on the draft notice to the Office of Water, an Office of Research and Development scientist noted that the agency's failure to present a comparison of the estimated daily exposure with the reference dose constituted a "serious omission," and characterized the infants' estimated exposure as "substantially higher" than the reference dose.

EPA's limited presentation of the PBPK analyses conducted by the Office of Research and Development in its preliminary regulatory determination notice validated the concern expressed at the time by Office of Research and Development scientists who conducted the analyses: that individual analyses could be used out of context in a way that could be misleading. Specifically, an Office of Research and Development official stated in September 2008 that while his office and the Office of Water had developed careful and sophisticated PBPK analyses to support the agency's preliminary regulatory determination, "the use of these science results in [the] draft regulatory determination is seriously flawed and misleading." As a result, Office of Research and Development officials and scientists that conducted the analyses concluded that the PBPK analysis done by the office did not support the draft preliminary regulatory determination's suggested health reference level of 15 parts per billion as being health protective for all sensitive subpopulations of concern to EPA.

EPA's Independence in Developing and Communicating Its Scientific Findings Was Limited by Its Acceptance of External Input on the Preliminary Determination Notice

Compounding scientists' concerns about the mischaracterization and lack of transparency regarding relevant scientific analyses, key language in EPA's preliminary regulatory determination notice appears to have been drafted by OMB rather than EPA. In working to finalize the preliminary regulatory determination notice, EPA's Office of Water worked with OMB, whose clearance of the notice was required per EPA's policy implementing Executive Order 12866 before the Office of Water could provide it to the EPA Administrator for review, approval, and publication in the *Federal Register*.²⁰ According to the Office of Water, in four iterations of review, OMB sent EPA a substantial number of comments on the notice; in response, EPA "clarified its description of the supporting analysis and strengthened the rationale for the determination." The following example highlights OMB's role in reviewing and approving the specific wording of EPA's scientific analyses regarding perchlorate exposure in infants and children:

Text EPA provided to OMB: "Because infants and children eat and drink more on a per body weight basis than adults, eating a normal diet and drinking water with 15 [micrograms per liter] of perchlorate *is likely* to result in exposure that is greater than the reference dose in these groups."

Revised text provided to EPA by OMB: "Because infants and children eat and drink more on a per body weight basis than adults, eating a normal diet and drinking water with 15 [micrograms per liter] of perchlorate *may result in* exposure that is greater than the reference dose in these groups."

By changing three words, OMB downplayed EPA's characterization of the health risks of perchlorate exposure. Importantly, the EPA scientist who wrote the text provided to OMB noted to EPA reviewers—before it was sent to OMB in August 2008—that the PBPK model actually showed exposures at levels "much higher" than the reference dose, but also said that he believed describing the exposure scenario as "likely" was the strongest characterization that might be retained through OMB review. In addition, in September 2008, during its review of the draft preliminary determination notice and before clearing it for publication, OMB reminded

²⁰The objectives of this executive order are to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public.

EPA that it expected the notice to “state a clear conclusion that the HRL [health reference level] is protective of all subpopulations, as agreed to in the August framework”—and accordingly, this conclusion appeared in the agency’s October 2008 preliminary determination notice.²¹

EPA’s Response to Our Recommendations Does Not Appear to Acknowledge the Scope and Significance of the Implementation Limitations We Identified

We provided a draft of this report to the Administrator of EPA for review and comment. In commenting on the draft report, EPA agreed with 2 of the 17 recommendations we made to improve its implementation of the Safe Drinking Water Act. Specifically, EPA agreed with our recommendations regarding its drinking water health advisories, stating that it would evaluate their utility and determine whether and how to revise the advisories to better serve states, localities, public water systems, and the public. However, EPA did not agree to implement the remaining 15 recommendations we made, including an overarching recommendation that EPA develop policies or guidance that clearly articulate the agency’s interpretation of the Safe Drinking Water Act’s broad statutory criteria—as well as eight additional recommendations identifying specific components of this guidance and calling for review of the draft guidance by one of EPA’s independent advisory committees and the establishment of an internal review mechanism to help ensure the determinations are consistent with the guidance. Another key recommendation with which EPA disagreed was for EPA to include in the public record OMB’s and other federal agencies’ comments on and revisions to regulatory determination notices and support documents to improve transparency and help EPA ensure that it maintains the fairness and openness of its operations.

We made these recommendations to support the development of regulatory determinations that are transparent, clear, and consistent and that follow applicable agency policy. However, EPA said it believed that establishing policies or guidance for regulatory determinations was not “practicable” because of the many combinations of health effects factors and potential ranges of frequencies and levels of contaminants measured in drinking water. We do not believe that the existence of variables or complexities is a basis for not developing guidance for EPA staff to implement the statutory requirements for regulatory determinations. In

²¹According to an EPA official, “August framework” refers to the agreement that was faxed to EPA from the Council on Environmental Quality that included this conclusion as a key component of the rationale EPA and other federal agencies agreed to in August 2008.

fact, the complexities cited would argue for, rather than against, the need to develop guidance for staff on applying the criteria. EPA also did not agree with these recommendations on the basis that policies or guidance could “inhibit its ability to continually improve its actions.” This perspective suggests that guidance *per se* lacks flexibility. We do not agree that guidance and flexibility are incompatible or that developing guidance would inhibit EPA’s ability to improve its actions. Rather, flexibility can and should be incorporated into guidance by establishing parameters or options for areas in which flexibility is deemed appropriate.

Moreover, consistency and accountability are lacking in this important program because EPA has not developed guidance on the application of the broad statutory criteria, which are susceptible to varying interpretations. In its comments, EPA highlighted that, under these criteria, ultimately it is the Administrator’s judgment as to whether regulation of a contaminant in drinking water presents a meaningful opportunity for health risk reduction, after considering the information presented by agency staff. As stated in our report, the statutory criteria are so broadly stated that they could potentially be interpreted so as to lead to regulating all the contaminants on the candidate list, some of them, or none of them. It is precisely for these reasons that we believe it is essential for the staff to have sufficient guidance on applying the broad criteria consistently and transparently so that the Administrator’s judgment can be based on sound and consistent information. Without such guidance, the basis for EPA’s determinations and the quality of the documentation the staff use to support them can fluctuate over time as a result of, among other reasons, changes in agency leadership and staff. In addition, regarding our recommendation that EPA provide in the public record OMB’s and other federal agencies’ comments on and revisions to regulatory determination documents, EPA’s position is that unless required by law, it is not a good policy because, among other things, the documents may be confusing to the public and undermine the ultimate policy choice. We disagree and believe that to improve transparency of these determinations, which are by law committed to the Administrator’s judgment, EPA should consistently make these documents available in the public record, regardless of whether there is a specific legal requirement for disclosure.

In large measure, EPA’s response to our recommendations essentially endorses conducting business as usual; a response that does not seem to acknowledge the scope and significance of the implementation limitations we identified. We are concerned that EPA’s lack of responsiveness to our recommendations may reflect a misplaced reliance

on the Office of Water to independently improve the management of this important program in the absence of (1) regulations, policies, or guidance that we believe are needed to provide a framework for current and future staff to apply in identifying and evaluating contaminants for regulation; (2) the identification of clear and specific actions needed to address our recommendations; and (3) an internal review mechanism to ensure identified actions are implemented effectively. We believe that EPA needs to adopt all of the recommendations in our report to better assure the public of safe drinking water.

Madam Chairman Boxer, Ranking Member Inhofe, and Members of the Committee, this concludes our prepared statement. I would be happy to respond to any questions that you or other Members of the Committee may have.

Contacts and Acknowledgements

For further information about this testimony, please contact me at (202) 512-3841. Christine Fishkin, Jamie Meuwissen, Elizabeth Beardsley, Kiki Theodoropoulos, and Michael Derr also made key contributions to this statement.

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