

Summer of 2000, which focused on protocol recommendations to the Agency. In addition, EPA representatives delivered presentations at a variety of meetings held by other organizations. Moreover, EPA did ask for and considered comments made on the sodium and sulfate Drinking Water Advisories during the comment period on the June 2002 notice (USEPA 2002a).

The Agency believes the 60-day public comment period for the June 2002 notice (USEPA 2002a) was sufficient. The Agency took steps to facilitate public review of its preliminary decisions, as well as supporting documentation. In addition to the July 2002 stakeholder meeting, these steps included making key materials available on the Agency's website and providing hard copies of materials upon request.

2. Health Effects Assessments

Comment Summary: Some commenters suggested that EPA's analysis of adverse health effects and calculation of the HRLs were too conservative. On the other hand, one commenter questioned how the Agency's analysis underlying the regulatory determination approach incorporated appropriate safety factors and exposure assessments relative to children's health concerns.

Commenters recommended that EPA use the revised Office of Water methodology for deriving ambient water quality criteria (AWQC), (USEPA 2000), in an effort to protect human health in the final health effects support documents. According to the comments, this revised methodology establishes five different consumption rates and body weight classifications as a means to make the human health exposure assessments. One commenter specified that EPA needs to use more accurate consumption data for sodium rather than simply incorporating U.S. Food and Drug Administration (FDA) assertions.

Agency Response: EPA believes it is appropriate to use a conservative approach to assessing the health effects of an unregulated contaminant in the context of a determination of whether it should be considered for NPDWR regulation. In order to determine whether to propose an NPDWR for an unregulated contaminant, SDWA requires EPA to determine whether the contaminant "may have an adverse effect on the health of the persons," Section 1412(b)(1)(A)(i), which is a very broad criterion. As a result, EPA believes that a conservative health effects analysis is appropriate.

The HRL used by EPA in these determinations is a conservative health-based value and is different depending on whether a contaminant is considered a carcinogen or a noncarcinogen. For carcinogens, a 10⁻⁶ risk was chosen as the HRL since the maximum contaminant level goal (MCLG) for such contaminants will generally be zero. For noncarcinogens, the reference dose and a 20 percent relative source contribution (RSC) factor was used in conjunction with a 70 kilogram (kg) adult body weight and a 2 liter (L) water intake for the HRL calculation. EPA uses these standard regulatory assumptions for determining the MCLG of a noncarcinogen that lacks specific data on the RSC. EPA used best available peer reviewed data and analyses in evaluating adverse health effects. Accordingly, EPA disagrees with those commenters that felt that EPA was too conservative in establishing the HRL. EPA followed practices and policies that are similar to those used to establish an NPDWR and that are consistent with the SDWA section 1412(b)(1)(A)(i) criterion. If such a conservative approach does not result in EPA deciding to initiate a regulatory process for a contaminant, the Agency may decide to use a non-regulatory approach in addressing the issue, such as issuing a Drinking Water Advisory.

Children's health issues were considered in making regulatory determinations for each of the nine contaminants included in this final notice. The details of the individual assessments are included in the Health Effects Support Documents or Drinking Water Advisories for each contaminant. These documents are available for review at the EPA Water Docket and on-line at <http://www.epa.gov/edocket/>.

The AWQC (USEPA 2000) methodology continues to recommend the use of 70 kg for adult body weight and 2 liters per day for water intake for risk calculations. These are the same parameters used by EPA to derive an MCLG. EPA believes that its current methodology, based on adult exposures, for the derivation of MCLGs, and for making regulatory determinations under SDWA section 1412, remains generally appropriate. EPA has not yet determined a protocol for making a regulatory determination for a chemical for which an infant's or a particular childhood age grouping's body weight and drinking water intake would be the basis of a regulatory action. A decision for such a contaminant would be made on the basis of the toxicity and exposure data, and could utilize the age groupings and body weight information from the

AWQC human health methodology if it were appropriate.

EPA did not use FDA's sodium consumption data of 4 to 6 grams/day (g/day) in establishing a benchmark value for sodium. EPA decided to use a benchmark value for sodium instead of an HRL because sodium lacks suitable dose-response data and there is considerable controversy regarding the role of sodium in the etiology of hypertension. EPA derived the benchmark value for sodium of 120 mg/L in drinking water from the National Institutes of Health, National Academy of Sciences, American Heart Association, and the U.S. Department of Agriculture recommended daily dietary intake of 2.4 g/day.

3. EPA Research Agenda

Comment Summary: Several commenters expressed concern that, in their view, there is a lack of progress by EPA in filling research gaps related to the CCL. In particular, commenters focused on high visibility contaminants, such as the microbiological contaminants, MTBE, and other "emerging contaminants." Commenters also stressed the need to establish a vehicle for publicly tracking research needs and progress made in research areas.

Agency Response: Before EPA can determine whether to regulate contaminants, additional data on health, treatment technologies, and analytical methods, are needed for contaminants on the Research Priorities portion of the CCL, and occurrence data is needed for contaminants on the Occurrence Data Needs portion of the CCL. The remaining 51 CCL contaminants for which decisions are not being made today do not have sufficient data to support a regulatory determination. The Agency considers obtaining this data to be the priority of its research and occurrence monitoring programs. The Agency continues to actively conduct research and/or to collect occurrence information on these 51 CCL contaminants and other emerging contaminants. Because these research issues are broader than those that EPA can address alone, it is anticipated that other entities will be involved in conducting much of the needed research to support this process. For example, EPA already is jointly undertaking research efforts, and encourages stakeholders, through close and regular consultation, to be partners in filling many of the research gaps. The EPA continues to identify and develop new collaborations to conduct research and gather the additional data to characterize occurrence and adverse