

- The solubility of DEHP in drinking water is well below any concentrations that would pose a risk to humans.

- If DEHP were to be considered for regulation under the statutory requirements of the 1996 SDWA, it would not be regulated.

- The legislative history of the 1996 SDWA indicates that Congress envisioned circumstances where relaxation of an MCL would provide the same level of health protection as the existing regulation. Accordingly, the commenter believes consideration should be given to increasing the MCLG for DEHP based on the new health effects data.

- Reproductive effects from DEHP as observed in rodents do not appear to be relevant for primates and the doses that are associated with effects in animals are well above those that would be experienced for humans exposed through drinking water because of solubility limitations. The commenter also highlighted the findings of the NTP Center for the Evaluation of Risk to Human Reproduction that there was "minimal concern for reproductive or developmental toxicity for the general population, based on estimates of total exposure to DEHP."

*EPA Response:* Revision of the NPDWR for DEHP is not appropriate at this time because an Agency health risk assessment is currently in process. The assessment is anticipated to be completed in the 2003–2004 time frame (68 FR 5870, February 5, 2003 (USEPA, 2003h)). Advances in understanding differences between the primate and rodent response to DEHP and the body of toxicological data that have become available in the past decade motivated the Agency's re-examination of DEHP and will be fully considered in the reassessment.

Once the Agency assessment is completed, EPA will consider the findings and will determine if there is a compelling reason to review the DEHP NPDWR prior to the next Six-Year Review cycle. As discussed in sections IV.A.1.b and IV.A.2.a of today's action, "revise" versus "not revise" decisions under the Six-Year Review take into consideration occurrence, advances in analytical methods, treatment technologies, available economic information, and other factors.

As stated by the commenter, the legislative history of the 1996 SDWA Amendments supports EPA's interpretation that the Agency could increase an MCLG and MCL as long as the relaxed standard does not lessen the level of public health protection. However, EPA does not believe, at the present time, that it can demonstrate

that deregulating DEHP would maintain the current level of public health protection (see section IV.A.1.c of today's action).

#### 11. Fluoride

EPA received three comments on the Agency's decision to place fluoride in the data gap category while the National Academy of Sciences (NAS) examines the toxicological and RSC data published over the last decade. Two of the commenters supported EPA's decision. One of these requested that the NAS concentrate its review on all of the data on the toxicology of fluoride and not just data on the critical skeletal effects. A third commenter requested that EPA not lower the MCL for fluoride from 4 mg/L to 2 mg/L and supported the 1986 EPA decision that dental fluorosis is a cosmetic effect rather than an adverse health effect. The commenter stated that the Public Health Service (PHS) recommended fluoridation level to be used at schools is 3 mg/L. The commenter also stated that if EPA were to lower the MCL, then schools that are currently fluoridating might have a conflict with the PHS recommendations and the EPA MCL.

*EPA Response:* The National Research Council (NRC) of the NAS has agreed to review the toxicological data on fluoride that have been published since it completed the 1993 study of "Health Effects of Ingested Fluoride" (NRC, 1993), and to examine the data on relative fluoride exposure from drinking water compared to fluoride exposure from the diet and fluoride-containing dental products. Although the Agency indicated in the April 17, 2002, **Federal Register** that new data on bone effects were a reason for initiating the data review (because bone effects were the basis of the present MCLG), the NAS review will look at the new toxicological data for all endpoints. It is anticipated that the NAS review will take about two years to complete. Because of this pending review, revision of the NPDWR for fluoride is not appropriate at this time.

It is therefore premature to make any judgment regarding the NAS findings and whether or not they may lead to a consideration of a change in the MCL. However, PHS recommendations for school fluoridation programs are designed to provide the benefits of fluoridation without increasing the risk for dental fluorosis. The PHS recommends school water fluoridation only if:

- The school has its own source of water;
- The school is not connected to a community water system;

- More than 25 percent of students are not served by a public water system that provides water at levels adequate to protect against dental caries; and

- The students served are kindergarten age or greater.

#### 12. Glyphosate

Two commenters made the statement that, despite continued use of glyphosate in pesticide applications, available data and the Agency's occurrence analysis, which includes a prediction of frequency of occurrence at levels below detection, indicate that glyphosate is not observed in compliance monitoring. One of these commenters stated that the occurrence appeared to be rare (less than 0.1 percent) at concentrations 1,000 times lower than the MCL. In addition, according to the commenters, the cost of analyzing for glyphosate is expensive, since it is a single analyte analysis. Accordingly, the commenters wanted EPA to reconsider the glyphosate standard taking costs and benefits into account. The commenters felt that the data may indicate that a glyphosate standard is inappropriate and does not result in any additional public health protection. Therefore, the commenters recommended EPA pursue data gaps that the Agency would need to fill in order to demonstrate that eliminating the glyphosate standard would not lower public health protection.

*EPA Response:* EPA is conducting an Agency risk assessment for glyphosate that will update the 1993 OPP assessment. As a part of this process, EPA is considering all the data that have been published or submitted to EPA since the completion of the RED in 1993 (USEPA, 1993). Accordingly, revision of the glyphosate NPDWR is not appropriate at this time due to the pending Agency assessment.

EPA recognizes that some utilities feel that the analysis of glyphosate in drinking water is expensive and that this should be taken into consideration with respect to cost and benefits. This will be considered when EPA evaluates glyphosate in the next review cycle (unless there is a compelling reason to evaluate glyphosate on an accelerated schedule). For the reasons stated in section IV.A.1.c of today's action, EPA does not believe it is appropriate to consider deregulation of glyphosate at this time.

#### 13. Lead and Copper

*a. Research Needs.* Three commenters acknowledged the Agency's January 2000 revisions to the Lead and Copper Rule (LCR) but stated that the Agency should continue to consider how to