

the RED risk assessment for lindane, issued after publication of the April 17, 2002, **Federal Register**, should be considered in the Agency's review of the NPDWR and expressed concerns regarding the existing regulation. The commenter stated that the current NPDWR is based on an RfD developed in 1988 on the basis of adverse kidney effects and should be revised (USEPA, 1988). The kidney effects were determined to occur through a pathway that is not relevant to human health risk assessment. The commenter stated that the new OPP toxicological assessment has resulted in a significant change to the quantitative dose-response assessment for lindane and that there are no data gaps or uncertainties which would prevent a revision of the NPDWR for lindane at this time.

EPA Response: Since the publication of the April 17, 2002, **Federal Register** and receipt of the comment regarding lindane, the Agency has finalized the risk assessment for lindane and signed the RED on July 31, 2002. The remaining paragraphs in this section include a brief background discussion about the original promulgation of the lindane NPDWR, the results of the appropriate six-year technical reviews and the Agency's revise/not revise decision.

a. Background. EPA published the current NPDWR for lindane on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 0.0002 mg/L. The Agency based the MCLG on an RfD of 0.0003 mg/kg/day and a cancer classification of C, possible human carcinogen.

b. Technical Reviews. EPA updated the risk assessment on July 31, 2002 (USEPA, 2002h). The new risk assessment established an RfD of 0.0047 mg/kg/day. The Food Quality Protection Act (FQPA) of 1996 provides for an additional safety factor of up to 10-fold, if necessary, in assessing the risks to infants and children to take into account the potential for pre- and post-natal toxicity, and the completeness of the toxicity and exposure databases. This is referred to as the FQPA safety factor. The Agency concluded that an FQPA safety factor of three was required for lindane since there is evidence for increased susceptibility of the young demonstrated in a developmental neurotoxicity and two-generation reproductive toxicity study in rats. The rationale for using an FQPA safety factor of three is detailed in the RED.

In accordance with the 1999 EPA Draft "Guidelines for Carcinogen Risk Assessment" (USEPA, 1999a), the Agency classified lindane as "suggestive evidence of carcinogenicity, but not

sufficient to assess human carcinogenic potential." Based on the RfD for lindane of 0.0047 mg/kg/day, the application of the additional FQPA safety factor of three to this RfD, a 20 percent RSC, and a 10-fold risk management factor of suggested evidence of carcinogenicity, EPA used 0.001 mg/L as a level for evaluating the occurrence data.

Analytical or treatment feasibility do not pose any limitations for the current MCL and would not be a limiting factor at the 0.001 mg/L level (USEPA, 2003a; USEPA 2003g). The Agency's review of possible "other regulatory revisions" did not identify any issues that are specific to lindane (USEPA, 2003b).

EPA evaluated the results of the occurrence and exposure analyses for lindane to determine whether possible changes to the standard would be likely to result in a meaningful opportunity for cost-savings to public water systems and their customers (USEPA, 2003d). Table IV-2 shows the results of the detailed occurrence and exposure analysis based on the 16-State cross-section for concentrations of 0.0002 mg/L (the current MCL), and for 0.001 mg/L. Based on the detailed analysis, it appears that lindane is unlikely to occur at concentrations above 0.0002 mg/L in the States used for the cross-section.

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