

recommending the use of a central estimate (ED<sub>10</sub>) point of departure.

EPA's decision to use an LED<sub>10</sub>, as opposed to an ED<sub>10</sub>, in deriving revised human health criteria for vinyl chloride is inconsistent with EPA's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency and the Information Quality Act (IQA). EPA's science policy decision to use the LED<sub>10</sub>, instead of the ED<sub>10</sub>, introduces significant uncertainty in the risk assessment that underlies the water quality criteria derivations, which is in violation of the IQA. The submitter requested that we correct this information.

**Response**—The 2000 Human Health Methodology includes toxicological and exposure assessment parameters derived from scientific analysis, science policy, and risk management decisions, including the 1986 cancer guidelines [see *Guidelines for Carcinogen Risk Assessment* (51 FR 33992)] and principles from the 1999 draft revised cancer guidelines [see *1999 Guidelines for Carcinogenic Risk Assessment—Review Draft* (NCEA-F-0644, July 1999)]. These principles arise from scientific discoveries about cancer made in the last 15 years and from EPA policy supporting full characterization of hazard and risk for both the general population and potentially sensitive groups like children.

In particular, EPA's 1999 draft revised cancer guidelines gave a rationale for selecting point of departures (PODs). For quantitative modeling of dose-response relationships in the observed range, the guidelines recommend calculating the lower 95 percent confidence limit on a dose associated with an estimated 10 percent increased tumor or relevant non-tumor response (LED<sub>10</sub>). The estimate of the LED<sub>10</sub> is used as the point of departure (POD) for low-dose extrapolation. This standard point of departure (LED<sub>10</sub>) is adopted as a matter of science policy to remain as consistent and comparable across different studies. It is also a convenient comparison point for noncancer endpoints. The rationale for using the LED<sub>10</sub> is that a 10 percent response is at or just below the limit of sensitivity for discerning a statistically significant tumor response in most long-term rodent studies and is also within the observed range for other toxicity studies. Using the lower limit takes experimental variability and sample size into account. Note that use of the lower 95 percent confidence limit on the ED<sub>10</sub> implies that, given the experimental parameters (e.g., sample size, variation

in response) of the study being used, there is a five percent chance or less that the "true" ED<sub>10</sub> would be lower than the LED<sub>10</sub>. For well-conducted studies with large numbers of animals, relatively close dose spacing, and little inherent variability in the animal responses, LED<sub>10</sub> values will be close to the central estimate of the ED<sub>10</sub> value. For studies that include smaller numbers of animals, wider dose spacing, and more variable responses in replicates at the same dose, the LED<sub>10</sub> value will be further removed from the ED<sub>10</sub> value. It is part of EPA's science policy to use the lower bound of a 95 percent confidence interval around a preferred value (e.g., central estimate of the ED<sub>10</sub>) as a point of departure to ensure that the criterion will be adequately protective, that is, that the experimental uncertainty is small (a few percent or less). The EPA's IRIS cancer assessment of vinyl chloride uses the LED<sub>10</sub> as the POD. EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (EPA/260R-02-008, October 2002) indicated that EPA intends to specify the central estimate of human health risk when it is available. The ED<sub>10</sub> (central estimate) for vinyl chloride is not presented in IRIS. More recent IRIS entries do include the central estimate, but this was not the policy at the time vinyl chloride was completed. The requirement for its inclusion was instituted in the 2003 Standard Operating Procedures for IRIS.

c. The vinyl chloride MCL is a more appropriate benchmark level.

**Scientific view**—A submitter indicated that the current maximum contaminant level (MCL) for vinyl chloride of two parts per billion (ppb) which was developed under the Safe Drinking Water Act (SDWA) is a more appropriate benchmark level.

**Response**—The human health water quality criteria developed under CWA section 304(a) are based solely on data and scientific judgments about the relationship between pollutant concentrations and environmental and human health effects. Unlike the MCLs, the criteria do not consider economic impacts or the technological feasibility of meeting the chemical concentrations in ambient water. Thus, MCLs are not considered counterparts to water quality criteria.

d. The vinyl chloride water quality criterion for consumption of organisms should only be based on incidental ingestion of non-potable, recreational waters.

**Scientific view**—A submitter stated that the revised vinyl chloride human

health criteria for potable water was derived based on the assumption that people would drink two liters of surface water each day over a lifetime. Thus, surface water is effectively considered a public water supply. However, if the intended use of the water quality criteria is to set NPDES limits for potable waters not being used as public water supplies, then the water consumption assumption is overly conservative. Such waters serve only as recreational or occasional use water bodies, so that a value for incidental water ingestion would be more appropriate. For regulatory consistency, the water quality criteria for vinyl chloride for potable water supplies should be the same as the MCL.

**Response**—As required by CWA section 304(a), EPA develops water quality criteria that reflect the latest scientific knowledge on effects of pollutants on human health. States and authorized Tribes use the Agency's recommended section 304(a) water quality criteria to adopt enforceable water quality standards, including designating uses of a water body consistent with CWA section 101(a) (e.g., public water supply, fishing, recreation). In developing the 2000 Human Health Methodology, we made assumptions about exposure to contamination from consuming surface waters of the U.S. Our assumptions ensure that, if criteria are met in a water body designated with the uses specified in section 101(a), people can safely consume water from that water body. In order to ensure this, it is necessary to assume that all of the consumed water is taken from water bodies at the criteria level (i.e., contaminated to the maximum safe level).

The designated use inherent in the submitter's example is drinking water (potable water), even though the particular water body might not be used that way at the moment. Thus, the main issue in the view relates to the State's (or authorized Tribe's) assignment of designated use, not to numeric values for the national ambient water quality criteria for vinyl chloride.

Again, the human health water quality criteria developed under CWA section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Unlike the MCLs, the criteria do not consider economic impacts or the technological feasibility of meeting the chemical concentrations in ambient water. MCLs are not counterparts to water quality criteria.

e. EPA's BCF for vinyl chloride is overstated and its water quality criterion