

proposed "Airborne Exposure Limits for Chemical Warfare Agents GA (tabun), GB (sarin) and VX" in the **Federal Register** (Vol. 67, No. 5, Pages 894–901, Tuesday, January 8, 2002), seeking public comment. This notice discusses major comments received, describes decisions regarding the public comments, and states the final recommendations. CDC received comments from the U.S. Army, the Agency for Toxic Substances and Disease Registry (ATSDR), the CDC's National Institute for Occupational Safety and Health (NIOSH), state of Utah, U.S. Army contractors, and two individuals.

The comments fell into the following general categories: assumptions used in the risk assessment, selection of uncertainty factors, determination of the relative potency factor for the VX exposure limits, and technical feasibility of air monitoring at the lower exposure limits. The key comments potentially impacting CDC's recommendations are discussed below.

The U.S. Army recommended that adjustment in the risk assessment algorithm for breathing rate be eliminated because the critical endpoint in deriving the exposure limits is miosis, a clinical sign that is recognized as a local effect on the muscles of the iris of the eye. This biologic endpoint is widely considered to be a direct effect of the nerve agent vapor on the surface of the eye (not related to breathing rate). Scientists from CDC/NIOSH however, indicated that the data do not completely rule out the potential contribution of inhaled agent to the miosis effect. The weight of the scientific data appears to support the Army's recommendation on this matter, and CDC has decided to eliminate the breathing rate adjustment. Eliminating the breathing rate adjustment increases the worker population limit (WPL) by a factor of slightly more than two. No significant change in the general population limit (GPL) would occur by eliminating the breathing rate adjustment.

In the derivation of the WPL for GB, CDC/NIOSH experts recommended that an additional uncertainty factor of three be added to account for individual worker variability. Although workers are medically screened, the recommendation is a reasonable public health decision. CDC therefore has incorporated the additional uncertainty factor of three into the risk assessment algorithm. Making this adjustment lowers the exposure limits by a factor of three. This adjustment and elimination of the breathing rate factor suggested above essentially cancel each other.

In the derivation of the VX exposure limits by using relative potency, the Army questioned the use of a relative potency of 12 with the application of a modification factor of three for the incomplete VX data set. The application of a relative potency of 12 with a modifying factor of three effectively resulted in a relative potency of 36 between the calculated exposure limits for GB and VX. As discussed in the January 8, 2002, **Federal Register** proposal, the relative potency factor of 12 was based on a 1971 British study that measured the ability of VX to cause 90 percent pupil constriction in rabbits. Because the critical effect in the study used to derive the GB exposure limit was miosis, CDC believes that miosis was appropriate to use as the health effect in determining the relative potency of VX. CDC/NIOSH experts and the state of Utah supported the proposed relative potency of 12 with a modifying factor of three. Therefore, CDC is retaining its relative potency assumptions for deriving the VX exposure limits.

As discussed in the January 8, 2002, **Federal Register** proposal, CDC adjusted the VX GPL because available air-monitoring methods do not reliably detect VX at the calculated value of  $3 \times 10^{-8}$  mg/m<sup>3</sup>. In the adjustment, CDC assumed that potential exposure would be identified and corrected within three days, precluding chronic exposure. Several people who provided comments pointed out that a similar adjustment also could have been made for the GB GPL. CDC recognizes that the assumptions used to derive the GPLs for GB and VX differ. Indeed, this adjustment could be applied to the GB exposure limits; however, the air-monitoring technology is currently functioning near the recommended level. CDC recommends no upward adjustment of the GB exposure limits; this recommendation is consistent with the accepted industrial hygiene practice of keeping exposure to the minimum practicable level.

The derivation of the VX exposure limits may be biased low because of the inadequate VX toxicity database. CDC believes that reliable air monitoring is a crucial aspect for implementing the exposure limits. Although CDC would have preferred a better toxicity database for VX, as well as improved air-monitoring methods for VX, these items are not currently available. Consequently, CDC is not further adjusting the final recommendation to the GPL for VX. However, CDC will reevaluate the VX exposure limits in the future if significant new VX toxicity data are available for setting exposure

limits, new risk assessment evaluation methods are demonstrated superior to methods used herein, or substantive technological advances in air monitoring methods are made.

Army contractors and CDC/NIOSH experts expressed concerns about the technical feasibility of meeting the new exposure limits. On the basis of these comments, CDC has adjusted the VX short-term exposure limit (STEL) to  $1 \times 10^{-5}$  mg/m<sup>3</sup> but added the provision that excursions to this special VX STEL should not occur more than once per day (in the typical STEL, four excursions per day are allowed). A lower STEL value would have required a longer response time for near real-time instruments; the recommended STEL is a result of balancing the detection capabilities and response time. A shorter instrument response time associated with the recommended STEL will minimize exposures. This adjustment to the VX STEL should not affect worker health.

To account for other technical feasibility concerns, CDC recommends that the GB and VX STEL be evaluated with near-real-time instrumentation, whereas the GB and VX WPLs and GPLs may be evaluated with longer-term historical air monitoring methods. CDC further recommends that, in implementing the WPLs, STELs and GPLs, specific reduction factors for statistical assurance of action at the exposure limits are not needed because of safety factors already built into the derivation of the exposure limit. This recommendation assumes that the sampling and analytical methods are measuring within  $\pm 25\%$  of the true concentration 95% of the time. If this criterion is not met, an alarm level or action level below the exposure limit may be required.

The Army recently indicated to CDC that the exposure limits as listed and implemented in this announcement are technically feasible to detect with the instrumentation and methods currently in use. However, whether the agent destruction sites can monitor at these exposure limits and still meet current quality control standards has not been determined. To allow the Army to implement program changes, regulatory adjustments, and to evaluate quality control issues, the final recommended exposure limits will become effective January 1, 2005.

**Final Recommendations:** CDC presents final recommendations for airborne exposure limits (AELs) for the chemical warfare agents GA (tabun or ethyl N,N-dimethylphosphoramidocyanidate, CAS 77–81–6); GB (sarin or O-isopropyl-