opportunity to make a presentation may be given this opportunity at the conclusion of the meeting, at the discretion of the presiding officer.

Comments on the topics presented in this notice and at the meeting should be mailed to the NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, Telephone 513–533–8303, Fax 513/533–8285. Comments may also be submitted by e-mail to *niocindocket@cdc.gov.* E-mail attachments should be formatted as WordPerfect 6/7/8/9 or Microsoft Word. Comments should be submitted to NIOSH no later than November 16, 2003, and should reference Docket Number NIOSH–010 in the subject heading.

Purpose: NIOSH will initiate conceptual discussions of standards and testing processes for powered air purifying respirator standards suitable for respiratory protection against CBRN Agents. NIOSH, along with the U.S. Army Soldier and Biological Chemical Command (SBCCOM) and the National Institute for Standards and Technology (NIST), will present information to attendees concerning the concept development for the powered air purifying respirator CBRN standard. Participants will be given an opportunity to ask questions on these topics and to present individual comments for consideration. Interested participants may obtain a copy of the powered air purifying respirator CBRN concept paper, as well as earlier versions of other concept papers used during the standard development effort, from the NPPTL Web site, address: *www.cdc.gov/niosh/npptl.* The September 15, 2003, concept paper will be used as the basis for discussion at the public meeting, as well as forming the basis for the new powered air purifying respirator CBRN statement of standard. The continuing threat of acts of terrorism has created an urgent awareness of domestic security and preparedness issues. Municipal, State, and Federal responder groups, particularly those in locations considered potential targets, have been developing and modifying response and consequence management plans. Since the World Trade Center and anthrax incidents, most emergency response agencies have operated with a heightened appreciation of the potential scope and sustained resources requirements for coping with such events. The Federal Interagency Board for Equipment Standardization and Interoperability (IAB) has worked to identify personal protective equipment that is already available on the market for responders' use. The IAB has identified the development of standards or guidelines for respiratory protection equipment as a top priority. NIOSH, NIST, the National Fire Protection Association, and the Occupational Safety and Health Administration entered into a Memorandum of Understanding defining each agency or organization's role in developing, establishing, and enforcing standards or guidelines for responders' respiratory protective devices. NIST initiated Interagency Agreements with NIOSH and SBCCOM to aid in the development of appropriate protection standards or guidelines. NIOSH has the lead in developing standards or guidelines to test, evaluate, and approve respirators. NIOSH, SBCCOM, and NIST hosted public meetings on April 17 and 18, 2001; June 18 and 19, 2002; October 16 and 17, 2002; April 29, 2003; and June 25, 2003, presenting their progress in assessing respiratory protection needs of responders to CBRN incidents. The methods or models for developing hazard and exposure estimates, and the status in evaluating test methods and performance standards that may be applicable as future CBRN respirator standards or guidelines were discussed at these meetings.

For Further Information Contact: NIOSH Event Management, 3610 Collins Ferry Road, P.O. Box 880, Morgantown, West Virginia 26507–0880, Telephone 304–285–4750, Fax 304–285–4459, E-mail *npptlevents@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 11, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03–23686 Filed 9–16–03; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Final Recommendations for Protecting Human Health from Potential Adverse Effects of Exposure to Agents GA (Tabun), GB (Sarin), and VX

AGENCY: Centers for Disease Control and Prevention (CDC), Public Health Service, Department of Health and Human Services.

ACTION: Notice of final recommendations for protecting human health from potential adverse effects of exposure to agents GA, GB, and VX.

SUMMARY: Agents GA, GB, and VX are stored and are in the process of being destroyed by the Department of Defense (DoD). Public Law 99–145 (50 U.S.C. 1521) mandates that all unitary (self-contained) lethal chemical munitions be destroyed. Public Law 91–121 and Public Law 91–441 (50 U.S.C 1512) mandate that the Department of Health and Human Services (DHHS) review DoD plans for disposing of these munitions and make recommendations to protect public health.

EFFECTIVE DATE: January 1, 2005. An implementation period is necessary to allow the DoD to make program adjustments and allow time for changes to environmental permits as required.

FOR FURTHER INFORMATION CONTACT: Dr. Paul Joe, Acting Chief, Chemical Demilitarization Branch, National Center for Environmental Health, CDC, 4770 Buford Highway, M/S F–16, Atlanta, Georgia 30341.

SUPPLEMENTARY INFORMATION: On January 8, 2002, DHHS, CDC published 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 3×10^{-8} mg/m^3. 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 bases of these comments, CDC has adjusted the VX short-term exposure limit (STEL) to 1×10^{-5} mg/m^3 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 ±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-dimethyl-phosphoramidocyanidate, CAS 77–81–6); GB (sarin or O-isopropyl-methylphosphonofluoridate, CAS 107–44–8); and VX (O-ethyl-S-(2-diisopropylaminoethyl)-methylphosphonothiolate, CAS 50782–69–9). CDC based its recommendations on comments by scientific experts at a public meeting convened by CDC on August 23–24, 2000, in Atlanta, Georgia; the latest available technical reviews; and the risk assessment approach frequently used by regulatory agencies and other organizations.

Additionally, CDC reviewed the substantial background information provided in the recent U.S. Army evaluations of the airborne exposure criteria for chemical warfare agents. AELs for chemical warfare agents GA, GB, and VX were reevaluated by using the conventional reference concentration risk assessment methodology for developing AELs described by the U.S. Environmental Protection Agency. This methodology is considered conservative; however, the calculated exposure limits are neither numerically precise values that differentiate between nonharmful and dangerous conditions, nor are they precise thresholds of potential human toxicity. The recommended changes to the AELs do not reflect change in, nor a refined understanding of, demonstrated human toxicity of these substances but rather the changes resulted from updated and minimally modified risk assessment assumptions. Overt adverse health effects have not been noted in association with the previously recommended exposure limits. This may be due to rigorous exposure prevention efforts in recent years as well as the conservative implementation of the existing limits (i.e., 8-hour time-weighted average exposure limits have been implemented as short-duration ceiling values). Recommended AELs for GB: CDC recommends a WPL value of 3×10^{-5} mg/m^3, expressed as an 8-hour time-weighted average (TWA). Additionally, CDC recommends a STEL of 1×10^{-4} mg/m^3 to be used in conjunction with the WPL. Exposures above the WPL up to the STEL should not be longer than 15 minutes and should not occur more than four times per day, and at least 60 minutes should elapse between successive exposures in this range. The

STEL should not be exceeded during the work day, even if the cumulative exposure over the 8-hour TWA is not exceeded. CDC recommends a decrease in the GPL to 1×10^{-6} mg/m^3. The WPLs and GPLs values are approximately threefold lower than levels previously recommended by CDC in 1988. An immediately dangerous to life or health (IDLH) value of 0.1 mg/m^3 is recommended for GB. Recommended AELs for GA: Although not as well-studied as GB, GA is believed to be approximately equal in potency to GB. Therefore, CDC recommends the same exposure limits for GA as for GB. Recommended AELs for VX: CDC recommends that the VX WPL, expressed as an 8-hour TWA, be decreased to 1×10^{-6} mg/m^3. Additionally, CDC recommends a VX STEL of 1×10^{-5} mg/m^3. An excursion to the STEL should not occur more than one time per day (compared to four times per day for a typical STEL). The recommended WPL is a factor of 10 lower than the CDC's 1988 recommendation. CDC recommends that the GPL for VX be decreased to 6×10^{-7} mg/m^3 (a factor of five lower than CDC's 1988 recommendation). An IDLH value of 0.003 mg/m^3 is recommended for VX. CDC's final recommendations are summarized in Table 1 below.

TABLE 1.—FINAL RECOMMENDED AIRBORNE EXPOSURE LIMITS (AELS) FOR GA, GB, AND VX

AEL (mg/m^3)	General population limit (GPL)*	Worker population limit (WPL)*	Short-term exposure limit (STEL)* (Workers)	Immediately dangerous to life or health (IDLH) (Workers)
GA, GB	1×10^{-6}	3×10^{-5}	1×10^{-4}	0.1.
GA, GB—Previous (1988)	3×10^{-6}	1×10^{-4}		0.2 (Army)
VX	6×10^{-7}	1×10^{-6}	1×10^{-5} **	0.003
VX—Previous (1988)	3×10^{-6}	1×10^{-5}		0.02 (Army)
Averaging time	24 hours	8 hours	15 minutes	= 30 minutes
Monitoring Method for Recommended Exposure Criteria.	Historical monitor***	Historical monitor	Near-real-time monitor	Near-real-time monitor

* An additional reduction factor for statistical assurance of action at the exposure limit is not needed because of safety factors already built into the derivation of the exposure limit.

** VX STEL has been adjusted from 4×10^{-6} mg/m^3 (up to four times per day) as proposed in the **Federal Register** announcement to 1×10^{-5} mg/m^3 (not more than one time per day) based on technical capabilities of existing air-monitoring technologies.

*** Historical monitoring typically refers to long-term sampling and analytical methods. Air-monitoring results from historical methods are not known until laboratory analyses are complete. CDC does not specifically recommend the use of these AELs for uses other than transportation, worker protection during the destruction process, or general population protection. For example, the 8-hour WPL historically has been used for the Army-designated 3X decontamination, surveillance activities of leaking containers in storage, and charcoal unit mid-beds. CDC did not evaluate the applicability of the WPLs for these activities; the specific technical and safety requirements for each activity need to be considered individually. This announcement does not address the allowable stack concentration (ASC). The ASC is a ceiling value that serves as a destruction process source emission limit and not as a health standard. It typically is used for monitoring the furnace ducts and final exhaust stack, providing an early indication of an upset condition. Modeling of worst-case credible events and conditions at each installation should confirm that the WPL is not exceeded on-site or that the GPL is not exceeded at the installation boundary as a consequence of a release at or below the ASC.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and ATSDR.

Dated: September 11, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0379]

Draft Guidance for Industry on Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition'' (the draft guidance). The draft guidance provides information to industry on how to prepare a claim of categorical exclusion or an environmental assessment (EA) for submission to the Center for Food Safety and Applied Nutrition (CFSAN) in notifications for food contact substances, food additive petitions, color additive petitions, requests for exemption from regulation as a food additive, generally recognized as safe (GRAS) petitions, and petitions for certain food labeling regulations.

DATES: Submit written or electronic comments on the draft guidance and the collection of information by November 17, 2003, to ensure their adequate consideration in preparation of a revised guidance, if warranted. However, you may submit comments at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition'' to the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3100, premarkt@cfsan.fda.gov. Send two self-addressed adhesive labels to assist that office in processing your requests. See **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments on the draft guidance and the collection of information provisions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Layla I. Batarseh, Center for Food Safety and Applied Nutrition (HFS–246), 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3016 or 202–