

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/m³. 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/m³ 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/m³. Additionally, CDC recommends a VX STEL of 1×10^{-5} mg/m³. 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/m³ (a factor of five lower than CDC's 1988 recommendation). An IDLH value of 0.003 mg/m³ 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/m³ (up to four times per day) as proposed in the **Federal Register** announcement to 1×10^{-5} mg/m³ (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–