

ACTION: Notice of request for comments and information relevant to occupational exposure to toluene.

SUMMARY: NIOSH is reviewing the recommendations in its document "Criteria for a Recommended Standard: Occupational Exposure to Toluene" [NIOSH 1973] (<http://www.cdc.gov/niosh/73-11023.html>). A review of recent literature indicates that the NIOSH recommended exposure limit (REL) of 100 ppm as an 8-hr time-weighted average (TWA) does not sufficiently protect workers from the adverse effects of exposure to toluene. NIOSH is requesting (1) comments and information relevant to the evaluation of the health risks associated with occupational exposure to toluene, (2) reports or other data that demonstrate adverse health effects in workers exposed to toluene at or below the NIOSH REL, and (3) information pertinent to establishing a more protective REL for toluene.

Comments concerning this notice must be received within 60 days after date of publication.

ADDRESSES: Comments may be transmitted either electronically to niocindocket@cdc.gov, by facsimile to 513/533-8230, or by regular mail or hand delivery to NIOSH Docket Office, M/S C-34, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226. E-mail attachments should be formatted as WordPerfect 7/8/9 or Microsoft Word.

FOR FURTHER INFORMATION CONTACT: Henryka Nagy, M/S C-32, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226, 513/533-8369.

SUPPLEMENTARY INFORMATION: In the document "Criteria for a Recommended Standard: Occupational Exposure to Toluene" [NIOSH 1973] (<http://www.cdc.gov/niosh/73-11023.html>), NIOSH recommended that exposure to toluene be limited to 100 ppm as an 8-hr TWA. This exposure limit was expected to prevent acute and chronic effects on the central and peripheral nervous system from exposures to toluene. NIOSH has conducted a literature review of the health effects data on toluene exposure and finds evidence that adverse effects on the central and peripheral nervous systems and reproductive system, as well as irritation of the eye and respiratory tract may occur in workers exposed to concentrations at and below the current NIOSH REL of 100 ppm [Andersen *et al.* 1983; Larsen and Leira 1988; Ørbæk and Nise 1989; Foo *et al.* 1990; Ng *et al.* 1992; ATSDR 2000; NEG 2000].

NIOSH seeks to obtain materials, including published and unpublished reports and research findings, to evaluate the possible health risks of occupational exposure to toluene at concentrations below 100 ppm. Examples of requested information include, but are not to be limited to, the following:

1. Identification of industries or occupations in which exposures to toluene may occur.
2. Trends in production, use, and import of toluene over the past 10 years.
3. Description of work tasks and scenarios with a potential for exposure to toluene.
4. Current occupational exposure concentrations in various types of industries and jobs and, if available, data to document these concentrations.
5. Case reports or other health data that demonstrate adverse health effects in workers exposed to toluene, or animal data (published or peer-reviewed data are preferred).
6. Description of work practices and engineering controls used to reduce or prevent workplace exposure.
7. Educational materials for worker safety or training on the safe handling of toluene.
8. Data pertaining to the technical feasibility of establishing a more protective REL for toluene.

NIOSH will use this information to determine the need for developing new recommendations for reducing occupational exposure to toluene.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

References

- Andersen I, Lundqvist GR, Molhave L, Pedersen OF, Proctor DF, Væth M, Wyon DP [1983]. Human response to controlled levels of toluene in six-hour exposures. *Scand J Work Environ Health* 9:405-418.
- ATSDR [2000]. Toxicological profile for toluene (update). Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry.
- Foo SC, Jeyaratnam J, Koh D [1990]. Chronic neurobehavioural effects of toluene. *Br J Ind Med* 47:480-484.
- Larsen F, Leira HL [1988]. Organic brain syndrome and long-term exposure to toluene: a clinical, psychiatric study of vocationally active printing workers. *J Occup Med* 30(11):875-878.
- NEG [2000]. Toluene. Stockholm, Sweden: The Nordic Expert Group

for Criteria Documentation of Health Risks from Chemicals.

Ng TP, Swee CF, Yoong T [1992]. Risk of spontaneous abortion in workers exposed to toluene. *Br J Ind Med* 49:804-808.

NIOSH [1973]. Criteria for a recommended standard occupational exposure to toluene. Rockville, MD: U.S. Department of Health, Education, and Welfare, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHEW (NIOSH) Publication No. 73-11023.

Ørbæk P, Nise G [1989]. Neurasthenic complaints and psychometric function of toluene-exposed rotogravure printers. *Am J Ind Med* 16:67-77.

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 the Agency for Toxic Substances and Disease Registry.

Dated: July 23, 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. 2003N-0199]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Importer's Entry Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by September 29, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on