

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Agency for Toxic Substances and Disease Registry**

[ATSDR-228]

Update to ATSDR Policy Guideline for Dioxins and Dioxin-Like Compounds in Residential Soil

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), U.S. Department of Health and Human Services (HHS).

ACTION: Request for public comments on the revised Policy Guideline document used by health assessors to evaluate health hazards associated with exposure to dioxins and dioxin-like compounds in residential soil.

SUMMARY: ATSDR is seeking public comment on the draft revision of its 1998 Policy Guideline for Dioxins and Dioxin-Like Compounds in Residential Soil. The policy is intended to assist health assessors who must evaluate the public health implications of dioxin and dioxin-like compounds (e.g., 2,3,7,8-tetrachlorodibenzo-p-dioxin [TCDD], chlorinated dibenzodioxins [CDDs], chlorinated dibenzofurans [CDFs], and other structurally related groups of chemicals from the family of halogenated aromatic hydrocarbons) in residential soils near or on hazardous waste sites. The 1998 policy established a screening level of 0.05 ppb TEQ (50 ppt), an evaluation level (>0.05 ppb TEQ, <1 ppb), and an action level of 1 ppb TEQ (1,000 ppt) for dioxins in residential soil.

ATSDR revised the 1998 policy because it has been used inconsistently over the past eight years. The ATSDR "action" level has been misinterpreted by health assessors and others as ... (1) A soil concentration that defines a public health hazard, (2) an ATSDR clean-up level which implies the need for site remediation, and (3) an initial screening level that defines a safe level of exposure, below which there is no public health concern. In addition, the "action" level triggered a set of "potential public health actions", including surveillance, research, health studies, community education, and exposure investigations. However, ATSDR believes that these actions could be considered in some circumstances when the 1 ppb level in soil is not exceeded. In response to these concerns ATSDR has updated its Policy Guideline for Dioxins and Dioxin-Like Compounds in Residential Soil. The key elements in the updated ATSDR Policy Guideline for Dioxins and Dioxin-Like

Compounds in Residential Soil are as follows:

- Deletion of the 1 ppb action level as the criteria for taking specific public health actions.

The 1-ppb dioxin soil concentration should not be used as a comparison value for defining public health hazards in public health assessments and consultations. The 1-ppb action level can be cited by health assessors as the Superfund Dioxin Cleanup policy criteria (EPA 1989, 1998).

Retention of the 0.05 ppb Screening Level

The minimal risk level (MRL)-based environmental media evaluation guide (EMEG) of 0.05 ppb for dioxin TEQ in soil is retained as the basis for screening soil concentrations. Levels exceeding this screening level should be evaluated as described in the ATSDR Public Health Assessment Guidance Manual (PHAGM) (ATSDR 2005). This clarification will ensure that evaluation of dioxins and dioxin-like compounds in soil will be done in the same manner as all other soil contaminants.

Recommendation To Conduct Exposure Pathways Analyses for Dioxins and Dioxin-Like Compounds

The focus of the guideline is the assessment of direct exposure to soil contamination, particularly soil ingestion. However, health assessors should be aware of the potential impact of indirect exposure pathways on exposed populations in site-specific health assessments. This document does not provide specific guidance on how these indirect pathways should be assessed. However, the PHAGM document does provide assistance in evaluating indirect exposure pathways such as food chain contamination (ATSDR 2005).

Updated TEFs

The 2006 World Health Organization Toxicity Equivalency Factors (TEFs) for dioxins and dioxin-like compounds have been included in the updated document.

Background Information

In 1998, the Agency for Toxic Substances and Disease Registry (ATSDR) adopted a Final Policy Guideline for Dioxin and Dioxin-Like Compounds (De Rosa et al. 1999a). The 1998 policy guideline was accompanied by a Technical Support Document for ATSDR Policy Guideline (De Rosa et al. 1999b). The initiative to develop this policy guideline was based on a request from the U.S. Environmental Protection Agency (EPA) to evaluate the

protectiveness of the EPA Superfund Policy for Dioxins in Residential Soils, which established 1 part per billion (ppb) (1,000 parts per trillion [ppt]) total dioxin toxicity equivalents (TEQ) as the starting point for making clean-up decisions. In addition, the 1998 policy guideline was to provide guidance to health assessors in evaluating the public health implications of dioxin and dioxin-like compounds (e.g., 2,3,7,8-tetrachlorodibenzo-p-dioxin [TCDD], chlorinated dibenzodioxins [CDDs], chlorinated dibenzofurans [CDFs], and other structurally related groups of chemicals from the family of halogenated aromatic hydrocarbons) in residential soils near or on hazardous waste sites. As stated in the 1998 document, "these guidelines and procedures apply to human exposure for direct ingestion of soils contaminated with dioxin and dioxin-like compounds in residential areas and may not be appropriate for other exposure scenarios." The 1998 Policy Guideline established a screening level of 0.05 ppb TEQ (50 ppt), an evaluation level (>0.05 ppb TEQ, <1 ppb), and an action level of 1 ppb TEQ (1,000 ppt) for dioxins in residential soil and made recommendations for specific considerations or public health actions.

ATSDR has established environmental screening values for chemicals to be used by health assessors to assess exposures. No other chemical has an action level as was established for dioxins in soil in the 1998 policy guideline. This inconsistency alone has led to confusion regarding the appropriate screening value for soil dioxin levels.

The primary objectives of the updated Policy Guidelines are to provide greater consistency in ATSDR Health Assessments and to bring dioxin assessments in line with how all other chemicals are evaluated by the agency.

Summary of Peer Review for Document

The public comment draft of the revised policy has undergone internal review and clearance within ATSDR. In addition, the revised draft was reviewed by the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) Board of Scientific Counselors (BSC). Public testimony was received during the meeting of the NCEH/ATSDR BSC. ATSDR also received peer review comments from health assessors in several state health departments.

Information about the "Update to ATSDR Policy Guideline for Dioxins and Dioxin-Like Compounds in Residential Soil", including the draft document, fact sheet, peer review

comments and ATSDR responses, is available on the ATSDR Web site at: <http://www.atsdr.cdc.gov/substances/dioxin/policy/index.html>.

DATES: Comments concerning this document must be received by February 27, 2007.

ADDRESSES: Public comments should be forwarded to Ms. Athena Gemella, ATSDR, Office of Science, 1600 Clifton Road, N.E., Mail stop E-28. Atlanta, GA. 30333, or e-mail at AGemella@cdc.gov.

FOR FURTHER INFORMATION CONTACT: Ms. Athena Gemella, Office of Science, telephone (404) 498-0621.

Dated: December 22, 2006.

Kenneth Rose,

Acting Director, Office of Policy, Planning and Evaluation, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-07-06A]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of

information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

Proposed Project

Metropolitan Atlanta Stillbirth Management Survey: Knowledge, Attitudes and Practice Patterns from Obstetricians,—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The U.S. Congress House Report 108-792 (joint conference report for the Fiscal Year 2005 omnibus appropriations bill) provides specific funding to devise a comprehensive strategy for expanding existing birth defects surveillance systems to incorporate surveillance data on all intrauterine fetal deaths of 20 or more week's gestation into the Metropolitan Atlanta Congenital Defects Program (MACDP). Stillbirth is largely an understudied adverse pregnancy

outcome even though it accounts for nearly one half of all perinatal mortality. There is currently no nationally accepted definition of what constitutes a stillbirth, and there are no universally recommended, standardized stillbirth evaluation protocols in use for the evaluation of fetal deaths. The proposed survey has been designed to evaluate and assess the knowledge, attitudes and practice management patterns of obstetricians in the metropolitan Atlanta area regarding stillbirths in general, as well as in their medical practice. This information will be used to identify prevailing deficiencies leading to incomplete and inaccurate reporting of data relative to stillbirths, and to develop targeted awareness and educational strategies for participating MACDP facilities. Ongoing, accurate and reliable population-based registries of stillbirths are essential for conducting epidemiologic studies on the causes of and risk factors for this pregnancy outcome. This survey will be mailed to randomly selected obstetricians whose practices serve residents of the 5 counties comprising metropolitan Atlanta. This survey will be conducted once and will take approximately 2-3 months to collect the data. NCBDDD is requesting OMB clearance for 1 (one) year. There is no cost to the survey respondents except for the time necessary to complete the survey. The total annual burden hours are 122

ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondents	Participant status	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Obstetricians	Non-Participant	120	1	1/60
	Participant	480	1	15/60

Dated: December 22, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-284]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed

collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection;