

Enhancing Protections for Research Subjects and Reducing Burden, Delay and Ambiguity for Investigators. The afternoon will also include a presentation from the Subpart A Subcommittee (SAS) to inform SACHRP of recent work. SAS is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment; this subcommittee was established by SACHRP in October 2006.

On February 29, SACHRP will hear recommendations from the Subcommittee on Harmonization (SOH). SOH was established by SACHRP at its July 2009 meeting, and is charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination. Following the SOH report, SACHRP will hear a discussion on the IRB use of component analysis, utilizing speakers from the FDA and academia.

Public Comment will be heard on both days.

Public attendance at the meeting is limited to space available. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact persons. Members of the public will have the opportunity to provide comments on both days of the meeting. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed materials distributed to SACHRP members for this scheduled meeting should submit materials to the Executive Director, SACHRP, prior to the close of business February 23, 2012.

Dated: February 3, 2012.

Jerry Menikoff,

Director, Office for Human Research Protections, Executive Secretary, Secretary's Advisory Committee on Human Research Protections.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[ATSDR-273]

Notice of Development of Set 25 Toxicological Profiles

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

ACTION: Notice.

SUMMARY: This notice announces the development of Set 25 Toxicological Profiles, which will consist of four updated profiles. ATSDR will make these profiles available to the public on or about October 17, 2012 and will solicit public comments at that time for a 90-day period. Electronic access to these documents will be available at the ATSDR Web site: <http://www.atsdr.cdc.gov/toxprofiles/index.asp>.

Set 25 Toxicological Profiles

The following toxicological profiles are now being developed:

	Name	CAS
1	Hexachlorobenzene (UPDATE)	118-74-1
2	Endosulfan (UPDATE)	115-29-7
	Endosulfan sulfate	1031-07-8
	Endosulfan-alpha	95-99-98
	Endosulfan-beta	33213-65-9
3	1,1-Dichloroethane (UPDATE)	75-34-3
4	Dinitrotoluenes (DNT) (UPDATE):	
	2,3-DNT	602-01-7
	2,4-DNT	121-14-2
	2,5-DNT	619-15-8
	2,6-DNT	606-20-2
	3,4-DNT	610-39-9
	3,5-DNT	618-85-9

SUPPLEMENTARY INFORMATION: The Superfund Amendments and Reauthorization Act of 1986 (SARA) (42 U.S.C. 9601 *et seq.*) amended the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund) (42 U.S.C. 9601 *et seq.*) by establishing certain requirements for ATSDR and the U.S. Environmental Protection Agency (EPA) with regard to hazardous substances that are most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these statutory requirements is a mandate for the Administrator of ATSDR to prepare toxicological profiles for each substance included on the Priority List of Hazardous Substances (www.atsdr.cdc.gov/SPL). This list

names 275 hazardous substances that pose the most significant potential threat to human health as determined by ATSDR and EPA. The availability of the revised list of the 275 priority substances was announced in the **Federal Register** on November 3, 2011 (76 FR 68193). For prior versions of the list of substances, see **Federal Register** notices dated April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17, 1990 (55 FR 42067); October 17, 1991 (56 FR 52166); October 28, 1992 (57 FR 48801); February 28, 1994 (59 FR 9486); April 29, 1996 (61 FR 18744); November 17, 1997 (62 FR 61332); October 21, 1999 (64 FR 56792); October 25, 2001 (66 FR 54014); November 7, 2003 (68 FR 63098); December 7, 2005

(70 FR 70284); and March 6, 2008 (73 FR 12178).

Notice of the availability of drafts of these four updated toxicological profiles for public review and comment will be published in the **Federal Register** on or about October 17, 2012, with notice of a 90-day public comment period for each profile, starting from the actual release date. Following the close of the comment period, chemical-specific comments will be addressed, and, where appropriate, changes will be incorporated into each profile.

FOR FURTHER INFORMATION CONTACT:

Commander Jessilyn B. Taylor, Division of Toxicology and Environmental Medicine, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road NE., Mail Stop F-62,

Atlanta, GA 30333, telephone 770-488-3313.

Dated: February 3, 2012.

Ken Rose,

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-12-09BK]

Agency for Toxic Substances and Disease Registry; Agency Forms Undergoing Paperwork Reduction Act Review

The Agency for Toxic Substances and Disease Registry (ATSDR) 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/ATSDR Reports Clearance Officer at (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Registration of Individuals Displaced by the Hurricanes Katrina and Rita (Pilot Project)—New—Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

On August 29, 2005, Hurricane Katrina made landfall on the coast of the Gulf of Mexico near New Orleans, Louisiana, and became one of the most

deadly and destructive storms in U.S. history. Also occurring in 2005, Hurricane Rita was the fourth-most intense Atlantic hurricane ever recorded and the most intense tropical cyclone ever observed in the Gulf of Mexico. Following the initial phase of the response, the Federal Emergency Management Agency (FEMA) assumed the primary role for housing displaced persons over the intermediate term. To support those needing temporary housing, FEMA provided over 130,000 travel trailers, park homes, and mobile homes for persons displaced by the above mentioned storms. However, some persons living in trailers complained of an odor or of eye or respiratory tract irritation.

FEMA entered into an Interagency Agreement with the Centers for Disease Control and Prevention (CDC)/ATSDR on August 16, 2007 to conduct a comprehensive public health assessment, based on objective and credible research, of air quality conditions present in FEMA housing units to guide FEMA policy makers and inform the public as to the actual conditions in the field and any actions required to better promote a safe and healthful environment for the disaster victims FEMA housed in the units. FEMA's agreement with the CDC includes an initial formaldehyde exposure assessment as well as a subsequent long-term study of the health effects among resident children. Formaldehyde testing conducted and evaluated by the CDC pursuant to the initial exposure assessment has identified the need to evaluate the feasibility of establishing a national registry to identify and monitor the health of disaster victims who occupied FEMA-provided temporary housing units. The establishment of such a registry would complement the long-term health effects study set forth in the FEMA-CDC Interagency Agreement.

The proposed pilot registry will have two goals: Primary Goal: Test the feasibility and cost of contacting and

enrolling members in a registry by collecting and verifying phone interview data. Secondary Goal: Test the difference in prevalence rates of health conditions compared to national surveys (*i.e.*, NHANES and NHIS).

The data collected in the pilot registry and the evaluation of the pilot registry will be used to determine the feasibility and estimate the costs of developing and populating a more complete registry of people affected by Hurricanes Katrina and Rita. In addition, comparisons of prevalence rates of health outcomes obtained through the pilot registry with estimates from national surveys will help determine the utility of conducting a full registry. For example, if all or most health outcomes do not appear to be in excess, the value of a full registry may be questionable.

A pre-registration datasets will be created before enrollment. This dataset will be populated with contact information of the occupants of temporary housing units provided by FEMA. FEMA provided the datasets for this pilot registry.

A computer-assisted telephone interview (CATI) system based on a paper questionnaire will be used during all interviews to collect data for this project. The first part will consist of screening questions to determine eligibility for enrollment. The second part will contain contact information of the registrant and other household members, demographics, and health status questions, focusing on respiratory outcomes and mental health.

The two minute screening questionnaire will be administered to a total of 8,000 respondents. Annualized over a two year period, 4,000 will be screened. The 25 minute main questionnaire will be administered to a total of 5,000 respondents. Annualized over a two year period, 2,500 occupants will complete the main questionnaire.

There are no costs to the respondents other than their time. The total estimated annual burden hours are 1,176.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Temporary and Non-Temporary housing unit occupants.	Screening	4,000	1	2/60
Main questionnaire	2,500	1	25/60	