Notice to the Reader: Health Consultation - Formaldehyde Sampling of FEMA Temporary-Housing Trailers issued February, 2007

This health consultation replaces the previous health consultation released in February 2007.

The previous health consultation dated February 1, 2007, contained insufficient discussion of the health implications of formaldehyde exposure, and some language may have been unclear, potentially leading readers to draw incorrect or inappropriate conclusions. Additionally, analyses of formaldehyde levels by trailer type and by daily temperature were not conducted.

# An Update and Revision of ATSDR's February 2007 Health Consultation:

# Formaldehyde Sampling of FEMA Temporary-Housing Trailers

Baton Rouge, Louisiana, September-October, 2006

# October 2007

# U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service Agency for Toxic Substances and Disease Registry Atlanta, Georgia 30333

#### **Health Consultation: A Note of Explanation**

An ATSDR health consultation is a verbal or written response from ATSDR to a specific request for information about health risks related to a specific site, a chemical release, or the presence of hazardous materials. In order to prevent or mitigate exposures, a consultation may lead to specific actions, such as restricting use of or replacing water supplies; intensifying environmental sampling; restricting site access; or removing the contaminated material.

In addition, consultation s may recommend additional public health actions, such as conducting health surveillance activities to evaluate exposure or trends in adverse health outcomes; conducting biological indicators of exposure studies to assess exposure; and providing health education for health care providers and community members. This concludes the health consultation process for this sampling, unless additional information is obtained by ATSDR which, in the Agency's opinion, indicates a need to revise or append the conclusions previously issued.

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# An Update and Revision of ATSDR's February 2007 Health Consultation:

# Formaldehyde Sampling of FEMA Temporary-Housing Trailers

# Baton Rouge, Louisiana, September-October, 2006

#### October 2007

#### **Table of Contents**

Executive Summary	4
Overview	6
Background	7
Sources of Formaldehyde Exposure	7
Formaldehyde Health Effects	9
Absorption, distribution, metabolism, and excretion	11
Irritation	11
Sensitization	12
Cancer	13
Reproductive and development toxicity	13
FEMA Trailer Air Sampling and Analysis Methods	13
Results	15
Discussion	19
Limitations	20
Conclusions	20
Recommendations	20
References	21
Appendix A: Quality Assurance and Quality Control Evaluation of 1-Hour	
Formaldehyde Sampling	24
Appendix B: Statistical Analysis	28
Appendix C: A Correction of the Data Table in the February 2007 Health Consult	tation 40

# An Update and Revision of ATSDR's February 2007 Health Consultation:

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## **Executive Summary**

In July 2006, the Federal Emergency Management Agency (FEMA) asked the Agency for Toxic Substances and Disease Registry (ATSDR) to evaluate formaldehyde air sampling data collected by the U.S. Environmental Protection Agency (EPA) in 96 unoccupied trailers. These unoccupied trailers were similar to those distributed by FEMA to house persons displaced by Hurricane Katrina. The exposure scenarios examined by the sampling were not intended to represent those that people living in trailers would experience.

EPA completed the sampling on October 10, 2006, and FEMA provided the data to ATSDR on December 6, 2006. ATSDR assessed the data and issued a report called a *health consultation* in February, 2007. In that health consultation there was insufficient discussion of the health implications of formaldehyde exposure and some language may have been unclear, potentially leading readers to draw incorrect or inappropriate conclusions. Additionally, analyses of formaldehyde levels by trailer type and by daily temperature were not conducted. As a result, this health consultation was prepared, and it replaces the previous health consultation released in February 2007.

This report addresses two questions. First, are air formaldehyde levels in closed, unventilated trailers high enough to be associated with health effects in humans? Second, can simple measures such as running air conditioning or opening windows lower the levels of formaldehyde? Accordingly, the data were generated by conducting air sampling for formaldehyde in new, unoccupied trailers under three specific conditions: 1) when the trailers had been closed and unventilated, and during a two-week intervention period with 2) air conditioning on or 3) windows open.

Analysis of the air sampling data provides answers to both questions. First, formaldehyde levels in closed trailers averaged 1.04 parts per million (ppm), with some measurements exceeding 3.5 ppm. Exposure in this range is sufficient to cause acute symptoms in some people. Allergic sensitization to formaldehyde may also occur. Risk of cancer will increase with increased formaldehyde concentration and duration of exposure. Second, both interventions—air

conditioning and windows open—lowered formaldehyde levels, with windows open achieving greater reductions (to an average of 0.09 ppm) than air conditioning (to an average 0.39 ppm). The levels during air conditioning remained in a range that may be associated with acute symptoms in some people. During both interventions, levels remained higher than some health-based federal exposure guidelines. Additional research is needed to clarify whether formaldehyde affects reproductive ability or damages the developing fetus.

Data analysis revealed two additional findings. First, there was an association between temperature and formaldehyde levels; higher temperatures were associated with higher formaldehyde levels in trailers with the windows closed. Second, different commercial brands of trailers yielded different formaldehyde levels.

It is important to highlight what this health consultation does *not* do. It does not assess formaldehyde levels in trailers under actual use conditions. It does not assess the health status of people currently living in FEMA trailers. The analysis results presented in this report cannot be generalized to all FEMA trailers and they cannot be used to predict the health consequences of living in those trailers. Because this health consultation is not analyzing human exposures it does not define a level of concern.

Based on the data reported here, further analysis of exposure conditions and potential health effects in occupied FEMA trailers is warranted. Likewise, effective interventions to reduce the level and duration of exposure and potential health effects should be identified.

# Formaldehyde Sampling of FEMA Temporary-Housing Trailers Baton Rouge, Louisiana, September-October, 2006

#### Overview

During the summer of 2006, the Federal Emergency Management Agency (FEMA) asked the Agency for Toxic Substances and Disease Registry (ATSDR) to evaluate air sampling data for formaldehyde collected by the U.S. Environmental Protection Agency (EPA) in 96 unoccupied trailers. These unoccupied trailers were similar to those distributed by FEMA to house people displaced by Hurricane Katrina.

On June 19, 2006, the first conference call was held to discuss concerns about formaldehyde in temporary housing units used by people displaced by Hurricane Katrina. Representatives from the Centers for Disease Control and Prevention (CDC), ATSDR, EPA, and FEMA participated in the call. While attending the EPA On-Scene Coordinator (OSC) Training in Los Angeles, CA, on July 10, 2006, ATSDR and EPA staff met to discuss the formaldehyde issue. On July 13, 2006, a conference call was held among representatives from CDC's National Center for Environmental Health (NCEH), ATSDR, EPA, and FEMA. At that time, FEMA requested that EPA initiate a sampling project and that NCEH/ATSDR evaluate the air sampling data for formaldehyde levels. A major issue identified by NCEH/ATSDR and EPA regarding FEMA's request was that results of ATSDR's sampling analysis could not be generalized and applied to occupied FEMA trailers in the Gulf region.

The sampling protocol was designed to address two questions. First, are air formaldehyde levels in closed, unventilated trailers high enough to be associated with health effects in humans? Second, can simple measures such as running air conditioning and opening windows lower the levels of formaldehyde? Accordingly, the data were generated by measuring formaldehyde air levels in new, unoccupied trailers under three specific conditions: 1) when the trailers had been closed and unventilated (baseline phase), and during a two-week period (intervention phase) with 2) air conditioning on and bathroom static vents open but exhaust fans were not running, or 3) windows open and static vents and exhaust vents open but exhaust fans not running.

EPA completed sampling on October 10, 2006, and subsequently validated its data. On December 6, 2006, ATSDR received the sampling data from FEMA. ATSDR assessed the data and issued a health consultation in February, 2007. In that health consultation there was insufficient discussion of the health implications of formaldehyde exposure and some language may have been unclear, potentially leading to incorrect or inappropriate conclusions. Additionally, analyses of formaldehyde levels by trailer type and by daily temperature were not conducted. As a result, this health consultation was prepared, and it replaces the previous health consultation released in February 2007. This present health consultation includes background information on formaldehyde exposure and health effects, presents the data collected by EPA, corrects the calculation errors in the February 2007 consultation, addresses the two questions posed above, and provides additional information about the role of other factors, such as temperature and trailer manufacturer.

## **Background**

#### **Sources of Formaldehyde Exposure**

Formaldehyde is a nearly colorless gas with a pungent, irritating odor even at very low concentrations (below 1 part per million [1 ppm]). Its vapors are flammable and explosive. Because the pure gas tends to polymerize, it is commonly used and stored in solution. Formalin, the aqueous solution of formaldehyde (30% to 50% formaldehyde), typically contains up to 15% methanol as a stabilizer [1]. Some of the basic physical and chemical properties of formaldehyde are listed in Table 1.

Table 1. Physical and Chemical Properties of Formaldehyde [reference 2]

Property	Information
Chemical formula	нсно
Molecular weight	30.03
Color	Colorless
Physical state	Gas
Melting point	-92° C
Boiling point	-21° C
Density at -20 C	0.815 g/mL
Odor	Pungent, suffocating odor; highly irritating odor
Odor threshold: water	50 ppm
Odor threshold: air	0.5–1.0 ppm
Taste	50 ppm

C=degrees Centigrade. g/mL=grams per milliliter. ppm=parts per million.

Formaldehyde is synthesized by the oxidation of methanol. It is among the 25 most abundantly produced chemicals in the world and is widely used in manufacturing plastics, resins, and ureaformaldehyde foam insulation. Formaldehyde or formaldehyde-containing resins are used in manufacturing chelating agents, a wide variety of organic products, glass mirrors, explosives, and dyes. It has been used as a disinfectant, germicide, and in embalming fluid. In agriculture, formaldehyde has been used as a fumigant, preventive against mildew in wheat and rot in oats, a germicide and fungicide for plants, an insecticide, and in manufacturing slow-release fertilizers.

Formaldehyde is found in construction materials such as plywood adhesives. Formaldehyde also is or has been used in the sugar, rubber, food, petroleum, pharmaceutical, and textile industries. Formaldehyde is naturally produced in small amounts in our bodies. The information in Table 2 illustrates the pervasiveness of formaldehyde in human environments.

Table 2. Airborne Levels of Formaldehyde in Various Settings [reference 2,3]

Formaldehyde Levels (ppm)	Description
0.0008-0.068	Urban background
0.08	Urban background during heavy traffic
ND-0.22	Buildings in which smoking is not permitted
ND-0.6	Buildings in which smoking is permitted
0.48–5.31	Indoor air while cooking fish
0.08	Mobile homes in winter
0.09	Mobile homes in summer

ND=Not detectable. ppm=parts per million.

Factors affecting the concentration of formaldehyde in indoor air include the type and quantity of materials containing formaldehyde, the age of the materials, ventilation, temperature, and humidity. Some of the major sources of formaldehyde indoors are the off-gassing of ureaformaldehyde foam insulation (UFFI) and particle board. The amount of formaldehyde released from wood-based materials is expected to decrease as they age [2]. The concentration of formaldehyde in mobile homes likely is higher than that found in conventional homes due to the lower rate of air exchange [2] and the presence of more formaldehyde emitting materials. The levels of formaldehyde appear to decrease in mobile homes as their formaldehyde-based resins age, with a half-life of 4 to 5 years [2].

Several monitoring studies were conducted in the United States during the 1980s to measure formaldehyde concentrations in indoor environments. Much of the data were collected in either older homes, in homes that had UFFI, or in homes in which occupants had filed complaints about formaldehyde irritant symptoms. In these earlier studies, mobile homes in which residents had health complaints had formaldehyde concentrations ranging from 0.01 to 4.2 ppm [4]. Randomly selected mobile homes in which residents did not necessarily have health complaints had formaldehyde concentrations ranging from less than 0.01 to 2.9 ppm [5]. Conventional homes overall had concentrations of formaldehyde ranging from less than 0.02 to 0.4 ppm [6].

In 1985, the Department of Housing and Urban Development (HUD) passed a standard specified in Title 24, Code of Federal Regulations, Chapter XX, Part 3280, Section 3280.308 specifying limits on the formaldehyde emissions of plywood and particle board used in manufactured housing intended for residential use. Since the mid-1980s, plywood and particle board manufacturing methods have changed to reduce formaldehyde emissions. Home construction methods also have changed to reduce UFFI use. Further studies have been conducted since these changes in construction practices were implemented. A study conducted on a newly constructed and unoccupied house approximately 30 days after formaldehyde releasing materials were installed found average indoor concentrations of formaldehyde to be 0.035 to 0.45 ppm [7]. In another, 1993 study, the ranges of formaldehyde concentrations in complaint homes, mobile homes, and homes containing large quantities of particle board or UFFI were generally 0.02 to 0.8 ppm, with outlier levels as high as 4 ppm. Levels at the higher end of this range are sufficient to cause irritating symptoms, which researchers observed in some instances. In this same study, formaldehyde concentrations in conventional homes less than one year old were within the range of 0.05 to 0.2 ppm, with a few measurements exceeding 0.3 ppm. Older conventional homes had the lowest indoor concentrations of formaldehyde with values typically less than 0.05 ppm [8].

Tables 3 and 4 present ATSDR health guidance values and permissible or recommended workplace levels of formaldehyde. Of note, the lower values in Tables 3 and 4 are in some cases below background levels found in some urban areas.

Table 3. ATSDR Health Guidance Values for Formaldehyde Exposure [references 1,2]

Description	Formaldehyde Exposure Level (ppm)	Basis for Health Guidance Values
ATSDR chronic minimal risk level (MRL) ≥ 365 days	0.008	The chronic inhalation MRL was derived from a human study. After 7.3 years exposure, the lowest observable adverse effect level (LOAEL) was 0.24 ppm, which caused lesions in nasal mucosa. Dividing by a safety factor of 30 yielded the MRL of 0.008.
ATSDR intermediate minimal risk level (MRL) 15–364 days	0.03	The intermediate inhalation MRL was derived from a monkey study. After exposure for 26 weeks, 7 days per week, 22 hours per day, the no observable adverse effect level (NOAEL) was 0.98 ppm. Dividing by a safety factor of 30 yielded the MRL of 0.03.
ATSDR acute minimal risk level (MRL) ≤ 14 days	0.04	The acute inhalation MRL was derived from a human study. After a 2-hour exposure the LOAEL was 0.4 ppm, which caused increased white blood cells (eosinophils) in nasal lavage fluid accompanied by increased itching, sneezing, and congestion. Dividing by a safety factor of 9 yielded the MRL of 0.04.
ATSDR Medical Management Guidelines: effect level for previously sensitized individuals	0.3	Previously sensitized individuals can develop severe narrowing of the bronchi, which may begin immediately or can be delayed for 3 to 4 hours. Effects may worsen for up to 20 hours after exposure and can persist for several days.

ppm=parts per million.

Table 4. Occupational Exposure Levels for Formaldehyde [reference 9]

Description	Formaldehyde Exposure Level (ppm)
NIOSH recommended exposure limit (REL) (time-weighted average [TWA]) not to be exceeded in 10-hour workday, 40-hour week.	0.016
NIOSH ceiling REL (15-minute TWA) not to be exceeded at any time.	0.1
ACGIH threshold limit value (TWA) not to be exceeded in 8-hour day.	0.3
OSHA permissible exposure limit (PEL) (TWA) not to be exceeded in 8-hour day.	0.75
OSHA short-term exposure limit (STEL, 15-minute TWA) not to be exceeded at any time.	2.0

NIOSH=National Institute for Occupational Safety and Health. ACGIH=American Conference of Government Industrial Hygienists.

# OSHA=Occupational Safety and Health Administration.

#### Formaldehyde Health Effects

Absorption, distribution, metabolism, and excretion: Formaldehyde is a small, reactive, water soluble molecule (CH<sub>2</sub>O) which is readily absorbed by the tissues of the respiratory tract (inhalation exposure) and gastrointestinal tract (oral exposure). Absorption from the nasal portion of the respiratory tract is estimated to be at or near 100%, and formaldehyde vapors that bypass the nasal mucosa are efficiently absorbed by the tracheal and bronchial mucosa. Little information is available on the oral absorption characteristics of formaldehyde in humans. However the sharp increases in blood formate levels seen in two studies result from either the rapid metabolism of formaldehyde to formate in the gastrointestinal tract followed by the fairly quick absorption of formate; the rapid absorption of formaldehyde and its metabolism to formate in the blood; or a combination of both mechanisms [10,11]. Formaldehyde is readily absorbed into the body and is very quickly broken down. It is not stored in fat. Formaldehyde also is naturally produced in small amounts in the human body as a part of normal metabolism. Formaldehyde has a half-life in blood of approximately 1.5 minutes [9]. Almost every tissue of the body has the ability to break down formaldehyde. It is usually converted to formate, which is excreted in the urine. In addition, formaldehyde can be converted to carbon dioxide and exhaled [2].

*Irritation*: Exposure to formaldehyde can occur through inhalation, dermal contact, or ingestion. Most formaldehyde exposures occur by inhalation or by skin or eye contact. At very low

concentrations, formaldehyde may have a noticeable irritating odor with an odor threshold of approximately 0.5 to 1.0 ppm [2,3]. Formaldehyde can be irritating to many tissues when it comes into direct contact with them. The most common symptoms of formaldehyde exposure include eye, nose, and throat irritation; along with increased tearing, which occurs at air concentrations of about 0.4 to 3.0 ppm [2]. Other symptoms at low concentrations may include headache, runny nose, and difficulty breathing [1]. At higher concentrations, formaldehyde has a pungent, distinct odor and may cause a burning sensation to the eyes, nose, and lungs [2].

Studies of people with repeated exposure to formaldehyde under occupational or residential conditions provide evidence that formaldehyde can be irritating to the upper respiratory tract, but there is only limited evidence that pulmonary function may be adversely affected by repeated exposure to formaldehyde [12-18]. A survey was conducted of 84 funeral directors and apprentices with occupational exposure to an estimated mean air concentration of 0.36±0.19 ppm (0.08–0.81 ppm) for an average of 8.2 years and compared to 38 non-exposed control subjects. Embalmers reported more frequently than control subjects that symptoms of irritation of the eyes, upper respiratory tract, and skin occurred during work. Chronic bronchitis (20% versus 3%), shortness of breath (20% versus 3%), and nasal irritation (44% versus 16%) were among the most common respiratory complaints [18].

Several studies have histologically examined nasal biopsy specimens in formaldehyde-exposed workers and observed epithelial lesions that are consistent with the irritant and reactive properties of formaldehyde [2].

Sensitization: Some people are more sensitive to the effects of formaldehyde exposure than others. These include people who are immunologically sensitized to formaldehyde and people who have reactive airways or asthma. Dermal exposure to liquid formaldehyde has been shown to induce allergic sensitization. Two separate studies in children have reported allergic sensitization, as measured by increased formaldehyde-specific IgE antibody formation, following inhalation exposure to environmental levels of formaldehyde (0.012-0.075 ppm) [19,20]. Animal studies have shown that inhalation exposure to formaldehyde also can enhance sensitization to other inhaled allergens, depending on the exposure regimen [21,22]. In people previously sensitized to formaldehyde, inhalation and dermal contact at low levels (not specified) may cause various skin disorders, asthma-like symptoms, and anaphylactic reactions [2].

Concerns involving asthmatics and formaldehyde exposure have focused on the potential for formaldehyde-induced bronchoconstriction. Older studies involving asthmatics generally indicated that formaldehyde does not induce bronchoconstriction at concentrations less than 3 ppm [23]. However, a number of more recent studies have reported a dose-related association between exposure to commonly-encountered domestic levels of formaldehyde and an increased prevalence in children of asthma and asthma-like bronchoconstrictive symptoms [24-28]. In a group of individuals potentially sensitized to formaldehyde, some with dermal hypersensitivity, symptoms of increased itching, sneezing, mucosal congestion, and transient burning sensation of the eyes and nasal passages were reported following exposure to 0.4 ppm formaldehyde for a period of 12 hours.

Cancer: The National Toxicology Program (NTP) has classified formaldehyde as "reasonably anticipated to be a human carcinogen" based on a positive association between occupational exposure to formaldehyde and squamous-cell carcinomas of the nasal cavities and paranasal sinuses [29]. The International Agency for Research on Cancer (IARC) has classified formaldehyde as "carcinogenic to humans" based on a reported excess of nasopharyngeal cancers in a US cohort of embalmers and among Danish workers at companies which use or manufacture formaldehyde [30]. The EPA has classified formaldehyde as a "probable human carcinogen" based on limited evidence in humans and sufficient evidence in animals. Human data include nine studies that show statistically significant associations between site-specific respiratory neoplasms and exposure to formaldehyde or formaldehyde-containing products. An increased incidence of nasal squamous cell carcinomas was observed in long-term inhalation studies in rats and mice [9]. These classifications are summarized in Table 5.

Table 5. Cancer Classifications for Formaldehyde

Agency	Classification
U.S. Environmental Protection Agency	Classification B1: probable human carcinogen, based on limited evidence in humans, and sufficient evidence in animals.
International Agency for Research on Cancer	Group 1: sufficient evidence in humans for the carcinogenicity of formaldehyde, and sufficient evidence in experimental animals for the carcinogenicity of formaldehyde.
National Toxicology Program	Reasonably anticipated to be a human carcinogen based on limited evidence in humans and sufficient evidence in animals.

Reproductive and development toxicity: IARC has recently reviewed 11 epidemiological studies for reproductive effects associated with formaldehyde exposure [30]. Based on its review, IARC concluded that: "Inconsistent reports of higher rates of spontaneous abortions and lowered birth weights were reported among women occupationally exposed to formaldehyde. Studies of inhalation exposure to formaldehyde in animal models have evaluated the effects of formaldehyde on pregnancy and fetal development, which have not been clearly shown to occur at exposures below maternally toxic doses" [30]. Other reviews [31,32] have concluded that additional research is needed to better define the reproductive and developmental risks posed by exposures to formaldehyde.

#### FEMA Trailer Air Sampling and Analysis Methods

FEMA and EPA developed a sampling plan and analytical program to evaluate formaldehyde concentrations in indoor air in unoccupied trailers selected and supplied by FEMA. Ninety-six trailers, 12 each from 8 different manufacturers were included. The objective was to characterize baseline formaldehyde levels in closed, unventilated trailers, and to determine the effects of two

ventilation interventions. The scenarios were not intended to represent those that people living in trailers would experience.

Three EPA sampling activities were conducted during a 19-day period:

- 1. Indoor air sampling in all 96 trailers with each trailer sampled once on days 1 through 4. Sampling was done with all trailer doors and windows shut and with no indoor ventilation. Results of this sampling activity are referred to as "baseline" throughout this report.
- 2. Indoor air sampling in half (48) of the trailers with air conditioning running and set to approximately 72° Fahrenheit on days 6 through 19. All doors and windows were shut, and bathroom static vents were open but the exhaust fans were not running. This is referred to as "Method A" by FEMA and in this report is referred to as "air conditioning."
- 3. Indoor air sampling in half (48) of the trailers with all windows open on days 6 through 19. Static vents and exhaust vents were open but the exhaust fans were not running. No air conditioning was operated. This is referred to as "Method B" by FEMA and in this report is referred to as "windows open."

During days 6 through 9, two 1-hour air samples were collected per day from each trailer (one morning sample and one afternoon or evening sample). For days 10 through 19, a single 1-hour air sample was collected from each trailer per day (either in the morning or in the afternoon or evening).

In addition to formaldehyde sampling, 24-hour air sampling for volatile organic compounds (VOC) was conducted once in each trailer during the baseline sampling period and again on day 19.

Other information collected during each sampling event included: ambient (outdoor) temperature, humidity, barometric pressure, wind direction and speed, and general meteorological conditions. Indoor air temperature and relative humidity also were measured.

EPA sampling method TO-11A was used for 1-hour formaldehyde sample collection. The air sample flow rate was 0.25 liters/minute. Flow rate was tested and calibrated pre- and post-air sample collection. Modified EPA sampling method T0-15-LL was used for 24-hour VOC collection.

Quality assurance samples consisted of:

- four ambient samples collected during each indoor sampling day (formaldehyde and VOC, only when sampled in the trailers),
- daily duplicate or co-located samples collected at a minimum of 10% of the sampling locations (formaldehyde only),
- daily split samples (i.e., a third sample analyzed at a different laboratory) collected at a minimum of half of the duplicate sample locations (formaldehyde only),

- one trip blank collected for each sampling day (formaldehyde only), and
- one field blank per sampling team collected for each sampling day (formaldehyde only). Laboratories were instructed to fulfill all quality assurance and quality control (QA/QC) requirements of the method.

ATSDR evaluated the sampling QA/QC data, and a detailed description of quality assurance results and analysis is presented in Appendix A. ATSDR concluded that the field sampling QA/QC procedures and results were within the limits specified by the EPA sampling method. No summary of laboratory QA/QC results were provided for review. Therefore, the assumption was made that the data provided to ATSDR met laboratory QA/QC standards. Appendix B provides a detailed description of the statistical methods used in the data analysis.

Quality assurance samples and blanks were inadvertently included in the calculations for the February 2007 health consultation but are not included in the calculations for the current report.

#### **Results**

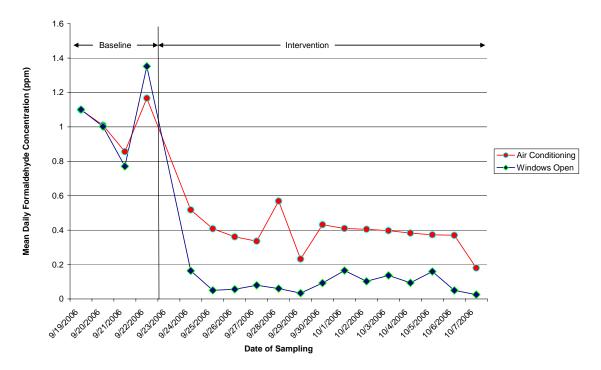
During baseline sampling, formaldehyde levels averaged 1.04 ppm (range, 0.01–3.66 ppm). With air conditioning running, formaldehyde levels fell to an average of 0.39 ppm and remained relatively stable for the remainder of the two-week sampling period as air conditioning continued to run. With windows opened, formaldehyde levels fell to an average of 0.09 ppm and remained relatively stable for the remainder of the two-week sampling period as the windows remained open. Summary results are shown in Table 6, and the time course of changes in formaldehyde levels is graphed in Figure 1. Additional data are presented in Appendix B. The table in Appendix C summarizes the results of the daily air monitoring by intervention and correct the table included in the February 2007 consultation by eliminating the blanks and quality assurance specimens from the statistical analysis.

Table 6. EPA Sampling at FEMA Temporary-Housing Trailers: Formaldehyde Levels in Test Units (ppm)

Test Condition	Number of Observations	Mean	Std Dev	Minimum	Median	Maximum
Baseline	96	1.04	0.69	0.01	1.06	3.66
Air conditioning	852	0.39	0.27	0.00	0.34	1.63
Windows open	863	0.09	0.08	0.01	0.07	0.49

Figure 1. EPA Sampling at FEMA Temporary-Housing Trailers: Mean Daily Formaldehyde Level by Intervention Method

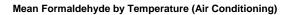
#### Mean Daily Formaldehyde Level by Intervention Method



ATSDR's analyses indicated an association between room temperature and formaldehyde levels; formaldehyde levels increased as room temperatures increased. This association was seen only in units with closed windows. Figures 2 and 3 show the association between temperature and mean daily formaldehyde levels for both intervention methods. Figure 2 shows that formaldehyde levels were associated with room temperature levels at baseline and when the air conditioning was running. This result is highly statistically significant (p<0.0001).

16

Figure 2. EPA Sampling at FEMA Temporary-Housing Trailers: Mean Formaldehyde Level by Room Temperature (Air Conditioning)



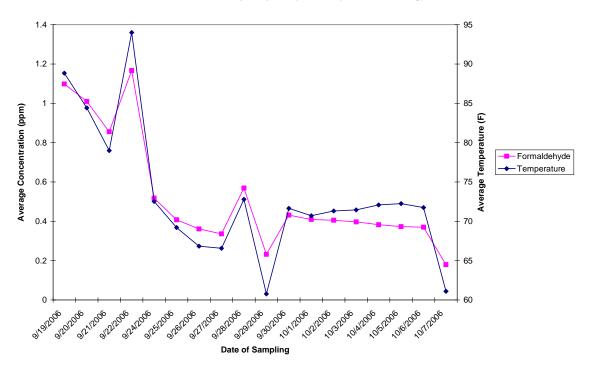


Figure 3 shows that when the windows were opened, formaldehyde levels were unrelated to room temperature.

Figure 3. EPA Sampling at FEMA Temporary-Housing Trailers: Mean Formaldehyde Level by Room Temperature (Windows Open)

Mean Formaldehyde by Temperature (Windows Open)

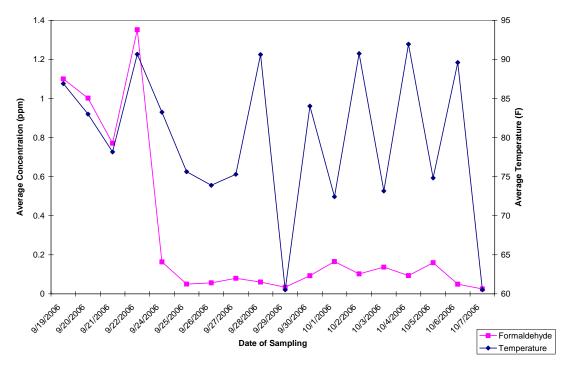
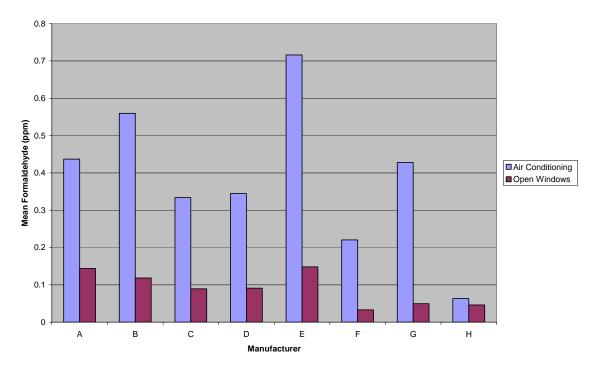


Figure 4 shows the relationship between the eight trailer manufacturers in the study (labeled A-H) and mean formaldehyde levels, by intervention method. A statistically significant difference was observed in mean formaldehyde level between manufacturers. However, mean formaldehyde levels were lower in trailers with open windows regardless of manufacturer. The details of this analysis are provided in Appendix B.

Figure 4. EPA Sampling at FEMA Temporary-Housing Trailers:
Mean Formaldehyde Level by Manufacturer and Intervention Method



#### Mean Formaldehyde by Manufacturer and Intervention Method

#### **Discussion**

During the baseline sampling, formaldehyde levels ranged from 0.01 to 3.66 ppm with an average of 1.04 ppm. Some of these levels exceed the odor threshold, and exposures at the upper end of these concentrations would be noticeable to many people. Levels of formaldehyde found in the trailers during baseline sampling were sufficiently high to cause acute health symptoms (e.g., headache; eye, nose, and throat irritation; tearing; and burning sensations in exposed persons).

Following the implementation of each intervention—air conditioning or windows open—formaldehyde levels declined within two days and remained stable. There was a substantial decline with each intervention. However, at the upper end of the range during air conditioning, people might still experience the same health symptoms described above. Allergic sensitization to formaldehyde may also occur. Risk of cancer will increase with increased formaldehyde concentration and duration of exposure. Moreover, long-term exposures even at the lower levels that followed both interventions might increase the possibility of reproductive or developmental toxicity. Additional research is needed to better clarify the potential reproductive and developmental toxicity of formaldehyde.

Air samples also were collected for volatile organic compounds. These data along with outdoor formaldehyde sampling results were not analyzed for this report.

#### Limitations

This report is based on EPA environmental air sampling data from 96 trailers. The results should not be generalized to other trailers, occupied or unoccupied, or to other ventilation conditions. The report provides data on new, unoccupied trailers only, and only under specific conditions—when the trailers have been closed, and during the two weeks following simple ventilation measures (air conditioning or opening windows). It does not provide data on occupied trailers in the Gulf region under conditions of actual use. Further measurements are needed to assess levels of formaldehyde under actual use conditions.

Different trailers, even from the same manufacturer, had different characteristics. We could not verify that all trailers within a manufacturer group had identical ventilation characteristics, design, or materials. Therefore, the effect of design and construction differences cannot be assessed from this data set.

This report provides an assessment of environmental data only. Because this consultation is not looking at human exposures, it does not define a level of concern. It does not address whether health problems are associated with formaldehyde or with other exposures in trailers, such as from other volatile organic compounds, mold, cleaning products, tobacco smoke, and carbon monoxide. A health study that examines exposures and health outcomes would be needed to address this set of questions.

#### **Conclusions**

These analyses support the conclusion of the February 2007 health consultation that running air conditioning with the vents open (but exhaust fans not running) or opening windows decreases formaldehyde levels in trailers. Opening windows is more effective that relying on air conditioning alone. Formaldehyde levels varied by manufacturer among the trailers examined in this activity. The formaldehyde levels increased with room temperature in the trailers using air conditioning. Exposure to the formaldehyde levels found during the baseline sampling and some of the higher values found in both intervention methods can result in acute health symptoms: headaches, eye, nose, and throat irritation; tearing; and burning sensations. Allergic sensitization to formaldehyde may also occur. Moreover, long-term exposures even at the lower levels that followed both interventions might increase the possibility of cancer or reproductive or developmental toxicity. Additional research is needed to better clarify the potential reproductive and developmental toxicity of formaldehyde.

#### Recommendations

Efforts to characterize exposure conditions and potential health effects in occupied FEMA trailers are warranted. Likewise, effective interventions to reduce the levels of formaldehyde and duration of exposure and potential health effects should be identified. Additional research is needed to better clarify the potential reproductive and developmental toxicity of formaldehyde.

#### References

- 1. Agency for Toxic Substances and Disease Registry. Managing Hazardous Materials Incidents, Medical Management Guidelines for Acute Chemical Exposures, Formaldehyde. Atlanta: US Department of Health and Human Services; 2001.
- 2. Agency for Toxic Substances and Disease Registry. Toxicological Profile for Formaldehyde. Atlanta: US Department of Health and Human Services; 1999.
- 3. Sexton K, Petreas MX, Llu KS. Formaldehyde exposures inside mobile homes. Environ Sci Technol 1989;23:985-8.
- 4. Gammage RB, Hawthorne AR. Current Status of Measurement Techniques and Concentrations of Formaldehyde in Residences. Advances in Chemistry Series; Washington, DC; American Chemical Society; 1985;210:117-130.
- 5. US Environmental Protection Agency. Assessment of health risks to garment workers and certain home residents from exposure to formaldehyde. Washington DC: Office of Pesticides and Toxic Substances; 1987.
- 6. Hawthorne AR, Gammage RB, Dudney CS. An indoor air quality study of 40 east Tennessee homes. Environ Int 1986;12:221-39.
- 7. Hare DA, Groah WJ, Schweer LG, et al. Evaluating the contribution of UF-bonded building materials to indoor formaldehyde levels in a newly constructed house. Presented at Washington State University 30<sup>th</sup> Annual Particleboard/Composite Materials Symposium; 1996; Pullman, Washington.
- 8. Gold KW, Naugle DF, Berry MA. Indoor concentrations of environmental carcinogens. In: Seifert B, van de Wiel HJ, O'Neill IK, editors. Environmental carcinogens: Methods of analysis and exposure measurement (IARC Scientific Publications No. 109). Lyon: International Agency for Research on Cancer; 1993:41-71.
- 9. TOXNET [database on the Internet]. Bethesda (MD): National Library of Medicine (US); Hazardous Substances Data Bank, Formaldehyde. [cited 2007 Sep 24]. Available from: http://toxnet.nlm.nih.gov.
- 10. Burkhart KK, Kulig KW, McMartin KE. Formate levels following a formalin ingestion. Vet Hum Toxicol 1990;32:135-137.
- 11. Eels JT, McMartin KE, Black K, et al. Formaldehyde poisoning: Rapid metabolism to formic acid. JAMA 1981;246:1237-8.
- 12. Alexandersson R, Hedenstierna G. Respiratory hazards associated with exposure to formaldehyde and solvents in acid-curing paints. Arch Environ Health 1988;43:222-7.

- 13. Alexandersson R, Hedenstierna G. Pulmonary function in wood workers exposed to formaldehyde: A prospective study. Arch Environ Health 1989;44:5-11.
- 14. Bracken MJ, Leasa DJ, Morgan WKC. Exposure to formaldehyde: Relationship to respiratory symptoms and function. Can J Public Health 1985;76:312-16.
- 15. Khamgaonkar MB, Fulare MB. Formaldehyde induced symptoms in medical laboratories. Indian J Ind Med 1992;38:129-31.
- 16. Krzyzanowski M, Quackenboss JJ, Lebowitz MD. Chronic respiratory effects of indoor formaldehyde exposure. Environ Res 1990;52:117-25.
- 17. Malaka T, Kodama AM. Respiratory health of plywood workers occupationally exposed to formaldehyde. Arch Environ Health 1990;45:288-294.
- 18. Holness DL, Nethercott JR. Health status of funeral service workers exposed to formaldehyde. Arch Environ Health 1989;44:222-8.
- 19. Wantke F, et al. Exposure to gaseous formaldehyde induces IgE-mediated sensitization to formaldehyde in school-children. Clin.Exp.Allergy 1996;26(3):276-80.
- 20. Garrett MH, Hooper MA, Hooper BM, Rayment PR, Abramson MJ. Increased risk of allergy in children due to formaldehyde exposure in homes. Allergy 1999;54(4):330-7.
- 21. Tarkowski M, Gorski P. Increased IgE antiovalbumin level in mice exposed to formaldehyde. Int Arch Allergy Immunol 1995;106:422-4.
- 22. Riedel F, Hasenauer E, Barth PJ, et al. Formaldehyde exposure enhances inhalative allergic sensitization in the guinea pig. Allergy 1996;51:94-9.
- 23. Sheppard D, Eschenbacher W, Epstein J. Lack of bronchomotor response to up to 3 ppm formaldehyde in subjects with asthma. Environ Res 1984;35:133-9.
- 24. Krzyzanowski M, Quackenboss JJ, Lebowitz M. Chronic respiratory effects of indoor formaldehyde exposure. Environ Res 1990;52:117–25.
- 25. Czap C, Nicolai T, Wolf R, Von Mutius E. Asthma, bronchial hyperactivity and formaldehyde exposure in children living near a chip-board factory. Eur Respir J 1993;6(Suppl. 17):S235.
- 26. Norbäck D, Björnsson E, Janson C, Widstrom J, Boman G. Asthmatic symptoms and volatile organic compounds, formaldehyde, and carbon dioxide in dwellings. Occup Environ Med 1995;52:388–95.
- 27. Garrett M, Hooper M, Hooper B. Low levels of formaldehyde in residential homes and a correlation with asthma and allergy in children. Proceedings of the 7th International Conference on Indoor Air Quality and Climate. 1996 Jul 21-28; Nagoya, Japan. Indoor Air Japan,

- Organizing Committee of the 7th International Conference of Indoor Air Quality and Climate 1996;1:617-22.
- 28. Rumchev, KB, et al. Domestic exposure to formaldehyde significantly increases the risk of asthma in young children. Eur.Respir.J 2002;20(2):403-8.
- 29. National Toxicology Program. Report on Carcinogens, Eleventh Edition. Washington DC: US Department of Health and Human Services; 2005. Available from: <a href="http://ntp.niehs.nih.gov/ntp/roc/toc11.html">http://ntp.niehs.nih.gov/ntp/roc/toc11.html</a>.
- 30. International Agency for the Research on Cancer, Formaldehyde, 2-Butoxyethanol and 1-*tert*-Butoxypropan-2-ol [monograph on the Internet]. Lyon, France: World Health Organization; 2006. [cited 2007 Sep 27]. Available from: <a href="http://monographs.iarc.fr/ENG/Monographs/vol88/volume88.pdf">http://monographs.iarc.fr/ENG/Monographs/vol88/volume88.pdf</a>.
- 31. Thrasher JD, Kilburn KH. Embryotoxicity and teratogenicity of formaldehyde. Arch Environ Health 2001;56:300-11.
- 32. Collins JJ, Ness R, Tyl RW, Krivanek N, Esmen NA, Hall, T. A review of adverse pregnancy outcomes and formaldehyde in human and animal studies. Reg Tox Pharm 2001;34: 17-34.

## Appendix A

#### **Quality Assurance and Quality Control Evaluation of 1-Hour Formaldehyde Sampling**

This evaluation covered field sampling QA/QC procedures and results. It does not evaluate laboratory QA/QC results; no summary of laboratory QA/QC results were provided for review. Therefore, the assumption was made that the data provided to ATSDR met laboratory QA/QC standards.

The sampling scheme and analytical methods are described in detail in the main body of the report and are not repeated here.

#### Summary:

- 1) The air sample flow rates (0.25 liters/minute) were below those recommended in EPA Method TO-11A (1–2 liters/minute). Although sampling rates as low as 0.1 liters/minute are acceptable, appropriate sampling rate and time depend upon contaminant concentrations in the atmosphere. For example, a lower air sample flow rate might result in a higher detection limit. Conversely, lower concentrations of the analyte might not be detected if the air sampling flow rate is low, the sampling period is short, or the concentrations in air are low. The low flow rate does not appear to be a problem in this study because indoor formaldehyde levels were high enough to be detected using the protocol's air sample flow rate and volume.
- 2) All field and trip blank formaldehyde results were below typical filter cartridge background levels.
- 3) Duplicate-sample mean formaldehyde values were within acceptable QA limits; however, there were a few outliers.
- 4) Front and back filter analysis did detect formaldehyde breakthrough. However, levels in the back filter were below typical cartridge background levels.
- 5) No information was provided to explain why 22 samples (13 primary samples, plus QC samples and blanks) had no laboratory results (e.g., damaged during shipment or lab error).
- 6) All samples reviewed in this analysis were results from one laboratory (Air Toxics Ltd.). Results from a second laboratory were not evaluated because results were provided in  $\mu$ g formaldehyde (e.g., not  $\mu$ g/m³ or ppb). In addition, analyzing split samples from a second laboratory is not part of EPA Method TO-11A QA/QC requirements.

The following QA/QC field samples were collected: 80 field blanks, 20 trip blanks, and 200 duplicates. In addition, the laboratory analyzed both the front and back halves of 111 filters.

#### Field and Trip Blanks

Appropriate numbers of field trip and field blank samples were collected during this sampling project. One trip blank was collected for each sampling day. One field blank per sampling team was collected for each sampling day.

Table A-1 displays results of field and trip blank laboratory analysis. For field blanks the mean formaldehyde result is 3.9 parts per billion (ppb); for trip blanks the mean formaldehyde concentration is 3.3 ppb. EPA Method TO-11A indicates typical formaldehyde background concentrations in the filter cartridges used is 8.0 ppb or less. Therefore, the field and trip blank samples collected in this sampling effort are within the required QA/QC limits.

Table A-1. EPA Sampling at FEMA Temporary-Housing Trailers: Field and Trip Blank Formaldehyde Analytical Results

Sample Type	Number of Samples	Range (ppb)	Mean (Median) (ppb)	SD ppb	Typical Cartridge Background <sup>+</sup>
Field blank	80	0.0-7.1	3.9 (3.7)	1.2	< 8.0 ppb
Trip blank	20	0.0-7.7	3.3 (3.5)	1.7	< 8.0 ppb

ppb=parts per billion.

#### **Duplicate Air Samples (Co-located Samples)**

Analytical results of co-located samples were within QA/QC limits for the method. The mean and median relative percent difference (RPD) for sample pairs was 12% (standard deviation of 25%) and 6%, respectively. The RPD range was from 0 to 199%:

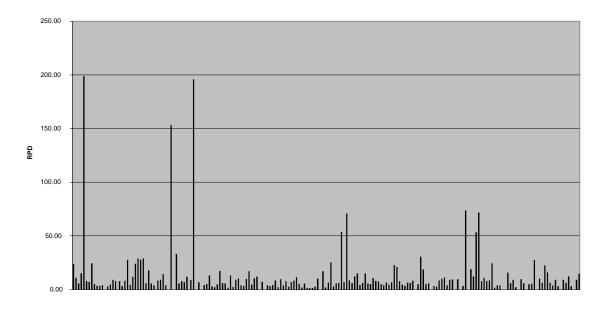
RPD=100[abs(duplicate 1-duplicate 2)/ (duplicate 1+duplicate 2)/2].

The method requires paired duplicate samples to have an absolute RPD no larger than 25%. Although several samples exceeded this RPD, the mean, standard deviation, and median results were within acceptable limits. Figure A-1 displays the RPD results of samples collected for this project.

EPA Method TO-11A requires collecting a duplicate sample for each sampling event. The number of duplicate samples collected in the FEMA trailer project exceeded this QA/QC requirement.

<sup>&</sup>lt;sup>†</sup>EPA Method T0-11A: Typical DNPH-cartridge specifications. Background formaldehyde concentration per cartridge < 8.0 ppb.

Figure A-1. EPA Sampling at FEMA Temporary-Housing Trailers: Relative Percent Difference of Duplicate 1-Hour Formaldehyde Sample Results



#### Front and Back Filter Analysis

The sample cartridges contained two separate filters (front and back). In normal sample analysis, both halves of the filter are combined and the contaminant concentration is calculated. In a certain percentage of filters sent for analysis, the front and back filters are analyzed separately. The purpose of this analysis is to determine if the contaminant is detected on the back filter. If none or low levels of the contaminant are detected on the back filter, it means sample collection, handling, and shipment occurred properly. However, if a noteworthy level of contaminant is detected on the back filter, it means one of the following:

- The concentration of the contaminant in the air was too high for the air sample flow rate or the sample time. The front filter then became overloaded and the contaminant "broke through" to the back filter.
- Contaminant desorbed from the front filter was adsorbed on the back filter during sample handling and shipping. This can occur if samples are not kept below the appropriate temperature (4°C).

EPA Method TO-11A requires front and back filter analysis if there is a reason to expect breakthrough (e.g., high contaminant concentrations in air). If the back filter contaminant concentration exceeds 10% of the concentration on the front filter, analysis of front and back filters should continue throughout the monitoring program. If the contaminant is not detected above the average blank-sample level in the back filter after the first sampling event, additional front and back filter analysis is not required unless field sampling conditions change.

Fourteen of the 111 (12.6%) back filter analyses detected formaldehyde breakthrough. The mean and median concentrations detected on these 14 samples were 4.2 ppb (standard deviation 1.4 ppb) and 4.0 ppb, respectively. The range of formaldehyde concentrations was 0.8-5.8 ppb.

The concentrations found on the back filter are below typical filter background concentrations (8.0 ppb or less). The formaldehyde percent breakthrough in the 111 samples ranged from 0.0-1.2%. The mean and median percent breakthrough was 0.5% (standard deviation 1.9%) and 0.0%, respectively. The samples collected during this sampling project were within the specified acceptable limits.

## Appendix B

#### **Statistical Analysis**

#### **Key Results**

The following statistically significant results were observed:

- A decrease in mean formaldehyde levels occurred during the intervention phase of the study.
- Lower mean formaldehyde levels among trailers with windows open compared with trailers with windows closed and air conditioning systems running.
- An association between temperature and formaldehyde levels.
  - o Formaldehyde levels increased as temperatures increased.
  - o This association was stronger in units with closed windows.
- Differences in mean formaldehyde levels among manufacturers.

#### **Study Design**

Formaldehyde levels were measured in 96 trailers from 8 manufacturers during a 3-part study that spanned 19 days (4 days baseline, 1 day of no measurements, 4 days of twice daily sampling and 10 days of once daily sampling). Levels were first observed during a baseline phase spanning 4 days in which, on any given day, one-fourth of the trailers received one formaldehyde measurement in the afternoon. Baseline measurements were followed by a day of no measurements and then followed by the intervention phase of the study, which incorporated two sampling plans. During the first four days of the intervention sampling, morning and afternoon measurements were taken on each trailer daily. Half of the trailers were assigned to the air conditioning group, in which windows were closed and air conditioning was turned on, vents were open, but the exhaust fans were not on. The remaining trailers were assigned to the windows open group, in which air conditioning was turned off and all windows and vents were open but vent fans not running. During the last 10 days of the intervention sampling, 1 measurement was taken daily. Time-of-sample alternated between morning and afternoon according to odd or even numbered days.

#### **Missing Data**

There were 13 primary samples without lab results which were thus excluded from the analysis. These missing data points all occurred during the initial four sampling days of the intervention phase (12 from the air conditioning group and 1 from the windows open group).

#### **Unique Statistical Properties of These Data**

Because of the sampling design, the data had these unique properties:

- Clustering: multiple observations per trailer.
- Longitudinal: data collected over time.
- Non-normal: non-normally distributed data.
- Unbalanced: daily number and timing of samples varied throughout the sample collection.
- Balanced: equal numbers of trailers from each manufacturer were allotted to each phase of the study, and to each intervention method.
- Continuous and categorically independent variables.

#### **Statistical Methods**

Dependent Variable: The primary dependent (outcome) variable was formaldehyde level, expressed in parts per million.

*Independent Variables*: The primary independent variables were: intervention group (air conditioning vs. windows open), temperature, humidity, barometric pressure, manufacturer, study phase (baseline and intervention phases), and time of collection (morning vs. afternoon).

*Statistical Methods*: Analysis began by computing descriptive measures of the data including means, standard deviations, and ranges. Key relationships also were summarized graphically.

The primary focus of this analysis was comparing mean formaldehyde levels among various subsets of the data. In order to account for correlation in the data and to evaluate subgroup differences while controlling for covariates, a mixed model regression analysis was used. Mixed models are appropriate for clustered, longitudinal, and unbalanced data. They also appropriately account for potential correlation in the data. Correlated data can occur when a formaldehyde reading is affected by a reading during a previous time or day. To address the non-normality of the data, all regression models were run using log10-transformed formaldehyde values. Akaike's Information Criteria was used to compare covariance structures. An ARMA(1,1) was found to be most appropriate. Type III F-tests were used to determine regression parameters. These tests can be used to assess the statistical significance of a particular variable while accounting for covariates in the model. Variables were retained in the model based on their importance as confounders, effect modifiers, or their statistical association with the outcome. All mixed model regression analyses were performed using SAS Version 9 Proc Mixed.

#### **Results**

*Summary of Mean Levels by Key Subgroups*: Table B-1 presents the results of the analyses of mean formaldehyde levels by the various subgroups.

*Mean Formaldehyde and Phase of the Study*: Table B-1 shows that mean formaldehyde level dropped from 1.04 ppm at baseline, to 0.24 and 0.23 ppm during the subsequent intervention phases. The difference in mean values between baseline and intervention was statistically significant (Mixed Model F Statistic=231.38, p<0.0001).

Table B-1. EPA Sampling at FEMA Temporary-Housing Trailers: Subgroup Analysis of Formaldehyde Level (ppm)

	N #	Mean	Std Dev	Minimum	Median	Maximum
Study Phase						
Baseline	96	1.0444	0.6941	0.0053	1.0584	3.6638
Initial 4 days of intervention sampling	755	0.2436	0.2653	0.0042	0.1303	1.6284
Final 10 days of intervention sampling	960	0.2335	0.2376	0.0065	0.1466	1.3841
Intervention						
Method*						
Air conditioning	852	0.3879	0.2740	0.0042	0.3420	1.6284
Windows open	863	0.0899	0.0780	0.0065	0.0651	.4885
Manufacturer**						
Α	228	0.3373	0.3451	0.0075	0.2280	1.7098
В	227	0.4048	0.3902	0.0261	0.3012	2.4426
С	227	0.2630	0.2966	0.0042	0.1791	1.7098
D	225	0.2675	0.3483	0.0061	0.1710	3.6638
E	224	0.5028	0.4630	0.0155	0.3501	2.6054
F	226	0.1415	0.1754	0.0065	0.0684	1.1399
G	228	0.2630	0.2783	0.0053	0.1303	1.2213
Н	226	0.0665	0.0707	0.0052	0.0493	0.5129

	N #	Mean	Std Dev	Minimum	Median	Maximum
A.M.						
Initial 4 days of intervention sampling	377	0.2034	0.2086	0.0042	0.1303	1.4655
Final 10 days of intervention sampling	480	0.2113	0.1996	0.0065	0.1547	0.9770
P.M.						
Baseline	96	1.0444	0.6941	0.0053	1.0584	3.6638
Initial 4 days of intervention sampling	378	0.2838	0.3068	0.0130	0.1303	1.6284
Final 10 days of intervention sampling	480	0.2557	0.2686	0.0072	0.1384	1.3841

<sup>\*</sup>Results are for the intervention phase of the study.

\*\*Results are for the baseline and intervention phases combined.

# Number of observations.

Summary of Temperature, Humidity and Barometric Pressure Levels by Intervention Method: Table B-2 Summarizes the interior environmental conditions (i.e., temperature, humidity, and air pressure) during sampling by intervention.

Table B-2. EPA Sampling at FEMA Temporary-Housing Trailers: Interior Environmental Conditions by Intervention

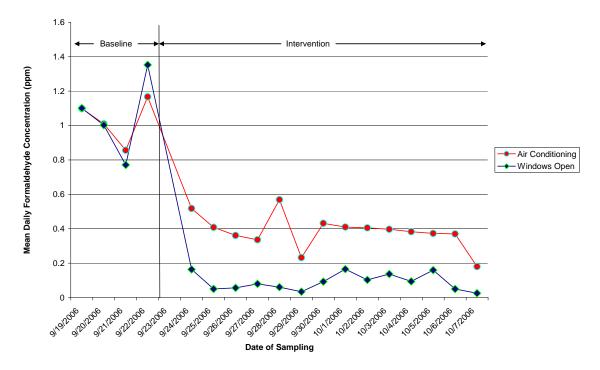
Phase of Study	N **	Mean	Std Dev	Minimum	Median	Maximum
Air Conditioning						
Start Temperature	900	69.5	6.5	57.8	70.7	94.0
Stop Temperature	900	70.1	6.5	59.0	71.0	97.0
Start Humidity	900	52.0	9.9	28.0	53.0	81.0
Stop Humidity	900	51.2	10.0	26.0	51.0	81.0
Start Pressure	900	761.8	1.7	757.0	762.0	765.0
Stop Pressure	900	761.8	1.7	753.0	762.0	765.0
Windows Open						
Start Temperature	911	76.6	10.9	57.8	79.7	93.0
Stop Temperature	911	78.4	11.6	58.0	82.0	95.0
Start Humidity	911	62.6	15.0	29.0	65.0	86.0
Stop Humidity	911	60.6	16.7	28.0	64.0	88.0
Start Pressure	911	761.8	1.7	757.0	762.0	765.0
Stop Pressure	911	761.8	1.7	757.0	762.0	765.0

<sup>\*\*</sup>Results are for the baseline and intervention phases combined

*Mean Daily Formaldehyde and Intervention Method*: Figure B-1 shows a graph of mean daily formaldehyde level by intervention method. Each point on the graph represents the mean of all formaldehyde readings taken during the day.

Figure B-1. EPA Sampling at FEMA Temporary-Housing Trailers:
Mean Daily Formaldehyde Level by Intervention Method

Mean Daily Formaldehyde Level by Intervention Method

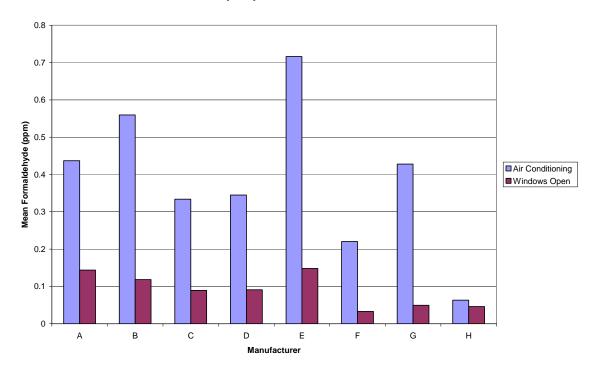


Daily mean formaldehyde levels were higher in trailers using air conditioning compared with trailers with windows open (0.39ppm vs. 0.09ppm). The difference was statistically significant (Mixed Model F Statistic=12.00, p=0.0008). Figure B-1 also illustrates the change in mean formaldehyde level between baseline and intervention phases of the study. Note that on September 29, 2006, and October 7, 2006, unusually low maximum daily temperatures occurred, accounting for the dip in the graph at those two points. Moreover, on those two days measurements were taken in the morning.

Mean Daily Formaldehyde Level and Manufacturer: Figure B-2 shows the relationship between manufacturer and mean formaldehyde levels, by intervention method. A statistically significant difference was observed in mean formaldehyde level among manufacturers. However, regardless of manufacturer mean, formaldehyde levels were lower in trailers with open windows. Manufacturer E recorded the highest mean daily levels (0.50 ppm) of formaldehyde and Manufacturer H recorded the lowest values (0.06 ppm) (see Table B-1). Note that it was not possible to verify that all trailers within a manufacturer's group were identical.

Figure B-2. EPA Sampling at FEMA Temporary-Housing Trailers: Mean Formaldehyde by Manufacturer and Intervention Method

Mean Formaldehyde by Manufacturer and Intervention Method

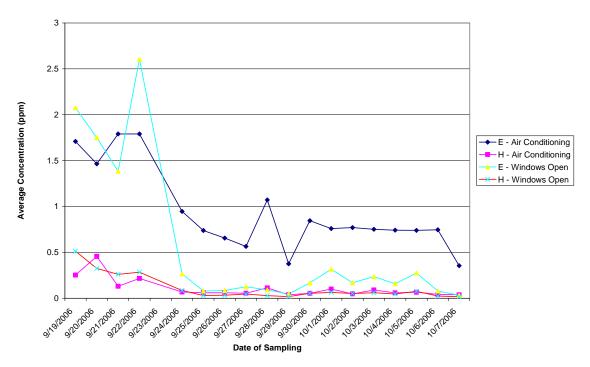


The difference in mean levels of formaldehyde among manufacturers is statistically significant (Mixed Model F Statistic=18.6, p<0.0001). Lacking additional manufacturer data, it was not possible to conduct extensive pair-wise tests. However, the highest and lowest ranked manufacturers, E and H, respectively, were compared.

Trailers from manufacturer E had statistically significantly higher formaldehyde levels than those from manufacturer H (Kruskal-Wallis=2.294, p<0.0109). Figure B-3 compares manufacturer E and manufacturer H. Supplementary data (photographic files) indicated that many H-trailers had air leaks. A follow-up analysis of leaking H-trailers in the air conditioning group found a statistically significant difference in mean formaldehyde levels between leaking and non-leaking trailers (0.058ppm vs. 0.073ppm; Wilcoxon Sum Rank=2213, p<0.0039).

Figure B-3. EPA Sampling at FEMA Temporary-Housing Trailers: Formaldehyde Level by Manufacturer and Intervention

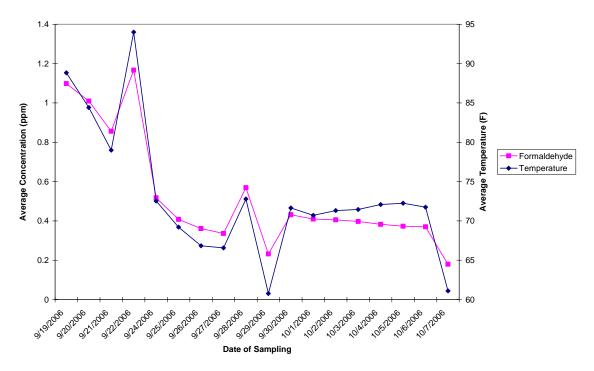




Mean Daily Formaldehyde Level and Temperature: Figures B-4 and B-5 show the association between room temperature and mean daily formaldehyde levels for the air conditioning and windows open interventions, respectively. Figure B-4 (air conditioning) shows that formaldehyde levels were associated with room temperature. This result was highly statistically significant (Mixed Model F Statistic=1151.69, p<0.0001).

Figure B-4. EPA Sampling at FEMA Temporary-Housing Trailers: Mean Formaldehyde by Room Temperature (Air Conditioning)

Mean Formaldehyde by Temperature (Air Conditioning)

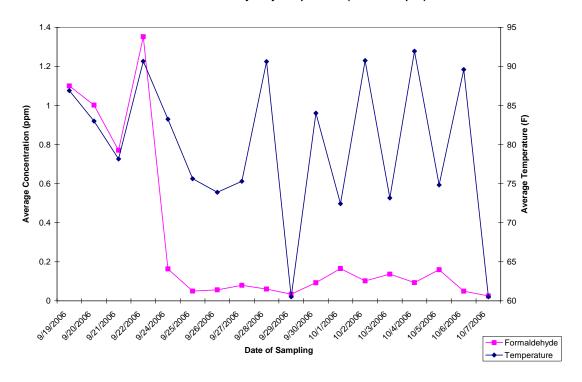


The mixed model regression analysis showed that the effect of temperature on mean formaldehyde levels varied by intervention method. In the windows open trailers, temperature had less effect on mean formaldehyde level than in the air conditioning trailers (Mixed Model F Statistic for Interaction=193.49, p<0.001).

Figure B-5 shows that Method B (windows open) formaldehyde levels were mostly invariant to temperature changes during the intervention phases (September 24 and onward).

Figure B-5. EPA Sampling at FEMA Temporary-Housing Trailers: Mean Formaldehyde by Room Temperature (Windows Open)

Mean Formaldehyde by Temperature (Windows Open)



Formaldehyde Level and Sampling Time: Although samples collected during the afternoons had higher mean formaldehyde levels than samples collected during the mornings (0.35 ppm versus 0.21ppm), the effect of sampling time was not statistically significant in the final regression models.

Mixed Model Regression Analysis Parameter Estimates: The expected log10-formaldehyde levels were modeled using mixed models (see Methods section for more detail). Regression analyses were done on both the entire dataset and on a subset consisting of only the intervention phases of the study. The tables of parameters for these analyses follow (Table B-3 and Table B-4).

Table B-3. EPA Sampling at FEMA Temporary-Housing Trailers: Mixed Model for All Phases of the Study

Effect	Estimate	Standard Error	DF	t Value	Pr >  t
Intercept	6.5345	2.6797	87	2.44	0.0168
Intervention Method					
Air Conditioning	0.8118	0.04424	87	18.35	<.0001
Windows open	0				-
Study Phase					
Baseline	0.5561	0.02639	189	21.07	<.0001
Phase 1	0.02930	0.01226	189	2.39	0.0179
Phase 2	0				
Manufacturer					
А	0.6773	0.08599	87	7.88	<.0001
В	0.7325	0.08600	87	8.52	<.0001
С	0.5206	0.08600	87	6.05	<.0001
D	0.5367	0.08601	87	6.24	<.0001
Е	0.8220	0.08602	87	9.56	<.0001
F	0.2239	0.08602	87	2.60	0.0109
G	0.4364	0.08599	87	5.07	<.0001
Н	0				
Temperature	0.01670	0.000786	1709	21.26	<.0001
Barometric Pressure	-0.01317	0.003487	1709	-3.78	0.0002
Relative Humidity	0.008538	0.000520	1709	16.42	<.0001

Table B-4. EPA Sampling at FEMA Temporary-Housing Trailers: Mixed Model for Intervention Phases of the Study

Effect	Estimate	Standard Error	DF	t Value	Pr >  t
Intercept	8.2214	1.9954	87	4.12	<.0001
Intervention Method					
Air conditioning	-0.3491	0.1008	87	-3.46	0.0008
Windows open	0				
Manufacturer					
А	0.6694	0.08672	87	7.72	<.0001
В	0.7153	0.08673	87	8.25	<.0001
С	0.4886	0.08673	87	5.63	<.0001
D	0.5239	0.08673	87	6.04	<.0001
Е	0.7953	0.08674	87	9.17	<.0001
F	0.2269	0.08674	87	2.62	0.0105
G	0.4263	0.08673	87	4.92	<.0001
Н	0				
Temperature	0.01709	0.000668	1615	25.58	<.0001
Temperature by Intervention Method - Interaction					
Air conditioning	0.01779	0.001279	1615	13.91	<.0001
Windows open	0				
Barometric Pressure	-0.01556	0.002606	1615	-5.97	<.0001
Relative Humidity	0.01025	0.000414	1615	24.73	<.0001

#### Appendix C

## A Correction of the Data Table in the February 2007 Health Consultation

Quality assurance samples and blanks were inadvertently included in the calculations for the February 2007 health consultation but were not included in the calculations for the current report. The following table (Table C-1) summarizes the results of the daily air monitoring by intervention and correct the table included in the February 2007 consultation by eliminating the blanks and quality assurance specimens from the statistical analysis.

Table C-1. EPA Sampling at FEMA Temporary-Housing Trailers: Formaldehyde in Test Temporary-Housing Units (ppm)

Date	Method	N	Mean	Std Dev	Minimum	Median	Maximum
09/19/06	Α	12	1.0985	0.6564	0.1303	1.2213	2.0355
09/20/06	Α	12	1.0096	0.5004	0.4152	0.8345	1.7098
09/21/06	Α	12	0.8557	0.6322	0.0505	0.7450	1.7912
09/22/06	Α	12	1.1665	0.7017	0.0749	1.0992	2.4426
09/24/06	Α	93	0.5174	0.3464	0.0052	0.5129	1.6284
09/25/06	Α	87	0.4079	0.2852	0.0042	0.3827	1.3841
09/26/06	Α	96	0.361	0.2571	0.0171	0.3094	1.2213
09/27/06	Α	96	0.3361	0.2434	0.0061	0.2850	1.1399
09/28/06	Α	48	0.5688	0.3602	0.0252	0.5455	1.3841
09/29/06	Α	48	0.2321	0.1460	0.0147	0.2117	0.6513
09/30/06	Α	48	0.4313	0.2647	0.0228	0.4112	1.1399
10/01/06	Α	48	0.4096	0.2364	0.0505	0.3664	0.9770
10/02/06	Α	48	0.4054	0.2549	0.0179	0.4152	0.9770
10/03/06	Α	48	0.3971	0.2376	0.0358	0.3786	0.9770
10/04/06	Α	48	0.3827	0.2370	0.0187	0.3827	1.0584
10/05/06	Α	48	0.3731	0.2299	0.0187	0.3501	0.9770
10/06/06	Α	48	0.3697	0.2382	0.0122	0.3582	1.0584
10/07/06	Α	48	0.1798	0.1072	0.0147	0.1547	0.4804

Table C-1. EPA Sampling at FEMA Temporary-Housing Trailers: Formaldehyde in Test Temporary-Housing Units (ppm), cont.

Date	Method	N	Mean	Std Dev	Minimum	Median	Maximum
09/19/06	В	12	1.1005	0.5953	0.3094	1.0992	2.2797
09/20/06	В	12	1.0021	0.6375	0.0075	1.1399	2.1169
09/21/06	В	12	0.7708	0.5467	0.1547	0.5414	1.5470
09/22/06	В	12	1.3520	1.1305	0.0053	1.3841	3.6638
09/24/06	В	95	0.1635	0.1093	0.0350	0.1384	0.4885
09/25/06	В	96	0.0503	0.0320	0.0106	0.0403	0.1547
09/26/06	В	96	0.0564	0.0320	0.0163	0.0480	0.1466
09/27/06	В	96	0.0796	0.0451	0.0187	0.0659	0.1954
09/28/06	В	48	0.0604	0.0349	0.0155	0.0537	0.1466
09/29/06	В	48	0.0342	0.0193	0.0106	0.0293	0.1058
09/30/06	В	48	0.0927	0.0530	0.0212	0.0806	0.2443
10/01/06	В	48	0.1651	0.1034	0.0350	0.1465	0.4559
10/02/06	В	48	0.1023	0.0614	0.0269	0.0814	0.2768
10/03/06	В	48	0.1368	0.0827	0.0285	0.1303	0.3664
10/04/06	В	48	0.0936	0.0649	0.0147	0.0855	0.2687
10/05/06	В	48	0.1594	0.0923	0.0432	0.1384	0.3827
10/06/06	В	48	0.0496	0.0326	0.0072	0.0460	0.1466
10/07/06	В	48	0.0254	0.0139	0.0065	0.0220	0.0773