

Health Consultation

Exposure Investigation

Environmental Monitoring for Formaldehyde

VERMONT FARM MANURE SITES

FRANKLIN COUNTY, VERMONT

Cost Recovery Number: AA6900

AUGUST 15, 2012

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

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In addition, consultations 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 site, 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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Prepared by:

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Agency for Toxic Substances and Disease Registry
Division of Community Health Investigations
Science Support Branch

Executive Summary

The Agency for Toxic Substances and Disease Registry (ATSDR), in cooperation with the Vermont Department of Health (VDH) and the Vermont Agency of Agriculture, Food and Markets (VAAFAM), conducted this Exposure Investigation (EI).

Some dairy farm owners in Vermont use solutions of formaldehyde to treat hairy heel wart disease in their cows. The cows walk through footbaths containing a 3 percent solution of formaldehyde. The waste formaldehyde solution from the footbath is then discharged into a drain, which empties into a manure pit on the farm. The liquid manure from this pit is sprayed on fields where corn and hay are grown. State agricultural regulations limit the spraying of manure on fields to the time period from April 1 to December 15 (VAAFAM 2012).

Some residents who live near these dairy farms have expressed concern over possible health effects from exposure to fugitive formaldehyde emissions from these operations. To investigate these concerns, we measured indoor and outdoor air concentrations of formaldehyde at two dairy farms in Franklin County, Vermont.

Air sampling was conducted from May 1 through June 1, 2012. We collected a total of 41 indoor air samples and 45 outdoor air samples at two farmhouses located on or near dairy farms that used formaldehyde footbaths or spread manure containing waste formaldehyde solutions on farm fields.

The concentrations of formaldehyde detected in indoor and outdoor air at the two farmhouses were similar to concentrations of formaldehyde detected in indoor and outdoor air in homes throughout the United States and Canada. These concentrations of formaldehyde were not at levels reported to cause adverse health effects.

The results from this investigation did not indicate that formaldehyde concentrations in outdoor air increased on days when manure from pits that received waste formaldehyde was spread on fields.

Introduction

In September 2011, ATSDR received a request for a Petitioned Health Assessment from a resident of Richford, Vermont. The petitioner stated that she had been experiencing respiratory and other health problems that she attributed to hazardous emissions from a nearby dairy farm. Other residents who live near dairy farms have expressed similar health concerns.

Some dairy farm owners use solutions of formaldehyde to treat papillomatous digital dermatitis, commonly known as hairy heel wart disease, in their cows. When entering or exiting the milking parlors, the cows are walked through footbaths containing a 3 percent solution of formaldehyde. The waste formaldehyde solution from the footbath is discharged into a drain, which empties into a manure pit on the farm property. The liquid manure from this pit is spread on fields where corn and hay are grown.

The petitioner expressed concern to ATSDR that formaldehyde in air from these operations is migrating onto their property and affecting their health, as well as the health of their neighbors. Residents have expressed similar concerns to the Vermont Department of Health (VDH) and the Vermont Agency of Agriculture, Foods and Markets (VAAFM). In March 2012, the VDH and VAAFM requested ATSDR to assist them in their investigation of the potential health impact of exposures to formaldehyde from dairy operations.

ATSDR agreed to collaborate with the VDH and VAAFM and conduct an Exposure Investigation (EI) to assess potential exposures to formaldehyde in air near dairy farms that use formaldehyde footbaths or spread manure containing waste formaldehyde solutions.

Project Overview

Purpose

The purpose of this EI was to determine whether indoor or outdoor air concentrations of formaldehyde were at levels of health concern for residents living on or near a dairy farm that used formaldehyde footbaths or spread manure containing waste formaldehyde solutions.

To address this question, air monitoring and analyses were conducted using validated, analytical methodologies with appropriate quality assurance/quality control (QA/QC). The participants of this EI were self-selected residents who could be exposed to formaldehyde from dairy farm operations. The test results from this investigation are specific to the participants and are not generalizable to the community-at-large or to other populations.

Investigators and Collaborators

The ATSDR Science Support Branch (SSB) was the lead for this Exposure Investigation. ATSDR collaborated with the Vermont Department of Health (VDH) and the Vermont Agency of Agriculture, Food, and Markets (VAAFAM) in conducting the field activities for this EI. Bureau Veritas, a private contract laboratory, analyzed the air samples. Bureau Veritas is accredited by the American Industrial Hygiene Association and follows NIOSH data quality objectives in its analyses.

ATSDR/SSB:

- (1) Developed the EI protocol (Appendix A) and consent form for environmental testing
- (2) Secured informed consent for environmental testing from the participants
- (3) Conducted the air sampling with the assistance of staff from the VDH and VAAFAM
- (4) Evaluated the analytical test results
- (5) Notified the participants of their individual test results and interpreted what they mean
- (6) Wrote this report that summarizes the EI findings

The VDH and VAAFAM:

- (1) Identified and recruited participants
- (2) Assisted ATSDR in conducting the air sampling
- (3) Provided and maintained a meteorological station for measuring and recording air temperature, wind speed/direction, and humidity

The Bureau Veritas Laboratory:

- (1) Provided equipment and supplies for collecting the air samples
- (2) Analyzed the air samples for formaldehyde using NIOSH analytical Method 2016

Methods

Selecting participants

The VDH, in collaboration with the VAAFM, selected two dairy farms in Franklin County for testing. ATSDR/VDH staff obtained informed consent from the owners to conduct air monitoring inside and outside of their homes (Appendix A). We also administered a questionnaire (Appendix B) to obtain information about possible sources of formaldehyde inside their houses.

The first property (Farm 1) was a dairy farm that did not use formaldehyde footbaths. However, other farms surrounding this farm spread manure on their fields that they hauled in from another farm that did use formaldehyde footbaths. Thus, the farms surrounding Farm 1 were a potential source of formaldehyde emissions.

The second property (Farm 2) was also a dairy farm. The owner of this farm used formaldehyde footbaths and discharged the waste formaldehyde solutions to his manure pit. The manure pit for this farm was located about 100 yards from the farmer's house. The manure from this pit was spread on the farmer's fields.

Field activities

Vermont state law prohibits the spraying of manure on fields between December 15 and April 1. This regulation was enacted to prevent the runoff of manure wastes from frozen ground into surface streams and bodies of water. In 2012, the state permitted manure spreading after March 22 because of the early arrival of warm spring weather. This EI was conducted from May 1 to June 1, 2012, a period of active manure spreading. Prior to testing, VAAFM staff met with dairy farmers to find out about their use of formaldehyde footbaths and select the farms for testing.

Sampling was conducted at each farmhouse 5 days a week (Monday through Friday) for 5 weeks at Farm 1 and four weeks at Farm 2. Sampling was also conducted on one Saturday when manure was being spread. ATSDR staff set up the air sampling equipment and worked with VDH and VAAFM staff to conduct the first week of sampling. For the remainder of the sampling period, VDH and VAAFM staff conducted the sampling as described below.

To assist us with data interpretation, the EI participants filled out a 3-question daily log sheet throughout the sampling period (Appendix C). The responses to the three questions provided information about manure spreading at the farm, odors, and self-reported health effects.

Air Sampling Procedures

Air sampling and analysis was conducted in accordance with NIOSH Method 2016 for formaldehyde (NIOSH, 2003). The sampling unit consisted of a low flow air sampling pump (Gilian LFS-113 DC pump) connected to the sampling tube with Tygon® tubing. We used SKC Formaldehyde tubes (No. 226-119), which contain silica gel with ultra-low background coated with 2,4-dinitrophenylhydrazine (2,4-DNPH). The tubes contained a back-up sorbent section to detect breakthrough, if it occurred.

We collected one indoor air sample and one outdoor air sample for about 8-hours each day of testing. The indoor air sample was collected in a living area at breathing zone height (4-5 feet). We collected the outdoor air sample on the same side of the house where the indoor air sample was collected. The outdoor air sample was also collected at about breathing zone height.

ATSDR/VDH/VAAFM staff visited the houses each day at an agreed upon time to conduct the sampling. Prior to collecting the air sample, each day we calibrated the pumps to an airflow rate of about 50-55 ml/minute using a digital airflow calibrator (Bios Defender 510-L). The pump was programmed to automatically shut down if the air flow rate changed by more than five percent. Over an 8-hour sampling time, an air volume of about 24 liters was sampled. For these sample parameters, the laboratory limit of detection (LOD) for formaldehyde concentrations in air was about 3 – 4 parts per billion (ppb).

At the end of a sampling event, the sample tube was removed, capped, sealed in a zip-lock bag, and placed on ice packs. In addition, we prepared one field blank for each week of testing. To protect the anonymity of the participants, the samples were labeled with a coded identification number.

Sample handling and shipping

After collection, the air sampling cartridges were stored at refrigerator temperature. It has been documented that samples are stable for at least 34 days at 5 °C (NIOSH, 1994). Each Monday, the sampling tubes from the previous week were placed in a shipping container with ice packs and a chain-of-custody form, and shipped by overnight delivery to the Bureau Veritas laboratory in Novi, Michigan, for analysis.

Lab processing and analysis

The air cartridges were analyzed for formaldehyde using NIOSH Method 2016 (NIOSH, 2003). In this method, the 2,4-dinitrophenylhydrazone derivative of formaldehyde is analyzed using HPLC with a UV detector. Ketones and other aldehydes can react with 2,4-DNPH; however, the derivatives formed are separated from the formaldehyde derivative by HPLC. QA/QC procedures, as specified in NIOSH method 2016, were followed.

Results

The concentrations of formaldehyde detected in indoor and outdoor air samples from this investigation are listed in Table 1. No formaldehyde was detected in any of the field blanks.

Table 1. Concentrations of formaldehyde (ppb) in indoor and outdoor air

| Date | Farmhouse 1 | | | Farmhouse 2 | | |
|--------|-------------|---------|---------------------------------|-------------|---------|---------------------------------|
| | Indoor | Outdoor | Manure Spreading ⁽¹⁾ | Indoor | Outdoor | Manure Spreading ⁽¹⁾ |
| May 1 | 15 | < LOD | no | ns | ns | no |
| May 2 | ns | < LOD | no | ns | ns | no |
| May 3 | ns | < LOD | no | ns | ns | no |
| May 4 | 17 | < LOD | no | ns | ns | no |
| May 7 | 12 | < LOD | no | ns | ns | no |
| May 8 | 11 | < LOD | no | ns | ns | no |
| May 9 | 11 | < LOD | no | 15 | < LOD | no |
| May 10 | 13 | < LOD | no | 17 | < LOD | no |
| May 11 | 14 | < LOD | no | 15 | < LOD | no |
| May 14 | 12 | < LOD | no | 16 | < LOD | no |
| May 15 | 13 | < LOD | no | 20 | < LOD | no |
| May 16 | 10 | < LOD | no | 13 | < LOD | no |
| May 17 | 12 | < LOD | no | 14 | < LOD | no |
| May 18 | 9 | < LOD | no | 11 | < LOD | no |
| May 21 | < LOD | < LOD | no | 9.4 | < LOD | no |
| May 22 | < LOD | < LOD | no | 14 | < LOD | no |
| May 23 | 6.8 | < LOD | no | 24 | < LOD | no |
| May 24 | < LOD | < LOD | yes | 15 | < LOD | yes |
| May 25 | < LOD | < LOD | yes | 19 | < LOD | yes |
| May 26 | < LOD | 4 | yes | 28 | < LOD | no |
| May 28 | 4.2 | < LOD | yes | ns | ns | no |
| May 29 | 6.4 | 4.1 | no | 28 | 5.7 | no |
| May 30 | < LOD | < LOD | no | 32 | < LOD | no |
| May 31 | < LOD | < LOD | no | 44 | < LOD | no |
| June 1 | 4.7 | < LOD | no | 47 | < LOD | no |

⁽¹⁾ Days that manure that contained waste formaldehyde from footbaths was spread on fields

ns = not sampled

LOD = limit of detection

Farm 1 did not use formaldehyde footbaths. However, some of the surrounding farms spread manure on their fields that they hauled in from another farm that did use formaldehyde footbaths.

Farm 2 did use formaldehyde footbaths and discharged the waste formaldehyde from the footbaths to its manure pit. The manure pit was located about 100 yards from the farmhouse.

At Farmhouse 1, 16 of 23 indoor air samples contained formaldehyde above the limit of detection. At Farmhouse 2, all 18 indoor air samples contained formaldehyde above the limit of detection.

Three of 45 outdoor air samples contained formaldehyde at a concentration above the limit of detection. Two outdoor air samples from Farmhouse 1 contained formaldehyde at 4.0 and 4.1 ppb, and one outdoor air sample from Farmhouse 2 contained formaldehyde at 5.7 ppb.

Summary statistics for the concentrations of formaldehyde detected in indoor and outdoor air samples are presented in Table 2.

Table 2: Formaldehyde concentrations (ppb) in indoor and outdoor air

| Location | Indoor Air | | Outdoor Air | |
|-------------|------------|-----------|-------------|-----------|
| | Median | Range | Median | Range |
| Farmhouse 1 | 9 | <LOD - 17 | < LOD | <LOD - 4 |
| Farmhouse 2 | 16 | 13 – 47 | < LOD | < LOD - 6 |

LOD = limit of detection. The LOD varied slightly between samples depending on the pump rate and the length of sampling. The LOD ranged from 2.7 – 4.8 ppb.

The residents of the two farmhouses did not report any unusual odors or health effects during the sampling period.

Discussion

Formaldehyde is a colorless gas with a distinct, pungent odor. It is produced in the environment by the incomplete combustion of organic material and is a constituent of motor vehicle exhaust, cigarette smoke, wood smoke, and emissions from power plants and incinerators. In the air, the secondary formation of formaldehyde can occur as the result of oxidation of volatile organic compounds and from reactions between ozone and alkenes (especially terpenes).

Formaldehyde concentrations in outdoor air vary depending on location, traffic, season of the year, weather, and other conditions. In outdoor air, formaldehyde concentrations in unpolluted areas are typically less than 5 ppb (Table 2), although concentrations of 50 ppb or more have been reported in areas with heavy air pollution (ATSDR 1999).

In indoor air, major sources of formaldehyde are plywood and particleboard, decorative laminates, new carpets, latex paints, and urea-formaldehyde foam insulation. Formaldehyde is also found in many consumer products used in the home such as glues and adhesives, carpet cleaners, dishwashing liquids, fingernail polish, and other cosmetics. Tobacco smoking also contributes to indoor air concentrations of

formaldehyde. Small amounts of formaldehyde are formed in the human body as the result of normal, metabolic processes.

Indoor air concentrations of formaldehyde vary depending on the type of house construction, age of building, source materials in the house, temperature, humidity, air exchange rates, and other factors. Published studies have reported typical indoor air concentrations that range from about 10 – 40 ppb (Table 2). Formaldehyde concentrations in indoor air can reach 400 ppb or more (Gordon et al. 1999), especially in prefabricated or mobile homes built with plywood and pressed wood products that contain formaldehyde resins.

Table 3: Residential indoor and outdoor air concentrations of formaldehyde (ppb) in published studies

| Study | Indoor Median (ppb) | Outdoor Median (ppb) |
|--|-----------------------|----------------------|
| Vermont ⁽¹⁾ | 10.5 | |
| Windsor, Ontario ⁽²⁾ | 18.5 (NS) 25.5 (S) | 1.5 |
| Arizona (NHEXAS) ⁽³⁾ | 17.0 | 5.1 |
| Eastern and Southeastern US ⁽⁴⁾ | 36 (geometric mean) | 2 |
| Prince Edward Island ⁽⁵⁾ | 24.0 (NS) 31.0 (S) | |
| Los Angeles, Elizabeth, Houston (RIOPA) ⁽⁶⁾ | 16.8 (NS) | 5.4 |

NS = Nonsmoker

S = Smoker

⁽¹⁾ Bress, Vermont Department of Health 1993

⁽²⁾ Bell et al. 1994

⁽³⁾ Gordon et al. 1999; NHEXAS = National Human Exposure Assessment Survey

⁽⁴⁾ Hodgson et al. 2000; new houses, 1-2 months after completion

⁽⁵⁾ Gilbert et al. 2005

⁽⁶⁾ Hun et al. 2010; RIOPA = Relationships of Indoor, Outdoor, and Personal Air

Indoor Air

The median indoor air concentrations of formaldehyde detected in the two farmhouses (9 and 16 ppb) were similar to or below indoor air concentrations reported in other studies (Table 3). There was some variability in day-to-day concentrations of formaldehyde in indoor air. At Farmhouse 1, formaldehyde levels ranged from less than the limit of detection to 17 ppb; at Farmhouse 2, the formaldehyde levels ranged from 13 to 47 ppb. This variability could result from differences in indoor air exchange rates, depending on whether the windows were opened or closed. The highest indoor air formaldehyde concentrations at Farmhouse 2 were detected over a period of several days when the house was not occupied and windows remained closed.

Outdoor Air

The outdoor air concentrations of formaldehyde were below the limit of detection (3-4 ppb) except for three days when concentrations of 4.0, 4.1, and 5.7 ppb were measured. Formaldehyde was detected in two outdoor air samples that were collected on a day when no manure that contained formaldehyde wastes from footbaths was being spread. Formaldehyde was detected in one outdoor air sample collected on a day when manure with waste formaldehyde was being spread, but the manure spreading was on a field that was downwind of the air sampler. No formaldehyde was detected in four of the air samples, even though manure with waste formaldehyde was being spread on fields upwind of the air samplers. Thus, this investigation produced no evidence that spreading manure with waste formaldehyde had a detectable impact on outdoor air formaldehyde concentrations.

Health Implications

Formaldehyde is irritating to tissues and mucous membranes. Some people are more sensitive to its effects than others. The most common symptoms include irritation of the eyes, nose, and throat, along with increased tearing, which occurs at air concentrations of about 400 to 3,000 ppb (ATSDR 1999). One large study of people with asthma found that they may be more sensitive to the effects of inhaled formaldehyde than people without asthma; however, many studies show that asthmatics are not more sensitive (ATSDR 1999).

The median air concentrations of formaldehyde measured in outdoor and indoor air in this EI are below ATSDR's acute Minimum Risk Level (MRL) of 40 ppb (for exposures of 14 days or less) and below the intermediate MRL of 30 ppb (for exposures of 14 – 364 days). The median air concentrations of formaldehyde in indoor air (but not outdoor air) exceeded ATSDR's chronic MRL of 8 ppb (for continuous exposures of more than 1 year). However, it should be noted that the chronic MRL does not represent a level that has been shown to cause an adverse health effect. Rather, it represents a minimal Lowest Observed Adverse Effect Level (240 ppb) that was reduced by a 30-fold uncertainty factor.

To assist state health officials in assessing exposures to formaldehyde, the Department of Health and Human Services, CDC, EPA, and other government agencies issued a fact sheet that contained the following statements (CDC 2008):

“Acute and chronic health effects of formaldehyde vary depending on the individual. The typical threshold for development of acute symptoms due to inhaled formaldehyde is 800 ppb; however, sensitive individuals have reported symptoms at formaldehyde levels around 100 ppb.”

“Additional studies have also supported that health effects can occur in sensitized individuals at 100 ppb when they are chronically exposed to formaldehyde.”

Several epidemiological studies have examined cancer risks in workers with high level exposures to formaldehyde, such as industrial workers involved in formaldehyde production, resin production, or other industrial activities involving formaldehyde (WHO 2010). Some of these studies found more cases of cancer of the nose and throat (nasopharyngeal cancer) in workers than expected. In addition, some epidemiological studies have reported an association between occupational exposure to formaldehyde and myeloid leukemia, although the biological mode of action for this cancer is unknown (NRC 2011). Based on occupational epidemiological studies and other information, the National Toxicology Program classified formaldehyde as a known human carcinogen (NTP 2012).

Epidemiological studies have shown that exposure to high concentrations of formaldehyde in air (>1,000 ppb) is associated with cancer. However, there is considerable uncertainty in how to estimate risk from low level (ppb) environmental exposure to formaldehyde (NRC 2011, WHO 2010). In developing its indoor air quality guideline (40 ppb) for formaldehyde, Health Canada stated:

“Although formaldehyde is probably carcinogenic in humans, the cancer risk associated with lifelong exposures to that concentration of formaldehyde (*40 ppb*) is estimated to be negligible.” (Health Canada 2005)

The World Health Organization developed an indoor air guideline value of 0.1 mg/m³ (80 ppb) to protect against sensory irritation (WHO 2010). Although this short-term guideline (30-minutes) was developed to protect against acute exposure effects, they noted that it was also protective of chronic exposure effects. “The short-term guideline will also prevent effects on lung function as well as long-term health effects, including nasopharyngeal cancer and myeloid leukemia.” (WHO 2010)

The concentrations of formaldehyde measured in indoor and outdoor air in this EI are within the range detected in other published studies in the United States and Canada. Exposure to these background concentrations of formaldehyde has not been reported to cause adverse health effects in humans.

Limitations of Exposure Investigation

This EI was conducted at two dairy farms in Franklin County, Vermont during May 1 to June 1, 2012. During at least part of this time period, manure from pits that received waste formaldehyde was spread on fields near the farmhouses being tested. It is not known if these test results would be representative of other locations or other times of the year.

Notifying the Participants of the Test Results

ATSDR sent a letter to the EI participants with their test results and an explanation of what the results meant. The letter contained information for contacting an ATSDR staff person if they wanted to further discuss their test results.

Further Investigations

The Vermont Department of Health and Vermont Agency of Agriculture, Food, and Markets has conducted additional studies to measure concentrations of formaldehyde in air in milking parlors where formaldehyde footbaths are used. In addition, they conducted studies to measure the concentration of formaldehyde in manure samples. The results of these investigations will be presented in a separate state report.

Conclusions

- (1) The concentrations of formaldehyde detected in indoor and outdoor air at two farmhouses were similar to concentrations of formaldehyde detected in indoor and outdoor air in homes throughout the United States and Canada.
- (2) The indoor and outdoor air concentrations of formaldehyde detected in this EI were not at levels that have been reported to cause adverse health effects.
- (3) The results from this investigation did not indicate that formaldehyde concentrations in outdoor air were increased on days when manure from pits that received waste formaldehyde was spread on fields.

Acknowledgements

ATSDR thanks the families of the two dairy farms for their generous participation in this investigation.

ATSDR acknowledges the following staff from the Vermont Department of Health and Vermont Agency of Agriculture, Foods, and Markets for helping to plan this EI and conduct the field activities: William Irwin, Andy Chevrefils, Chris Kinnick, Chris Zuidema, Kate Crawford, Sarah Vose, Cary Giguere, Jeff Comstock, and Trevor Lewis.

Tarah Somers, ATSDR Region I, also assisted in planning and coordinating this EI and participated in the field activities.

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Appendix A



Exposure Investigation Protocol

Environmental Monitoring for Exposure to Formaldehyde

Vermont Farm Manure Site

Richford, Vermont

Cost Recovery Number AA6900

April 9, 2011

Prepared by:

Kenneth Orloff, PhD

ATSDR/DHAC/EISAB

INTRODUCTION

In September 2011, ATSDR received a request for a Petitioned Health Assessment from a resident of Richford, Vermont. The petitioner stated that she has been experiencing respiratory and other health problems that she attributes to hazardous emissions from a nearby dairy farm. Other residents of the state who live near dairy farms have expressed similar health concerns.

Some dairy farm owners use solutions of formaldehyde to treat hairy heel wart disease in their cows. The cows are periodically walked through footbaths containing a 3 percent solution of formaldehyde. The waste formaldehyde solution from the footbath is then discharged into a drain, which empties into a manure pit on the farm property. The liquid manure from this pit is sprayed on nearby fields where corn and hay are grown.

The petitioner expressed concern that formaldehyde from these operations is migrating onto her property and affecting her health, as well as the health of her neighbors. Furthermore, the petitioner stated that she purchased a home test kit for formaldehyde and measured indoor air concentrations in her home that were “off-scale” (> 0.8 ppm).

ATSDR cannot assess the health risk posed by this potential hazard because of the lack of verified environmental sampling data. Therefore, ATSDR is conducting this Exposure Investigation (EI) to collect data using approved analytical methodologies and appropriate quality assurance/quality control (QA/QC) data that can be used to assess these potential exposures.

PROJECT OVERVIEW

A. Purpose

The purpose of this EI is to measure indoor and outdoor air concentrations of formaldehyde at residential properties located near dairy farms that use formaldehyde footbaths.

The air monitoring and analyses will be conducted using validated, analytical methodologies with appropriate QA/QC. The results of this investigation will tell the residents if they are being exposed to formaldehyde in air at concentrations of health concern.

The participants of this EI will be self-selected residents who live near fields where manure that potentially contains formaldehyde wastes is spread. The test results from this investigation will be specific to the participants and are not generalizable to the community-at-large or to other populations

B. Investigators and Collaborators

The ATSDR Science Support Branch (SSB) will be the lead for this Exposure Investigation. The Vermont Department of Health (VDH) will assist ATSDR in conducting the field activities for this EI. Bureau Veritas, a private contract laboratory, will analyze the air samples. Bureau Veritas is accredited by the American Industrial Hygiene Association and follows NIOSH data quality objectives in its analyses.

ATSDR/SSB will:

- (1) Develop the EI protocol and consent form for environmental testing
- (2) Secure informed consent for environmental testing from the participants
- (3) Conduct the air sampling with the assistance of the VDH
- (4) Evaluate the analytical test results
- (5) Notify the participants of their individual test results and interpret what they mean
- (6) Write a report that summarizes the findings of the EI

The Vermont Department of Health will:

- (1) Identify and recruit participants for the EI
- (2) Assist ATSDR in conducting the air sampling for the EI
- (3) Provide and maintain meteorological instruments for measuring and recording air temperature, wind speed/direction, and humidity

The Bureau Veritas Laboratory will:

- (1) Provide equipment and supplies for collecting the air samples
- (2) Analyze the air samples for formaldehyde using a NIOSH approved analytical method

METHODS

A. Selection of participants

The VDOH, in cooperation with the Vermont Agency of Agriculture, Foods, and Markets (VAAF), will identify dairy farms where formaldehyde footbaths are being used. They will invite people who live in close proximity to fields where manure from the dairy farms is spread to participate in the EI.

B. Field activities

Approach: ATSDR staff will obtain informed consent from the residents for testing the air inside and outside of their homes (Appendix A). We will also administer a questionnaire (Appendix B) to obtain information about possible sources of formaldehyde inside their house.

State law prohibits the spraying of manure on fields between December 15 and April 15. This regulation was enacted to prevent the runoff of manure wastes from frozen ground into surface streams and bodies of water. In 2012, the state permitted manure spreading after March 22 because of the early arrival of warm spring weather. This EI will be conducted during April-May 2012, a time period of active manure spreading. The VAAFMM has indicated that some dairy farmers in the state are willing to notify them when manure spreading on their farms will occur. This will allow us to collect air samples before, during, and after a manure spreading event.

The number of homes that we test is subject to the availability of willing participants. We will attempt to recruit occupants of two residential properties at each targeted dairy farm. To the extent possible, the homes will be located on opposite sides of the field where manure is spread. We will conduct sampling for 5 consecutive days at each residence. We will select one farm property that has never used formaldehyde as a control/background location.

ATSDR staff will set up the air sampling equipment and work with VDH staff to conduct the first week of sampling. For the remainder of the sampling period, VDH staff will conduct the sampling as described below.

To assist us with data interpretation, participants will be asked to fill out a 3-question daily diary throughout the sampling period (Appendix C). The three questions provide information about manure spraying at the farm, odors, and self-reported health effects.

Air Sampling Procedures: Air sampling and analysis will be conducted in accordance with NIOSH Standard Method 2016 for formaldehyde (NIOSH, 2003). The testing unit will consist of a low flow air sampling pump (model SKC 222-4) connected to a sampling tube with Tygon® tubing. We will use SKC Formaldehyde tubes (No. 226-119). The tube contains silica gel with ultra-low background coated with 2,4-dinitrophenylhydrazine (2,4-DNPH). The tube also contains a back-up sorbent section to detect breakthrough, if it occurs.

One 8-hour indoor air sample and one 8-hour outdoor air sample will be collected during the day at the home of the participant. The indoor air sample will be collected from a room facing the dairy farm or fields. The intake tube on the cartridge will be adjusted to breathing zone height (4-5 feet) for the indoor air samples. Prior to collecting the air

sample, we will calibrate the pump to the desired airflow rate using an air flow calibrator (Gilian Gilibrator® - Standard).

A second pump for collecting an outdoor air sample will be set up in the same room. The intake tubing for this pump will be extended through a window in order to collect an outdoor air sample at window height. Alternatively, an outdoor air sample may be collected by setting up the collection apparatus in the yard of the resident.

ATSDR/VDH staff will visit the house each day at an agreed upon time to conduct the sampling. Sample airflow rates will be tested for each pump before and after sampling events. The air sampling pumps will be adjusted to an airflow rate of about 0.05 liters/minute. Over an 8-hour sampling time, this equates to an air volume of about 24 liters. The range of detection for formaldehyde concentrations in air for these sampling parameters is about 0.008 to 1.25 ppm.

At the end of a sampling event, the sample cartridge will be removed, capped, sealed in an airtight pouch, and placed on ice packs. One field blank will be prepared for every 15 samples. To protect the anonymity of the participants, the samples will be labeled with a coded identification number.

C. Sample handling and shipping

After collection, the air sampling cartridges will be stored at refrigerator temperature. It has been documented that samples are stable for at least 34 days at 5 °C (NIOSH, 1994). At the end of the collection period, the air cartridges will be placed in a shipping container with ice packs and a chain-of-custody form, and shipped by overnight delivery to the Bureau Veritas laboratory in Novi, Michigan, for analysis.

D. Lab processing and analysis

The air cartridges will be analyzed for formaldehyde using NIOSH Method 2016 (NIOSH, 2003). In this method, the 2,4-dinitrophenylhydrazone derivative of formaldehyde is analyzed using HPLC with a UV detector. Ketones and other aldehydes can react with 2,4-DNPH; however, the derivatives formed are separated from the formaldehyde derivative by HPLC. QA/QC procedures, as specified in NIOSH method 2016, will be followed.

E. Evaluation of Data

The concentrations of formaldehyde detected in the air samples will be evaluated using the ATSDR Minimal Risk Levels for formaldehyde (ATSDR, 1999) and standard health assessment methodologies as outlined in ATSDR's Public Health Assessment Guidance Manual (Update) (ATSDR, 2005).

The test results will reflect the participants' exposure to formaldehyde at the time of the

testing. Test results for samples collected during other times of the year could be different.

RISKS AND BENEFITS TO PARTICIPANTS

There are no risks from participating in this investigation.

The potential benefit to the participants of this investigation is that they will learn if they were exposed to formaldehyde during the test period, and how these exposures compare to health-based comparison values.

NOTIFYING THE COMMUNITY OF TEST RESULTS

ATSDR will send a letter to the EI participants with their test results and an interpretation. The letter will also contain information for contacting an ATSDR staff person if they want to further discuss their test results.

At the conclusion of this investigation, ATSDR will prepare a written report that presents the findings of the EI. This report will contain no personal identifiers in order to protect the anonymity of the participants. The report will be available to federal, state, and local agricultural, environmental, and public health agencies, as well as to the general public.

The consent form will request permission from the participants for ATSDR to share their test results with Vermont Department of Health and the Vermont Agency of Agriculture, Foods, and Markets.

References

ATSDR. Toxicological Profile for Formaldehyde. July 1999.
<http://www.atsdr.cdc.gov/ToxProfiles/tp.asp?id=220&tid=39>

ATSDR. Public Health Assessment Guidance Manual (Update) 2005.
<http://www.atsdr.cdc.gov/hac/PHAManual/toc.html>

NIOSH (1994) *Manual of Analytical Methods (NMAM®)*, 4th ed. *National Institute for Occupational Safety and Health* (NIOSH, 1994) Publication 94-113. August, 1994, 1st Supplement Publication 96-135, 2nd Supplement Publication 98-119, 3rd Supplement 2003-154. <http://www.cdc.gov/niosh/nmam/pdfs/2016.pdf>

Appendix A

U.S. Department of Health and Human Services
Agency for Toxic Substances and Disease Registry

Exposure Investigation

Richford, Vermont

Consent Form for Environmental Testing

WHO ARE WE AND WHY ARE WE DOING THIS EXPOSURE INVESTIGATION (EI)?

We are from the Agency for Toxic Substances and Disease Registry (ATSDR), a sister agency to the Centers for Disease Control and Prevention (CDC), a federal public health agency. The purpose of the EI is to measure the levels of formaldehyde in indoor and outdoor air on your property.

ATSDR is conducting this EI in conjunction with the Vermont Department of Health (VDH) and the Vermont Agency of Agriculture, Food, and Markets (VAAFMM).

WHAT IS INVOLVED IN THIS TESTING?

We will set up two air sampling pumps inside your house to collect air samples. These pumps are not loud. They sound like a fish tank aerator. We will collect one air sample from inside your house and one sample from outside your house. A lab will test the air samples for formaldehyde.

On each collection day, someone from ATSDR/VDH will visit your house at agreed-upon times to conduct the sampling. We will come to your house in the morning and at the end of the day. We will also ask you to record on log sheets: (1) when manure is spread on the fields, (2) any unusual odors, and (3) any health effects you are experiencing.

WHAT ARE THE BENEFITS FROM BEING IN THIS EI?

By being part of this EI, you will find out if you are being exposed to formaldehyde in your home at levels of health concern.

This test will not tell you if your health problems are caused by exposure to formaldehyde.

There is no cost to you for this testing.

WHAT ARE THE RISKS OF THIS EI?

There is no risk to you for participating in this EI. People coming into your house might be an inconvenience.

WILL I BE PAID?

You will not be paid for being in this EI.

WHAT ABOUT MY PRIVACY?

We will protect your privacy as much as the law allows. We will give you an identification (ID) number. This number, not your name or address, will go on the air samples. We will not use your name or address in any report we write. We will keep a record of your name, address, and ID number so that we can send you the test results. Your name and address will be kept in a password-protected computer at ATSDR and VDH. Only staff working on this site will have access to this information. Copies of your consent form will be kept in a locked file cabinet.

HOW WILL I GET MY TEST RESULTS

We will mail your test results (and what they mean) to you 1-2 months after your samples are collected. We will also give you a telephone number that you can call to discuss your test results.

MAY WE SHARE YOUR TEST RESULTS?

May we share these test results with your name and address with the Vermont Department of Health and the Vermont Agency of Agriculture, Food, and Markets?

YES _____ NO _____

WHAT IF I DON'T WANT TO DO THIS?

You are free to choose whether or not you want to be part of this testing. If you agree to this testing, you may change your mind at any time and drop out without penalty.

WHO DO I CONTACT IF I HAVE QUESTIONS?

If you have any questions about this testing, you can ask us now. If you have questions later, contact Dr. Kenneth Orloff, at ATSDR at 770-488-0735 or 888-232-4636 or send him an e-mail at KEO1@CDC.GOV.

If you have questions about your rights as part of this EI, please call the CDC Human Research Protection Office at 1-800-584-8814. Leave a message with your name and

telephone number and say that you are calling about the Vermont EI. Someone will return your call.

VOLUNTARY CONSENT

I have read this form or it has been read to me. I have had a chance to ask questions about this testing and my questions have been answered. I know I can change my mind at any time. I will be given copy of this form to keep. I agree to be part of this testing.

Participant's Signature

Date

Participant's Printed Name

Address _____

Telephone number _____



The person named above read the consent form. He/she was given an opportunity to ask questions about the investigation, and the questions were answered.

Signature of person administering consent form

Printed name of person administering consent form

Date

Appendix B

Questionnaire for Exposure Investigation – Vermont Farm Manure Site

Name of participant _____

Address _____

Telephone number _____

How old is this house? _____

What is the drinking water source for this house? _____

How long have you occupied this house? _____

How many people live in this house with you? _____

How many hours per day do you stay in the house? _____

Do you, or anyone else in the house, smoke? _____

If yes, how many cigarettes (or other tobacco smoking products) are smoked per day inside the house? _____

What is your source of heating for this house? _____

What is the source of cooking fuel in the house? _____

Do you use space heaters inside the house? _____

Do you have a fireplace or wood-burning stove inside the house? _____

Do you have air conditioning? _____

At this time of year, how many hours a day do you keep your windows or doors open? _____

Do you have pets in your house? If yes, describe. _____

Have you recently done any remodeling? If yes, specify. _____

Have you recently replaced any carpets or added new furniture to the house? If yes, specify. _____

Person administering questionnaire _____ Date _____

Appendix C

Log Sheet for Richford, Vermont, Exposure Investigation

Name _____

Address _____

In the calendar log below, please enter the requested information.

(1) Did you observe any manure spreading on the farm fields? If yes, hours of application?

(2) Did you notice any odors? If yes, describe.

(3) Did you experience any health effects? If yes, describe.

Date _____

(1) _____

(2) _____

(3) _____

Date _____

(1) _____

(2) _____

(3) _____