



OFFICE OF INSPECTOR GENERAL

Catalyst for Improving the Environment

Quick Reaction Report

EPA Needs to Plan and Complete a Toxicity Assessment for the Libby Asbestos Cleanup

Report No. 2007-P-00002

December 5, 2006

Abbreviations

ATSDR	Agency for Toxic Substances and Disease Registry
CAG	Community Advisory Group
EPA	U.S. Environmental Protection Agency
NCP	National Contingency Plan
NPL	National Priorities List
NTP	National Toxicology Program
OIG	Office of the Inspector General
OSWER	Office of Solid Waste and Emergency Response



At a Glance

Catalyst for Improving the Environment

Why We Did This Review

At the request of both Montana Senators, the Office of Inspector General (OIG) initiated this review of the U.S. Environmental Protection Agency's (EPA's) efforts to clean up amphibole asbestos contamination in Libby, Montana. We are issuing this quick action report to bring EPA management's immediate attention to significant, time-critical issues we identified during our limited review.

Background

After 1999 media reports called attention to Libby citizens' health problems, EPA officials requested that we review EPA's actions. Also in 1999, EPA began a cleanup of Libby asbestos contamination. In January 2000, due to citizen concerns, EPA started sampling and analyzing lawn and garden products that contained vermiculite. In March 2001, we reported that EPA had addressed asbestos contamination at other sites, but failed to institute regulations or other controls that might have protected Libby's citizens from the health effects of asbestos contamination. In 2002, EPA began an emergency response cleanup of Libby residential and commercial properties.

For further information, contact our Office of Congressional and Public Liaison at (202) 566-2391.

To view the full report, click on the following link:
www.epa.gov/oig/reports/2007/20061205-2007-P-00002.pdf

EPA Needs to Plan and Complete A Toxicity Assessment For the Libby Asbestos Cleanup

In our limited review, we identified the following significant issues that we believe are critical to a successful cleanup in Libby, Montana.

- EPA has not completed a toxicity assessment of amphibole asbestos necessary to determine the safe level for human exposure; therefore, EPA cannot be sure that the Libby cleanup sufficiently reduces the risk that humans may become ill or, if ill already, get worse.
- EPA's public information documents *Living with Vermiculite* and *Asbestos in Your Home* are inconsistent about safety concerns.

We recommend EPA:

- Fund and execute a comprehensive amphibole asbestos toxicity assessment to determine (1) the effectiveness of the Libby removal actions, and (2) whether more actions are necessary. The toxicity assessment should include the effects of asbestos exposure on children. The EPA Science Advisory Board¹ should review the toxicity assessment and report to the Office of the Administrator and the Libby Community Advisory Group whether the proposed toxicity assessment can sufficiently protect human health.
- Review and correct any statements that cannot be supported in any documentation mailed or made available to Libby residents regarding the safety of living with or handling asbestos until EPA confirms those facts through a toxicity assessment.

¹ Congress established the EPA Science Advisory Board in 1978, in part, to review the guidelines governing the use of scientific and technical information in regulatory decisions.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
INSPECTOR GENERAL

December 5, 2006

MEMORANDUM

SUBJECT: EPA Needs to Plan and Complete a Toxicity Assessment for the
Libby Asbestos Cleanup
Report No. 2007-P-00002

TO: Marcus Peacock
Deputy Administrator

Susan Parker Bodine
Assistant Administrator for Solid Waste and Emergency Response

Robbie Roberts
Region 8 Administrator

This report contains time-critical issues the Office of Inspector General (OIG) identified during the limited work performed on this review, and proposes corrective actions. This report represents the opinion of the OIG and does not necessarily represent the final position of the U.S. Environmental Protection Agency (EPA). EPA managers will make final determinations on matters in this report.

Action Required

Please provide a written response to this report within 30 calendar days. You should include a corrective action plan for agreed upon actions, including milestone dates. We have no objections to the further release of this report to the public. This report will be available at <http://www.epa.gov/oig>.

You may contact me at (202) 566-0847 or roderick.bill@epa.gov, or Eileen McMahon at (202) 566-2391, if you have any questions concerning this report.

Sincerely,

A handwritten signature in black ink, appearing to read "Bill A. Roderick", written over a horizontal line.

Bill A. Roderick
Acting Inspector General

Purpose

On August 22, 2006, the Office of Inspector General (OIG) initiated a project to review EPA's efforts to clean up amphibole asbestos contamination in Libby, Montana (Region 8). The impetus for the review was two congressional requests to evaluate whether potential problems exist with the Libby asbestos National Priorities List (NPL) site cleanup. In our limited work to date, we identified some issues, which we believe to be of imminent concern, and are presenting them in this report.

The preliminary review objective was to determine whether the U.S. Environmental Protection Agency's (EPA's) Office of Solid Waste and Emergency Response (OSWER) and Region 8 personnel developed and executed an effective cleanup based upon Federal requirements that protect human health. However, once we determined that EPA had not followed its own guidance regarding the conducting of a toxicity assessment, we felt it necessary to bring the issue up for immediate attention and resolution because – as reported to EPA by the Agency for Toxic Substances and Disease Registry (ATSDR) in their assessment on public health in Libby in 2003 – “people in the Libby area have elevated levels of disease, and death, associated with exposure to asbestos.”

Background

The National Contingency Plan (NCP) governs the clean up of NPL sites. The NCP requires EPA conduct a remedial investigation and a (baseline) risk assessment for all NPL sites. The NCP designates ATSDR, a component of the Department of Health and Human Services, as the responsible agency for performing public health assessments for NPL sites. The NCP also states that the responsible agency shall keep the public informed about the cleanup progress.

On May 28, 2003, ATSDR released the final version of its report, *Public Health Assessment for the Libby NPL site, Operable Unit 4, Town of Libby and Affected Libby Valley Residential and Commercial Properties*. The report concluded in part, that the citizens of Libby were exposed to hazardous levels of asbestos, and had elevated levels of disease and death from exposure to asbestos. It also recommended, in part, that EPA conduct a toxicological investigation (toxicity assessment) and epidemiology studies. (See more information about asbestos in Appendix A, Background of Libby Asbestos.)

Toxicology. In their Public Health Assessment report, ATSDR defines toxicology as the study of the harmful effects of chemicals on humans or animals.² The National Toxicology Program (NTP), a component of the Department of Health and Human Services, states that they generally perform tests on rodents to determine the toxicity of substances.

Epidemiology. ATSDR's Public Health Assessment report also defines epidemiology as the study of different factors that determine how often, in how many people, and in which people

² This sentence, corrected in January 2007, originally stated the definition as “the study of the harmful effects of chemicals on humans and animals.”

disease will occur. The NTP states that toxicology studies along with epidemiology studies are the best means available for identifying potential human hazards.

Superfund cleanups go through two phases before they are considered complete: the emergency response phase and the remedial action phase. While in the emergency response mode, the emphasis is on removing “hot spots,” or areas of high contamination. During the remedial action mode of a Superfund cleanup, risk is established through a formal, step-by-step, scientific process for quantifying health risks to humans called a risk assessment.

OSWER staff and EPA Region 8 personnel acknowledge the importance of the toxicity assessment. Specifically, Region 8 defines the risk assessment as a formal step-by-step scientific process for quantifying human health risks. Region 8’s Human Health Risk Assessment procedures for Libby asbestos identify the toxicity assessment as central to completing the risk assessment.

Scope and Methodology

We conducted our review from August 22, 2006, to November 22, 2006. However, many of the significant facts surfaced during a related OIG investigation, which began on March 9, 2006, and is ongoing. We included this data in our review as well. We interviewed (or obtained responses from) EPA’s OSWER (senior officials and staff) and Region 8 personnel, and obtained documents related to the issues dated from 1990 to 2006. We are issuing this quick action report to bring to management’s immediate attention significant issues we identified during our initial review. Specifically, the objective of this quick action report is to ensure that EPA fully considers the role of toxicology in the remaining clean up of asbestos contamination in Libby.

Preliminary Findings

EPA has neither planned nor completed a risk and toxicity assessment of the Libby amphibole asbestos to determine the safe level of human exposure. Thus, EPA cannot be sure that the ongoing Libby cleanup is sufficient to prevent humans from contracting asbestos-related diseases. Also, EPA presented inconsistent positions on safety issues in two public information documents. EPA issued *Living with Vermiculite* to Libby residents in October 2003; the other, *Asbestos in Your Home*, is now on the EPA Internet Website.

Risk and Toxicity Assessments

EPA personnel stated that the Libby cleanup, which began in 1999, was limited to removing the most visible and prevalent signs of danger to the community. We agree that it was appropriate to conduct these initial cleanup actions, and they should continue. However, EPA has no way to determine whether the initial removals sufficiently reduced the risk that Libby residents would become ill or get sicker. EPA personnel informed us that this is the case because EPA had not completed an amphibole asbestos risk assessment. A risk assessment includes:

- data collection (site, history, exposure potential, contaminant type and distribution),
- exposure assessment (how much and in what ways exposure can occur),

- toxicity assessment (potential of the contaminants to cause harmful effects to humans), and
- risk characterization (integrates previous steps to calculate risk to humans).

The key element of the risk assessment, which the Agency has not completed, is the toxicity assessment. A toxicity assessment is necessary to determine the safe level of amphibole asbestos exposure for humans.

OSWER Studies of Libby Asbestos

We have had extensive conversations and correspondence with OSWER officials regarding EPA's nonperformance of a toxicity assessment of the Libby asbestos. OSWER officials responded that a toxicity assessment was proposed but denied for two reasons: (1) EPA did not approve the budget request and (2) OSWER believed that they could obtain the information they needed to determine the toxicity of Libby asbestos based on other epidemiology studies (completed and ongoing).

OSWER Epidemiology Work. As evidence that they did not ignore Libby asbestos toxicity assessment work, OSWER officials cited EPA's funding, for several years, a number of efforts to assess hazard and risk. Those efforts included various epidemiological studies, and the updating of the Integrated Risk and Information System for cancer and non-cancer endpoints. However, that work does not include ATSDR defined toxicology (animal) studies. In addition, OSWER staff, as distinguished from OSWER officials, stated that:

- The work ongoing and planned was not sufficient to determine the toxicity of the Libby asbestos.
- A toxicity assessment could take up to 2 years and should include assessing the effects of amphibole asbestos exposure on children.

Benefits of Toxicology and Epidemiology. Toxicology and epidemiology are not the same although they share the same goal of determining the hazardous effect of a substance on humans. Toxicology specifically determines the harmful effects on humans through animal testing. Epidemiology attempts to forecast how often a person gets sick, who gets sick, and how many people get sick. The NTP suggests that together, toxicology and epidemiology are the best means available for identifying potential human hazards. ATSDR agrees with the NTP suggestion that the studies together would be protective of human health. In their Public Health Assessment report, ATSDR:

- Concluded that Libby residents could still be exposed to hazardous levels of asbestos, and that these levels could be especially hazardous to sensitive populations (adults previously exposed or who smoked, and young children).
- Recommended that EPA conduct a toxicity assessment to help determine whether the chemical makeup and fiber size found in Libby pose additional risks.

In addition, an ATSDR official stated the epidemiology studies alone could not reliably provide this information due to the uncertainty associated with determining the level and duration of Libby asbestos exposure in individuals who are tested.

Therefore, we do not agree that OSWER can characterize epidemiology work as toxicology work, or that epidemiology work alone is sufficient to protect human health. We do agree that the epidemiology work is a key component in protecting human health in Libby, and that work should continue.

OSWER Guidance. OSWER has not ruled out performing a toxicity assessment in the future; however, they stated that in the guidance they prefer to use, a toxicity assessment was not necessary. Specifically, OSWER cited EPA's March 2005 *Guidelines for Carcinogen Risk Assessment*:

“When human data of high quality and adequate statistical power are available, they are generally preferable over animal data and should be given greater weight in hazard characterization and dose-response assessment, although both can be used.”

Additionally, OSWER cited EPA's December 2002 *A Review of the Reference Dose and Reference Concentration Process*:

“Adequate human data are the most relevant for assessing risks to humans. When sufficient human data are available to describe the exposure-response relationship for an adverse outcome(s) that is judged to be the most sensitive effect(s), reference values should be based on human data.”

Neither document is official policy for EPA personnel. Specifically:

- *Guidelines for Carcinogen Risk Assessment* does not establish any substantive rules and has no binding effect on EPA and any regulated entity.
- *A Review of the Reference Dose and Reference Concentration Process* is a review, not guidance, but makes recommendations that users should consider.

We agree that human studies would provide better data; however, ATSDR recognized that, for ethical reasons, personnel could not perform toxicity tests on humans. Further, the documents do not discourage the use of animal studies; rather, they state their importance and how researchers can use animal data with, or instead of, human data. Specifically:

- *Guidelines for Carcinogen Risk Assessment* states that epidemiologic (human) studies that show elevated cancer risk that correspond to findings in animal studies strengthen the evidence of human carcinogenicity. The document also states that actual exposure measurements are not available for many retrospective (past events) epidemiology studies, which could lead to misclassifications (individuals placed in the incorrect exposure group). That in turn could reduce the reliability of the epidemiology study.

- *A Review of the Reference Dose and Reference Concentration Process* states that when sufficient human data are not available, users must employ animal studies. However, it would be advantageous to compare the animal data with human data even if the human data is not quantifiable to determine whether toxicity occurs in the same organs and the nature of the effect is similar.

Communication with Libby Residents

Region 8 personnel stated that because EPA does not know the toxicity of amphibole asbestos, EPA cannot substantiate the accuracy of any communication with Libby residents that says that the removal process eliminated the danger of contracting asbestos-related diseases. Region 8 recently changed the leadership managing the Libby removal process. The new Remedial Program Manager stated that he has not reviewed all the communications that his predecessor had with Libby residents.

Living with Vermiculite

In *Living with Vermiculite*, EPA recommended that Libby homeowners not disturb asbestos because no guidelines exist on what is or is not safe. However, the document then states that homeowners would have little risk of exposure if they handle asbestos to clean up an undefined small release of asbestos. We believe this recommendation is inconsistent with the uncertainty of the dangerous levels of exposure. Potentially, Libby homeowners could expose themselves to dangerous levels of amphibole asbestos if they interpret the document to mean that no significant risks exist.

Asbestos in Your Home

Asbestos in Your Home, a document on the EPA Internet Website, was a product of a workshop with the American Lung Association and the Consumer Product Safety Commission. It provides information similar to that found in *Living with Vermiculite*. In this document, EPA defines a small release of asbestos to be no larger than a homeowner's hand. Contrary to the EPA position, the American Lung Association warns that the homeowner should not attempt to remove or repair any level of asbestos. EPA does not address the difference in opinion with the American Lung Association so homeowners could make a fully informed decision regarding handling asbestos.

Developments

EPA Region 8 personnel have begun to address concerns with the Libby cleanup and EPA's communications with Libby residents, as evidenced in the minutes of the August and September 2006 Community Advisory Group (CAG) meetings, posted on EPA's Website. Specifically, EPA personnel responded that new information, from toxicity assessment, might indicate that Libby homes may not be as safe as EPA thought and that EPA may have to do additional cleanup. EPA personnel agreed to participate in a panel to redraft *Living with Vermiculite* because an audience member stated that the document promoted a lackadaisical attitude toward the asbestos contamination. Additionally, the Acting Deputy Director for the Office of

Superfund Remediation and Technology Innovation and Region 8 personnel stated that EPA had removed the *Living with Vermiculite* document from the EPA Website on October 11, 2006, as a result of consultations with the CAG, and EPA is reviewing the *Asbestos in Your Home* document. We believe the actions of OSWER and Region 8 personnel, coupled with our recommendations, will help to ensure a swift and effective cleanup.

Recommendations

1. We recommend that EPA fund and execute a comprehensive amphibole asbestos toxicity assessment to determine (1) the effectiveness of the Libby removal actions, and (2) to determine whether more actions are necessary. The toxicity assessment should include the effects of asbestos exposure on children. The EPA Science Advisory Board should review the toxicity assessment and report to the Office of the Administrator and the Libby Community Advisory Group whether the proposed toxicity assessment can sufficiently protect human health.
2. We recommend that EPA review and correct any statements that cannot be supported in any documentation mailed or made available to Libby residents regarding the safety of living with or handling asbestos until EPA confirms those facts through a toxicity assessment.

Background of Libby Asbestos

ATSDR is tracking the human health effects of Libby asbestos in 28 locations throughout the country that received over 80 percent of the Libby vermiculite. In *What is Asbestos?*, ATSDR makes the following statements regarding vermiculite and asbestos contamination in Libby Montana.

Vermiculite Production. Zonolite Mountain in Libby produced vermiculite for more than 65 years (until 1990). The mine itself is approximately 6 miles from the town. A transfer facility was located approximately 3 miles from Libby. From the transfer facility, vermiculite was loaded on trains or trucks. Two expansion ("popping") facilities operated at different times within the town; these plants heated vermiculite to approximately 600 degrees Fahrenheit to expand the crystals. One of these facilities was next to a baseball field, which was readily accessible to the community's children.

Types of Asbestos. There are two general types of asbestos, amphibole and chrysotile. Some studies show that amphibole fibers stay in the lungs longer than chrysotile. This tendency may account for their increased toxicity (harmfulness to the body). Regulatory agencies such as EPA and the Occupational Safety and Health Administration recognize six asbestos minerals: chrysotile, a serpentine mineral with long and flexible fibers; and five amphibole (with relatively brittle crystalline fibers) minerals, actinolite asbestos, tremolite asbestos, anthophyllite asbestos, crocidolite asbestos, and amosite asbestos.

Libby Asbestos. Vermiculite is usually free of asbestos. However, the vermiculite ore taken from a mining operation in Libby contained asbestiform (asbestos-like) amphibole minerals, including the regulated forms tremolite and actinolite. The vermiculite also contains winchite, richterite, and ferroedenite asbestos, which the U.S. does not currently regulate. Research has linked all of these forms to asbestos related diseases.

Asbestos Risk Factors. The heating process released asbestos fibers from the vermiculite ore into the air. Inhalation of asbestos fibers suspended in air can result in lung diseases such as asbestosis, mesothelioma, and lung cancer. The risk of developing any of these diseases depends on many factors, including the type of fiber, the level and duration of exposure, and the smoking history of the exposed individual.

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