Asbestos and Other Mineral Fibers

A Roadmap for Scientific Research

February 2007 Draft

Presented at Public Meeting, Washington, DC May 4, 2007

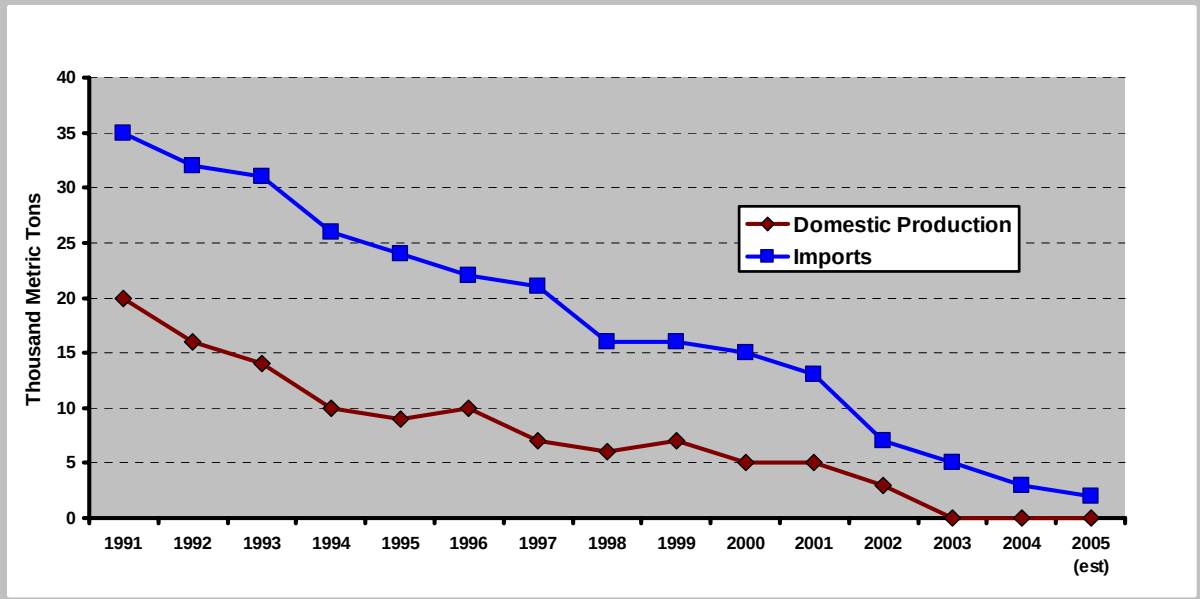
The findings and conclusions in this presentation have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy

Purpose of the *Roadmap*

- Describe current understanding of the science
- Provide background
- Identify key scientific issues
- Identify research directions

Asbestos Use

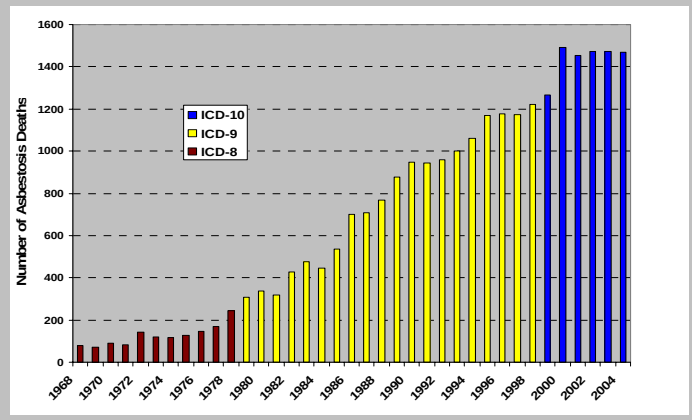
- Domestic production eliminated
- Imports of raw asbestos down
- Import of asbestos-containing products unknown



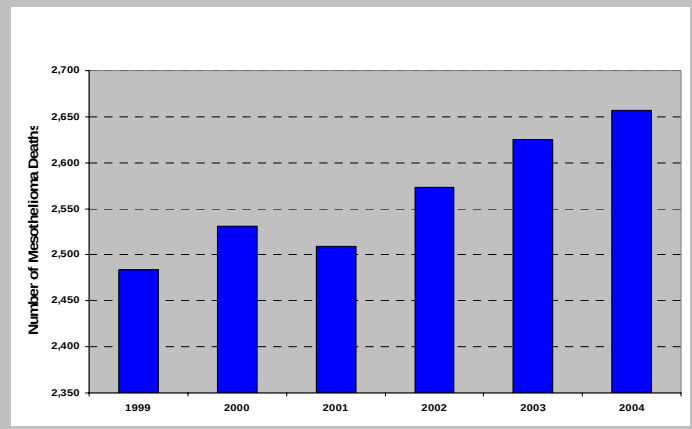
Data are found at:
http://minerals.usgs.gov/minerals/pubs/commodity/asbestos/asbesmcs04.pdf.

Asbestos-related Disease

- **Asbestosis**
  - Deaths increased 20-fold from 1960s to 1990s
  - Anticipated to continue but decline



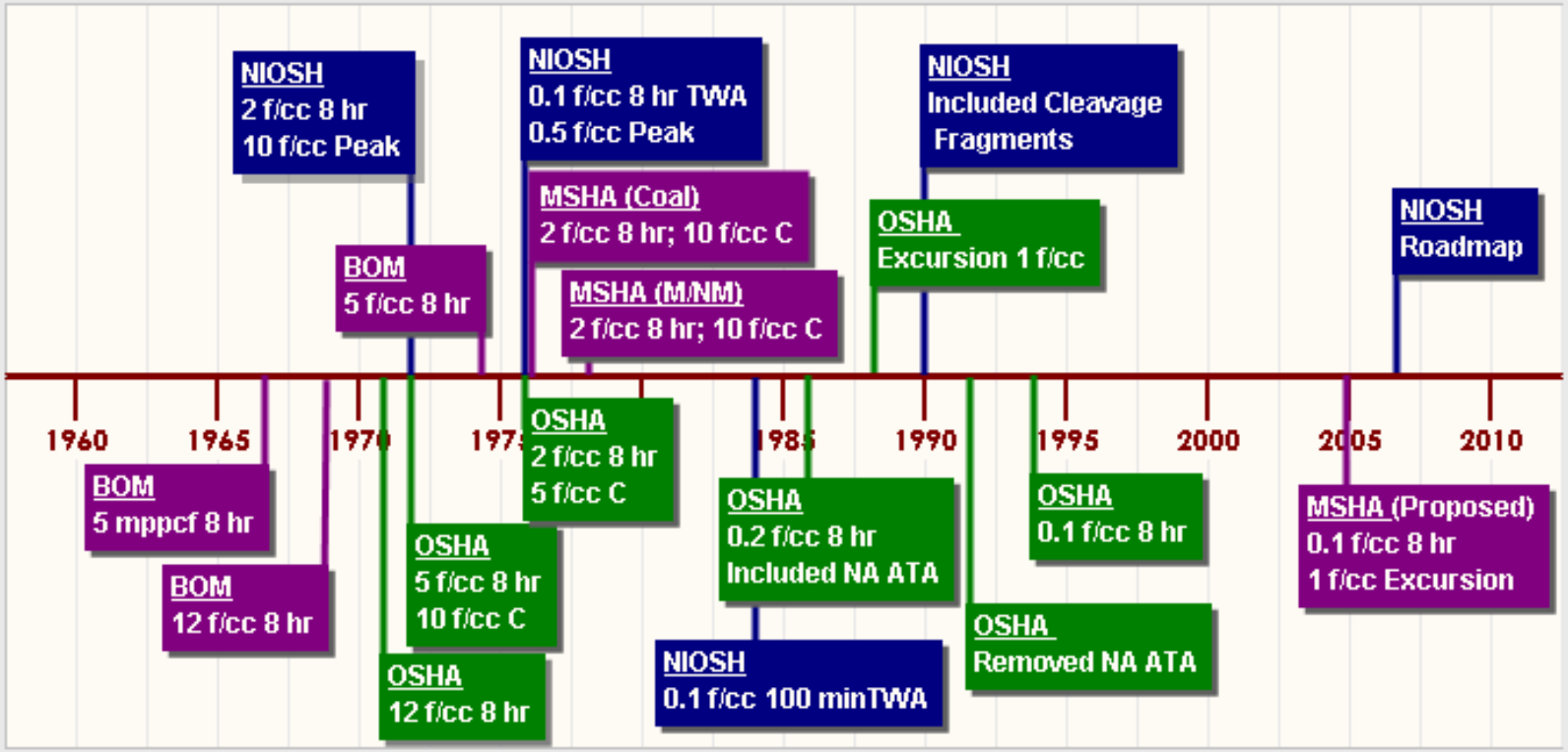
- **Mesothelioma**
  - Has not peaked
  - Longer latency than asbestosis



- **No trend data for other**

Source: NORMS, found at: http://webappa.cdc.gov/ords/norms.html.

Asbestos Occupational Regulations and Recommendations (selected)



NIOSH Definition of Asbestos

Developed in 1990

Policy Component

Particles viewed by PCM that have:

- **Aspect ratio ≥ 3:1**
- **Length > 5 μm**

And also have

- **Crystal structure and elemental composition of asbestos minerals**

Analytical Component

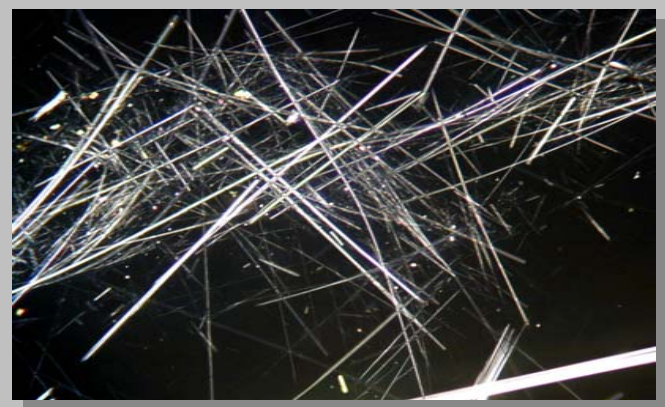
NIOSH Analytical Method #7400

- **Uses Phase Contrast Microscopy**
- **Specifies counting procedures**

TEM can also be used (Method #7402)

NIOSH Definition of Asbestos

- **Serpentine**
  - Chrysotile
- **Amphibole**
  - Actinolite asbestos
  - Amosite
  - Anthophyllite asbestos
  - Crocidolite
  - Tremolite asbestos



NIOSH Definition of Asbestos

- **Includes cleavage fragments of**
  - **Serpentine**
    - Antigorite
    - Lizardite
  - **Amphiboles in series:**
    - Cummingtonite-grunerite
    - Tremolite-ferroactinolite
    - Glaucophane-riebeckite
  - **Fiber dimensions viewed microscopically**

Inclusion of Fiber-Like Cleavage Fragments (FLCF)

Based on 4 elements:

1. **Animal studies**
   - *Carcinogenic potential depends on:*
     - particle length
     - diameter, and
     - biopersistence
   - *Not Critical factors*
     - mineralogic identity
     - origin

Inclusion of FLCF

2. Epidemiologic studies

- Exposure to mixed asbestiform and FLCF
- Carcinogenic potential of FLCF is Equivocal

3. Co-location of asbestiform and nonasbestiform minerals

- Locating asbestiform within non-asbestiform deposits difficult
- May lead to inadvertent contamination

Inclusion of FLCF

4. Limitation of routine analytical methods

- PCM and TEM cannot differentiate between FLCF and asbestiform fibers

Because epidemiological evidence was equivocal, NIOSH relied on other three elements

Criticism of FLCF Inclusion

- Human and animal toxicity studies do not definitively demonstrate carcinogenicity of FLCF
- Does not provide additional protection of worker health
- Increases costs and liability exposure

Uncertainties Have Led to Different Federal Regulations

- In 1992 OSHA adopted a different regulation than NIOSH recommended
  - Uncertainties in the data
  - Body of data showing no carcinogenic effect
  - Does not appear to be in workplace
- In 2005 MSHA proposed OSHA-harmonized regulation

Uncertainties Have Led to Different Recommendations

- In 2003 EPA Peer Consultation Panel
  - Knew of little data to address the question
  - Dimension and durability are critical to pulmonary pathogenesis
  - Concluded :
    - ***"prudent to assume equivalent potency for cancer in the absence of other information to the contrary"***

Policy Component Issues

1. **Include other minerals?**
   - Other amphiboles (e.g., winchite and richterite)
   - Fibrous minerals

2. **Include cleavage fragments of asbestos analogs?**

3. **Are the specified dimensions appropriate?**

Analytical Issues

NIOSH REL based on analytical methods limitations

- **Counting rule does not restrict width**
  - Diameter > 3 μm less likely to reach lung
- **PCM**
  - Resolution down to ~ 0.25 μm
  - Cannot differentiate asbestiform fibers and FLCF

Analytical Issues

- **TEM**
  - **Does not differentiate between asbestiform fibers and:**
    - Other amphiboles with similar elemental composition
    - Nonamphiboles with similar electron diffraction patterns
- **No validated methods exclude FLCF**

Goals of the Research Agenda

2007

- To provide scientific basis for evidence-based worker protection recommendations
- To address the broad range of mineral fibers to which workers are exposed.
- To refine understanding of fiber characteristics associated with toxicity.

Strategic Goals

For Fibers and Fiber-like Cleavage Fragments

I. Develop improved sampling and analytical methods

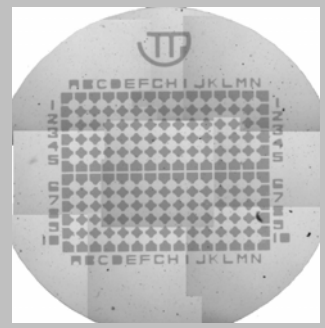
II. Develop information and knowledge on occupational exposures and health outcomes

III. Develop a broader understanding of the important determinants of toxicity

I. Develop Improved Sampling and Analytical Methods

- Provide accurate information about fibers covered
- Differentiation important for epidemiological and toxicological studies
- Opportunities for improvements to PCM limited
- TEM is costly and time-consuming

I. Develop Improved Sampling and Analytical Methods



1) Reduce inter-operator and inter-laboratory variability

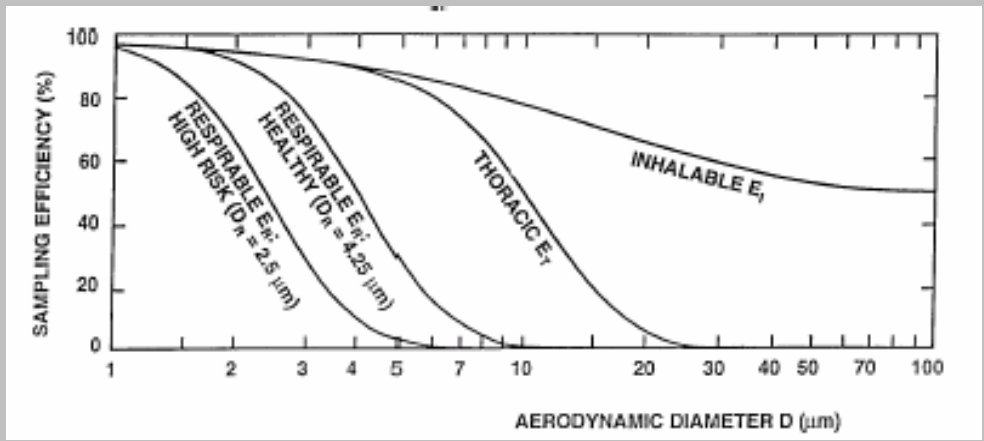
2) Develop fiber analytical methods with improved resolution

3) Develop air sample methods to differentiate between asbestiform fibers and FLCF

I. Develop Improved Sampling and Analytical Methods

4. Develop analytical methods to assess fiber durability

5. Develop and validate thoracic-size selective sampling methods



II. Develop information and knowledge on occupational exposures and health outcomes

- **Need to:**
  - Ascertain number and where workers are potentially exposed
  - Measure and characterize worker exposures to analyze risk.
  - Conduct health surveillance
- **Outcomes:**
  - Identify study populations
  - Prioritize research

II. Develop information and knowledge on occupational exposures and health outcomes

1. Ascertain the characteristics and extent of occupational exposure

2. Develop information on health outcomes associated with exposures

3. Conduct epidemiologic studies of workers to define associations between exposures and health effects

III. Develop a broader understanding of the important determinants of toxicity

- Epidemiological and health studies limited
- Toxicological studies of biopersistence and health outcomes:
  - fibers with a range of chemical compositions
  - morphological characteristics (including crystalline habits)
  - a range of discrete lengths
  - uniform diameters

III. Develop a broader understanding of the important determinants of toxicity

1. *In vitro* studies to ascertain important physical and chemical properties

2. Animal studies to ascertain important physical and chemical properties

The Path Forward

- Ultimate goal: Unified theory of thoracic-sized fiber toxicity
  - Currently-known and newly identified mineral fibers
  - Synthetic vitreous fibers
  - Nanofibers
- Toxicity predicted by combination of:
  - Chemistry
  - Dimension
  - Biopersistence
  - Other factors

The Path Forward

- Basis for developing evidence-based risk management approaches
- Advantageous if based on *in vitro* and short-term *in vivo* tests

The Path Forward

- **Partnerships will be used to:**
  - Focus and conduct research
  - Develop and disseminate outcomes
  - Foster adoption in practice
- **Achieving Roadmap goals:**
  - Requires significant investment
  - Consonant with NIOSH's mission to:
    - Generate new knowledge in OSH
    - Transfer knowledge to benefit of workers

Discussion Issues

1) Whether the hazard identification and discussion of health effects for asbestos and other mineral fibers are a reasonable reflection of the current understanding of the evidence in the scientific literature.

Discussion Issues (cont'd)

2) the appropriateness and relevancy of

a) the discussion of the current understanding of the analytical issues and

b) the research needs for analysis of asbestos and mineral fibers

Discussion Issues (cont'd)

3) the appropriateness and relevancy of

a) the discussion of the current understanding of the epidemiological issues and

b) the research needs for understanding the health effects of asbestos and mineral fibers

Discussion Issues (cont'd)

4) the appropriateness and relevancy of

a) the discussion of the current understanding of the toxicological issues and

b) the research needs for understanding the health effects of asbestos and mineral fibers

Discussion Issues (cont'd)

5) the appropriateness and relevancy of

a) the discussion of the path forward and

b) whether the ultimate vision is a reasonable outcome for the proposed research strategy for asbestos and mineral fibers

Discussion Issues

Does the draft *Roadmap* appropriately address:

1. current understanding of hazard identification and health effects relating to asbestos and other mineral fibers?
2. current understanding of issues and research needs relating to analysis of asbestos and mineral fibers?
3. current understanding of epidemiological issues and research needs relating to health effects of asbestos and mineral fibers?
4. current understanding of toxicological issues and research needs relating to health effects of asbestos and mineral fibers?
5. a path forward with a reasonable ultimate outcome of the proposed research strategy for asbestos and mineral fibers?