Toxicological Review of Libby Amphibole Asbestos
IRIS Development and Review Process

Complete draft of IRIS Toxicity Assessment

Internal EPA Review

Interagency Review

Public Review and Science Advisory Board Review

Repeat Internal EPA and Interagency Reviews

Post Final Assessments on IRIS

Where we are now !!!

Refer to website: http://www.epa.gov/IRIS/process.htm
EPA Timeline for LAA Toxicity Review

2006 Region 8 begins development on reference concentration (RfC) – (Non-cancer Toxicity value based on localized pleural thickening)
2007 EPA/NCEA begins development of inhalation unit risk (IUR) – (Cancer Toxicity value based on lung cancer and mesothelioma)
2011 Draft LAA Toxicity Review made available to the public and to the Science Advisory Board (SAB); Public listening sessions held
2012 SAB meetings in February, May, July, and September; public comments made to EPA and to SAB
2013 EPA receives SAB final report in January and begins revision
2014 EPA completes revised draft LAA Toxicity Review; Completes Final Agency Review and Interagency Science Discussion
2014 EPA completes LAA Toxicity Review in December
Basis for Libby Amphibole Asbestos Toxicity Values

- Review and analysis of experimental animal and human epidemiological data

- Toxicity value for cancer (IUR) based on EPA analysis of workers at the Libby operations

- Toxicity value for non-cancer (RfC) based on EPA analysis of workers exposed to Libby vermiculite at O. M. Scott facility in Marysville, OH
Asbestos-Related Diseases

A Normal lungs

B Lungs with asbestos-related disease

- Pleural plaque (thickened and hardened pleura)
- Lung cancer
- Asbestosis (scarred lung tissue)
- Pleural plaques on diaphragm
- Mesothelioma (cancer of the pleural coverings)
EPA Concludes LPT is endpoint for RfC

- Localized pleural thickening (LPT) is the critical effect for deriving an RfC.

- LPT (pleural plaques) are well-recognized as a marker of exposure to asbestos, meaning they rarely occur except following exposure to asbestos (i.e., they are “specific” to asbestos).

- Although pleural plaques have long been considered inconsequential markers of asbestos exposure, studies of large cohorts have shown a significant reduction in pulmonary function attributable to the plaques, averaging about 5% of FVC, even when interstitial fibrosis (asbestosis) is absent radiographically.

- Thus, LPT is a pathological change associated with decreased pulmonary function, and thus is considered an appropriate adverse effect for deriving the RfC.
What is localized pleural thickening (LPT)?

Gross appearance at autopsy of asbestos-associated pleural plaques overlying the lateral thoracic wall.

Gross appearance of large asbestos-related pleural plaque over the dome of the diaphragm.
## Toxicity Values

<table>
<thead>
<tr>
<th>Year/Version</th>
<th>1988 General Asbestos Draft</th>
<th>2011 Final</th>
</tr>
</thead>
<tbody>
<tr>
<td>IUR (Cancer)</td>
<td>0.23 (f/cc)(^{-1})</td>
<td>0.17 (f/cc)(^{-1})</td>
</tr>
<tr>
<td>RfC (Noncancer)*</td>
<td>No value</td>
<td>0.00002 fiber/cc (= 20 \text{ fibers/m}^3)</td>
</tr>
</tbody>
</table>

*Following expert peer-review advice from the SAB, EPA implemented recommended changes in the exposure-response modeling resulting in a change in the RfC.*

Cubic centimeter (cc):

![Cubic centimeter](image)

Cubic meter (m\(^3\)):

![Cubic meter](image)
Summary

- EPA has conducted an extensive review and analysis of the cancer and non-cancer literature and data.

- Based on human epidemiological data from the Libby miner population and the Marysville, OH worker population, EPA has developed toxicity factors for both cancer and non-cancer endpoints.

- The cancer toxicity value [IUR] is 0.17 (f/cc)^{-1}.

- The non-cancer toxicity value [RfC] is 0.00009 f/cc (or 90 fibers/m^3).
  - This is the first non-cancer toxicity value for a mineral fiber.

- These values will be used in the risk assessment for the Libby Asbestos Superfund Site.
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- EPA OSRTI Asbestos Technical Review Workgroup
- EPA Libby Action Plan Workgroup
- EPA Agency Review: Office of Solid Waste and Emergency Response, Office of Water, Office of Children’s Health Protection and Regions 2,7,8, and 10

Interagency Science Consultation & Discussion:
- Department of Defense
- NASA
- Department of Health and Human Services (ATSDR, NIEHS and NIOSH)
- Office of Management and Budget & OSTP
- Council on Environmental Quality
- Science Advisory Board