What is the Integrated Risk Information System (IRIS)?

EPA's IRIS Program is an assessment program that evaluates qualitative and quantitative information on human health effects that may result from exposure to environmental contaminants. Through the IRIS Program, EPA provides science-based human health assessments that have undergone rigorous peer review to support the Agency's activities. The IRIS database contains hazard characterizations and toxicity values for the first two steps (hazard identification and dose-response evaluation) of the risk assessment process. IRIS assessments are not regulations, but they provide a critical part of the scientific foundation for managing human health risks. By combining IRIS toxicity values with information on chemical exposure, government and other entities can characterize health risks of environmental contaminants.

How was the IRIS assessment of Libby Amphibole asbestos (LAA) developed?

The development of the IRIS assessment of Libby Amphibole asbestos included:

- Development of a draft toxicological review, followed by internal Agency review and consultation with other federal agencies and White House offices;
- Public comment and external peer review conducted by the EPA's Science Advisory Board;
- Final Agency review and EPA-led interagency science discussion;
- Posting of the toxicological review on the IRIS database.

More information on the IRIS Process can be found on the IRIS Process page.

What is hazard identification?

As the first step in the process of developing an IRIS health assessment, EPA's IRIS Program conducts a characterization of the hazards associated with exposure to a chemical substance based on available scientific data. This is referred to as hazard identification. The purpose of hazard identification is to determine whether or not exposure to a chemical substance may cause specific adverse health effects (including cancer and noncancer effects) and whether these effects are likely to occur in humans. Exposure to a chemical substance may result in different adverse effects in humans, including cancer, reproductive effects, neurotoxicity, or other noncancer effects.

What is a dose-response evaluation?

The second step in developing an IRIS health assessment involves conducting a quantitative dose-response evaluation of the available scientific data. A dose-response relationship describes how the likelihood and severity of an adverse health effect (the response) is related to the amount of a chemical substance to which a population is exposed (the dose).

What is an inhalation reference concentration (RfC)?

When supported by available data, IRIS provides toxicity values specific to the cancer and noncancer health effects of exposure to chemical substances. One of the values that EPA derives for noncancer health effects is called an inhalation reference concentration, or RfC. The RfC estimates the amount of a chemical substance that one can breathe daily over a lifetime that is likely to be without adverse noncancer health effects. For the IRIS assessment of Libby Amphibole asbestos (LAA), EPA developed an RfC value that can be used to inform future risk management decisions in the Libby, Montana region and other sites with exposure to asbestos fibers from material derived from Libby, Montana vermiculite.

What is an inhalation unit risk (IUR)?

When supported by available data, IRIS provides toxicity values specific to the cancer and noncancer health effects of exposure to chemical substances. One of the values that EPA derives for cancer is called

an inhalation unit risk, or IUR. The IUR is an estimate of cancer risk from breathing in a specific amount of a chemical substance; it is used to compute an upper-bound estimate of cancer risks to a population at different chemical exposure levels. For the IRIS assessment of Libby Amphibole asbestos (LAA), EPA developed an IUR that can be used to inform future risk management decisions in the Libby, Montana region and other sites with exposure to asbestos fibers from material derived from Libby, Montana vermiculite.

What research did EPA conduct to evaluate the health effects of the Libby Amphibole asbestos?
EPA's Integrated Risk information System (IRIS) Program evaluated the peer-reviewed, publicly available literature on the health hazards (including cancer and noncancer effects) resulting from exposure to Libby Amphibole asbestos (LAA) and subjected the evaluation to a rigorous scientific peer review with public involvement.

What were the conclusions that EPA reached on the health effects from exposure to Libby Amphibole asbestos?
This IRIS assessment addresses the potential cancer and noncancer human health effects from inhalation exposure to Libby Amphibole asbestos (LAA).

The noncancer findings of this assessment concluded that exposure to LAA may cause thickening of the pleura. The pleura are the membranes that envelop the lungs and line the chest cavity. The thickening of the pleura detectable on X-ray is called "localized pleural thickening" (LPT). LPT is associated with decreased lung function. Based on these effects, the assessment estimates the amount of LAA that one can breathe daily over a lifetime that is likely to be without adverse health effects (inhalation reference concentration - RfC).

The assessment concludes that LAA is "carcinogenic to humans," and includes an inhalation unit risk (IUR) to quantify cancer risks. This conclusion is based on strong evidence of lung cancer and mesothelioma in humans from epidemiological studies. The International Agency for Research on Cancer (IARC) has also concluded that all forms of asbestos are carcinogenic (including tremolite, a component of LAA).

What is localized pleural thickening (LPT)? How does it relate to pleural plaques?
The term localized pleural thickening (LPT) describes discrete areas of scar tissue on the pleura (the membranes that envelop the lungs). This thickening is detectable on X-ray and is associated with an average 5% decrease in lung function measures. The external peer review draft and final assessment concluded that exposure to Libby Amphibole asbestos (LAA) may cause such thickening of the pleura, and a panel of independent scientists organized by the EPA's Science Advisory Board (SAB) to peer review the assessment agreed with the finding that LPT is an adverse health effect. Under current International Labour Organization (ILO) definitions, the terms "localized pleural thickening" and "pleural plaques" are the same, but older ILO definitions of pleural plaques differ.

What process was used to develop the toxicity values for the IRIS assessment of Libby Amphibole asbestos? Was it peer-reviewed?

EPA scientists developed a cancer inhalation unit risk (IUR) value and a non-cancer inhalation reference concentration (RfC) for Libby Amphibole asbestos (LAA). The supporting document, *Toxicological Review of Libby Amphibole Asbestos*, has undergone a rigorous peer review process, including an internal review at EPA, an interagency review, a public comment period, and an expert peer review by EPA's Science Advisory Board (SAB). The revised document and associated toxicity values have also undergone a final Agency and interagency review.

How will EPA use the toxicity values?

The IRIS assessment for Libby Amphibole asbestos contains information on the first two steps (hazard identification and dose-response assessment) of the human health risk assessment process. The last two steps of the risk assessment process involve exposure assessment and risk characterization. Human exposure to LAA is known to occur in the Libby, Montana region, at sites where the LAA-contaminated vermiculite was processed, and at locations where it was used, including homes with insulation derived from Libby vermiculite. Inhalation of LAA is the route of exposure that is the primary concern for human health. When the mining and milling operations were active, residents of the Libby, Montana region were exposed to high ambient air concentrations of LAA. People in Libby, Montana may also have been exposed to LAA from residual fibers brought into a home on clothing, shoes or other materials from the work site. Now that mining and milling operations have ceased, exposures could arise from soil at sites that processed asbestos-containing vermiculite from Libby in the past. Additionally, residents may also be exposed if there remain unremediated soils in Libby, Montana with high concentrations of LAA.

Risk assessors will combine the toxicity values for LAA with exposure information to help characterize the public health risks. This information will then be used to support risk management decisions designed to protect human health.

Can the cancer and noncancer findings in this assessment be used for asbestos not originating from Libby, Montana?

The assessment is explicit in stating that the toxicity values are specific to LAA, meaning for exposures to the mixture of amphibole mineral fibers of varying elemental composition (e.g., winchite, richterite, tremolite, etc.) that have been identified in the vermiculite ore mined near Libby, Montana. This includes sites outside of the Libby, Montana area where Libby vermiculite ore was processed or used. The RfC is derived from a cohort employed at a plant in Marysville, Ohio that was using the vermiculite ore. While this assessment is informed by studies of other types of asbestos, it is not a complete toxicological review of other amphiboles or of chrysotile asbestos.