Toxicity and Risk Assessment

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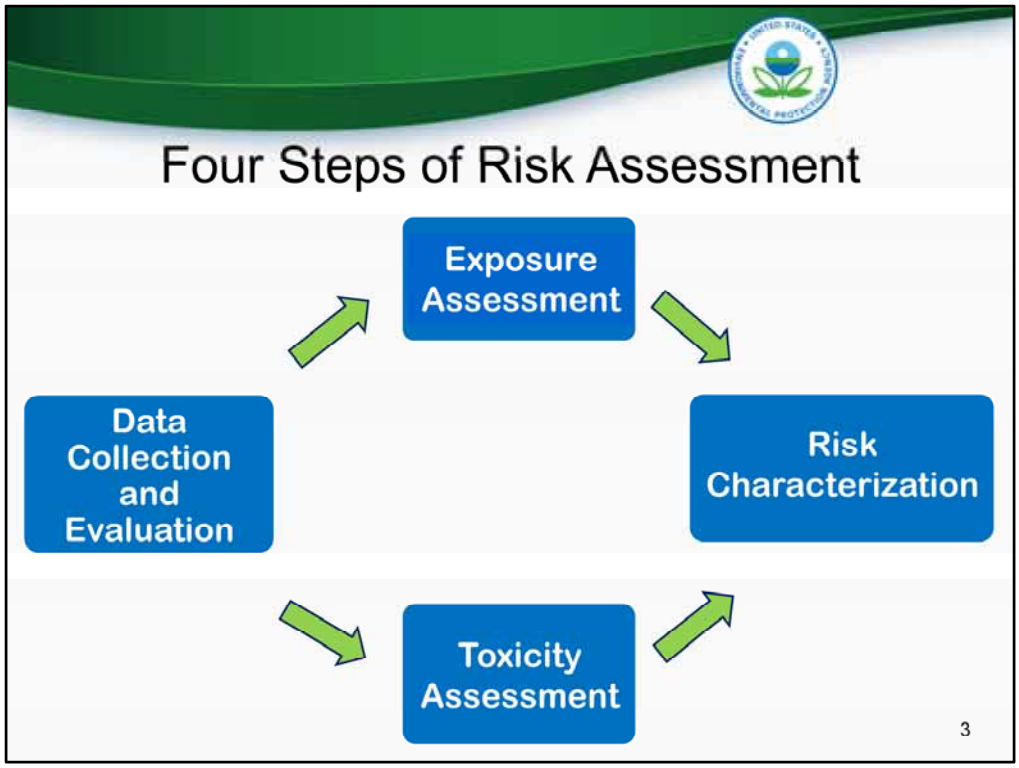
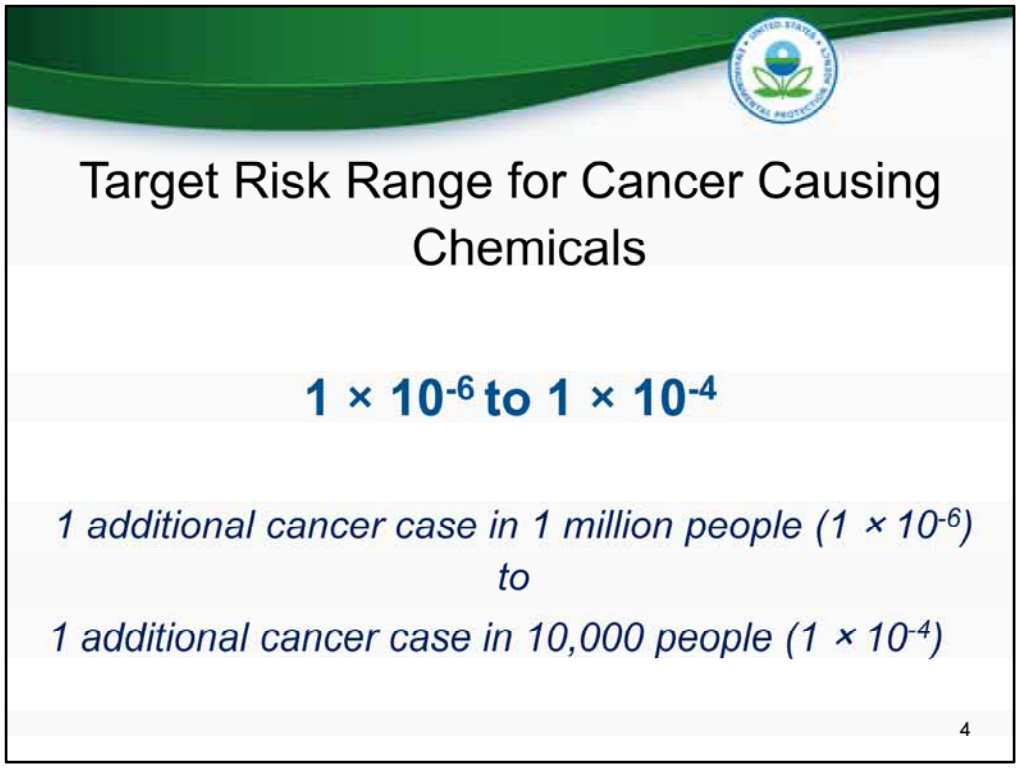
Presentation #2
Fact Sheet 2A

Introduction

- Today we are sharing the draft toxicity values for Libby amphibole.
- Values are used to estimate potential risks.
- Graphs are based on draft toxicity values and exposure estimates both of which may change pending scientific review and further data collection.



- Data Collection:
  - Activity based sampling and air monitoring data used to estimate concentration of asbestos fibers in the air
- Exposure Assessment:
  - Estimate of magnitude, frequency, and duration of exposure.
  - Estimates based on reasonable worst case (for example: mowing a dry lawn rather than a wet lawn).
- Toxicity Assessment:
  - Estimation of the relationship between dose of a substance and the biological response.
- Risk Characterization:
  - The toxicity data and the exposure data are combined to estimate health risk.

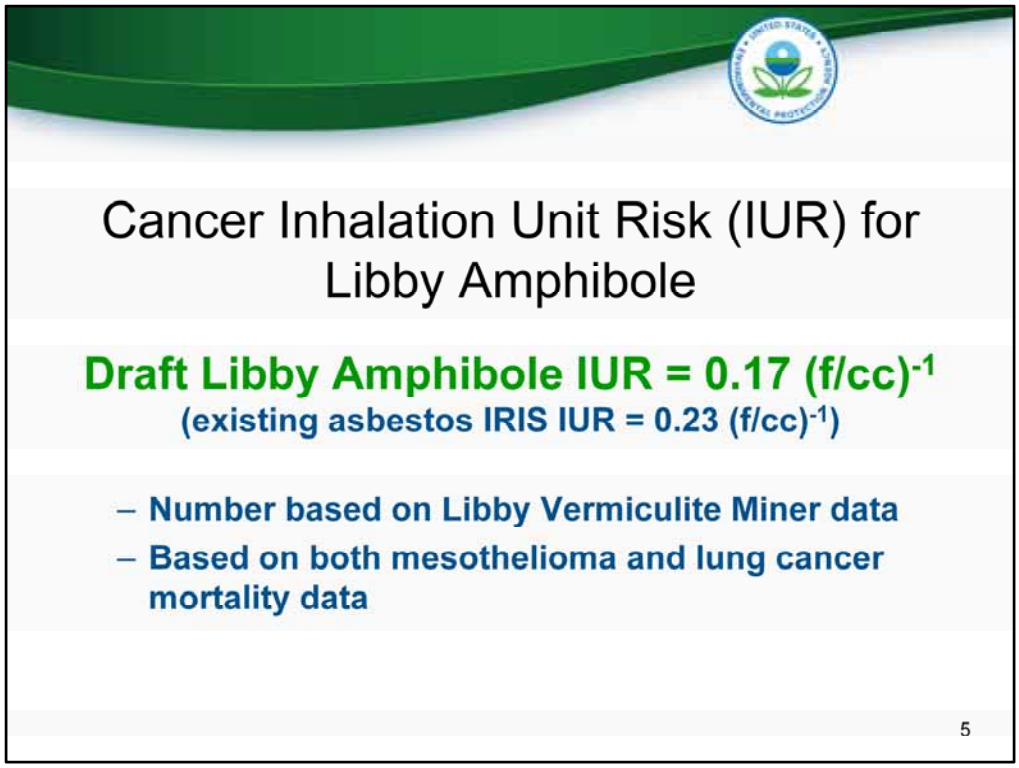


EPA's target risk range for cancer

- 1 additional cancer in a population of 1 million (also written as $1x10^{-6}$ or 10^{-6}) to 1 additional cancer in a population of 10,000 (also written as $1x10^{-4}$ or 10^{-4}).

EPA uses information from risk assessments to make decisions on Superfund sites.

- Risk management (whether to take some action or not) may occur within the target range.
- Above that range (about a cancer risk of 10^{-4}) some action is typically warranted to reduce risk.
- That action can be cleanup or some measure to reduce exposure.

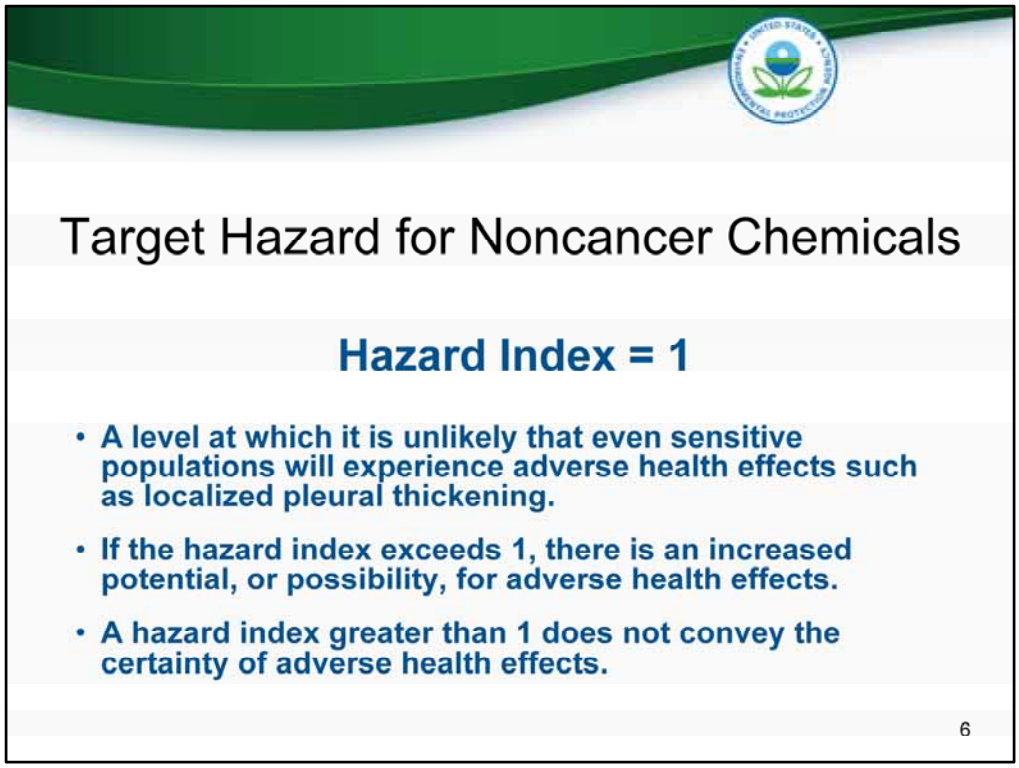


Inhalation Unit Risk (IUR) value

- IUR provides and estimate of the exposure-response relationship for cancer
- Asbestos-related cancer effects include mesothelioma as well as other lung cancers

The new, draft IUR for Libby Amphibole is 0.17 f/cc^{-1}

The current IRIS IUR for a mixture of asbestos types is 0.23 f/cc^{-1}



Noncarcinogenic Chemicals

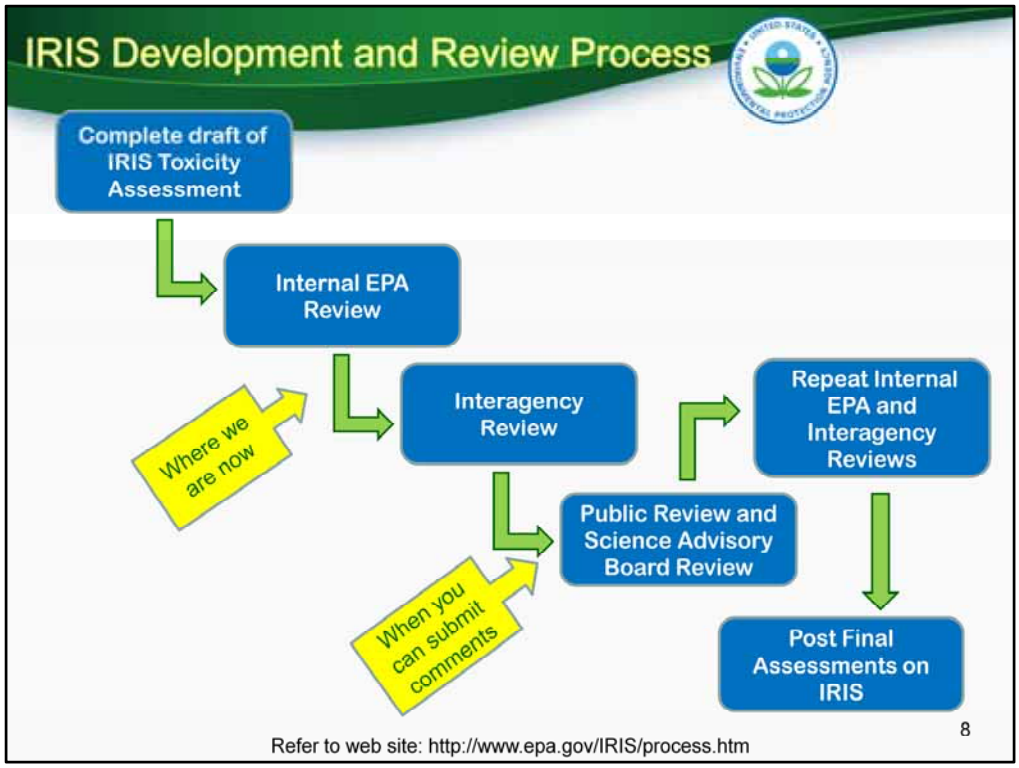
- Tend to act by threshold mechanisms. This means that there is some level of exposure to a chemical that is unlikely to cause harm.
- The comparison of the exposure to the threshold dose (RfC) is called the Hazard Index.

EPA uses information from risk assessments to make decisions on Superfund sites.

- Risk management (whether to take some action or not) may occur within the target range.
- Above that range (about a cancer risk of 10^{-4} or a hazard index of one) some action is typically warranted to reduce risk.
- That action can be cleanup or some measure to reduce exposure.

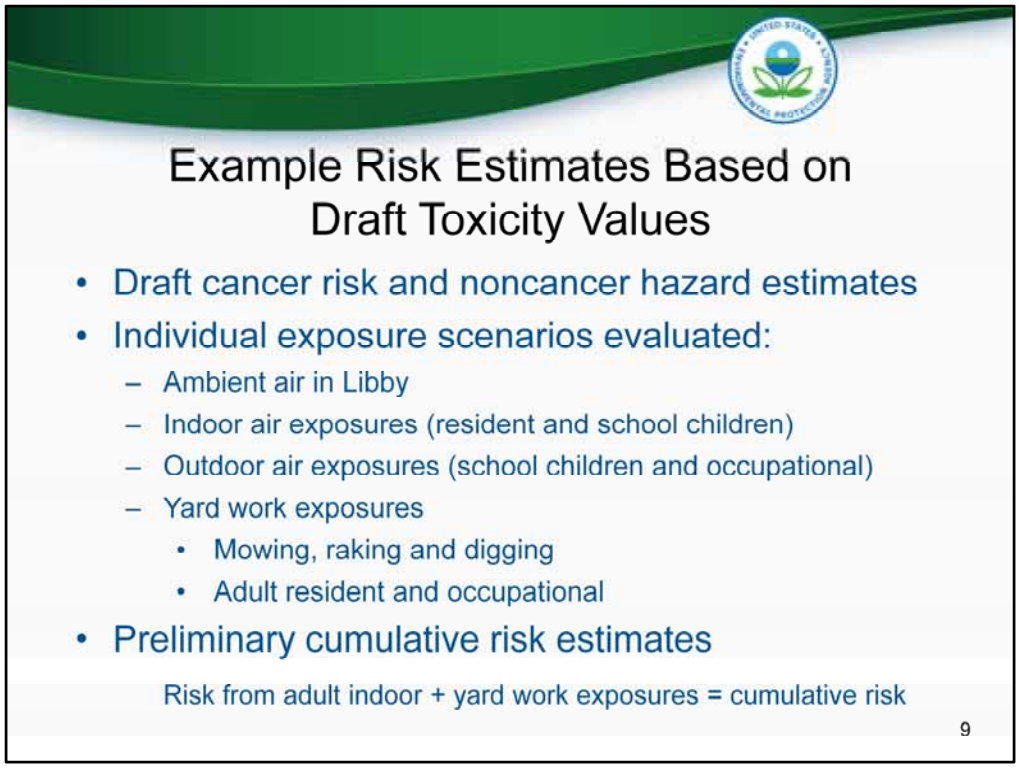
Noncancer Reference Concentration (RfC)

- There is currently no estimate of noncancer harm from asbestos exposure in the EPA's IRIS data base = there is currently no RfC
- Estimates noncancer harm that people might experience from breathing LA.
- The data used to estimate the LA RfC came from data on both exposure and health effects collected at a vermiculite processing plant in Marysville Ohio.
- Noncancer illnesses from exposure to LA include pleural abnormalities called localized pleural thickening, and asbestosis (an illness of progressive scarring of lung tissue).
- Localized pleural thickening
  - Growths of fibrous tissue within the sack that surrounds the lung. In the early stages of this illness, it is often not possible to measure any change in lung function.
  - As exposure continues, it is possible to experience a decrease in lung function and some pain.
  - A limited number of those affected may progress to asbestosis.
- Using localized pleural thickening as the threshold response for the estimate of the toxicity of LA is a very cautious, health protective approach.
- The new, draft RfC for LA is 0.00001 f/cc (or $1x10^{-5}$ f/cc).



The draft LA toxicity values, both the cancer and noncancer values, are currently undergoing review through EPA's IRIS process.

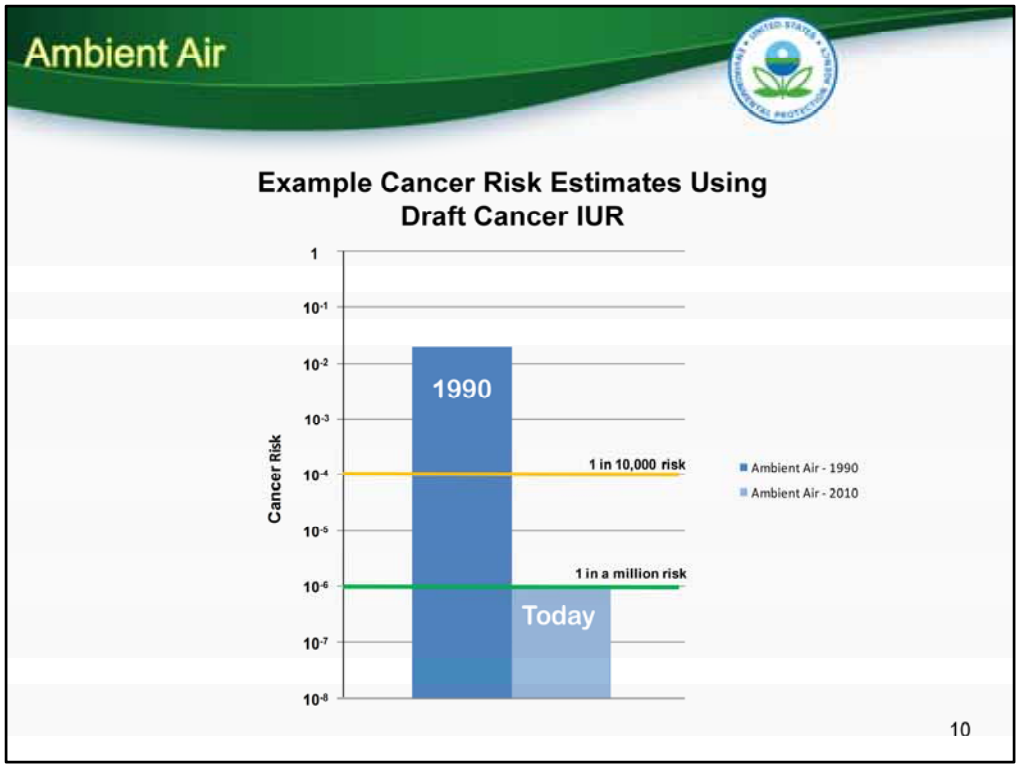
- Internal review is just about completed
  - It is currently highly unusual for EPA to release draft toxicity values prior to the completion of the review process
  - EPA is committed to transparency and openness with the Libby community
- About to begin Interagency review
- When the values reach the Public Review stage, just before entering SAB review, you will have the opportunity to comment on the toxicity estimates.
  - Your comments will be evaluated by the SAB and they will be published in the federal register.
- After the SAB review, the documents will again be reviewed by EPA scientists and other Federal agencies.
- Final values used in the human health risk assessment of exposures in Libby and Troy and, also, will be used to help make cleanup decisions in Libby and Troy.



Graphs:
- Toxicity values and the exposure estimates are still in a draft status
- Some of the calculated values may change as we refine our estimates.

Examples of a variety of exposure scenarios:
- Different outdoor air concentrations throughout the past 20 years.
- Indoor air concentrations that may be experienced within the home or within schools.
- Outdoor exposures in school yards as children play
- Some occupational exposures
- Some typical yard work exposures that someone may experience in their yard from mowing, raking and digging.
- Estimates represent what we call reasonable maximum exposures.

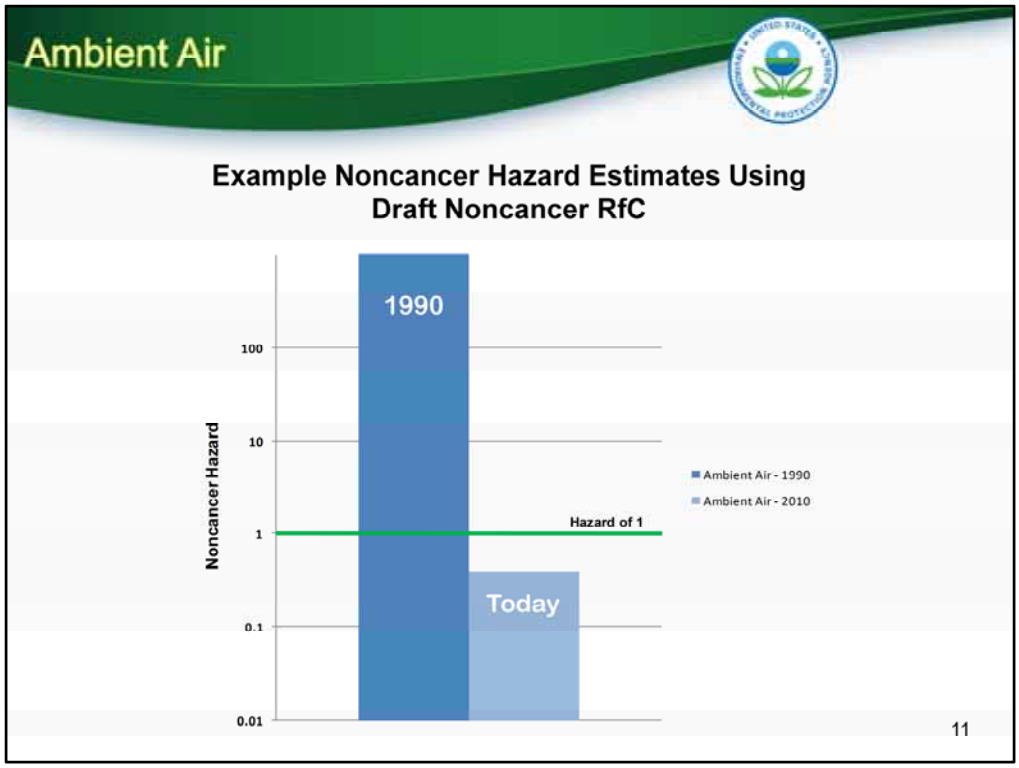
- Also – partial cumulative estimate – one that combines indoor and outdoor residential exposures



For each type of exposure represented by the following series of graphs (this one is exposure to ambient air):

- First of each pair is the cancer estimate
  - Vertical axis ranges from risk of $1x10^{-8}$ (10-8) to 1
  - Yellow line points to $1x10^{-4}$ target risk
  - Green line points to $1x10^{-6}$ target risk
- Second of each pair is the noncancer estimate (next slide)

- Shown here are exposures to ambient air.
  - Ambient air is the outdoor air surrounding us that we breathe.
  - The dark blue bar represents adult exposures to the ambient air in 1990 before EPA began the cleanup.
  - The light blue bar represents exposures to ambient air today.
  - Some of the decrease in the air concentration between 1990 and today is due to the closure of the WR Grace facilities; some is due to the EPA cleanup.
  - Today, the cancer risk to adults breathing air in Libby is below $1x10^{-6}$.

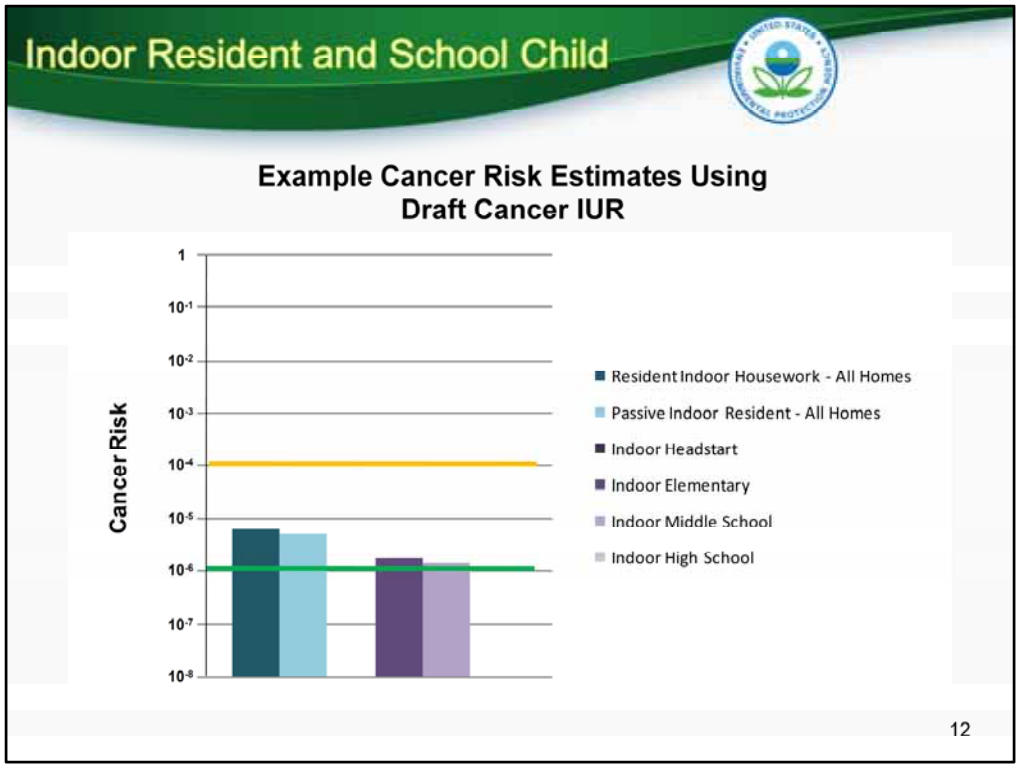


Here are the same exposures, but with a calculation of noncancer hazard.

- Vertical axis ranges from a noncancer hazard of 0.01 to over 100.
- Green line points to target hazard of 1.

The noncancer hazard:

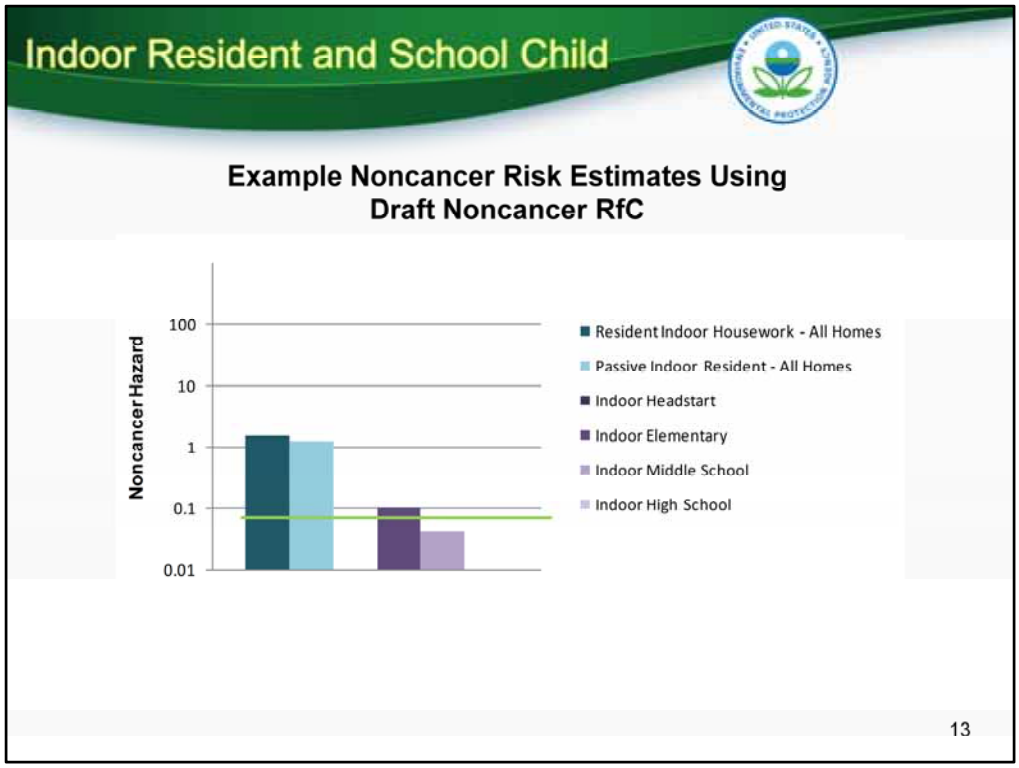
- Hazard index for adult breathing air back in 1990 is over 100.
- Today, the hazard index from breathing ambient outdoor air is less than 1.



Graphs representing indoor exposures – Cancer risk.

- Dark blue bar = activities such as housework – averaged over all homes
- Light blue bar = quiet activities in the home – averaged over all homes
- Purple bars = breathing by school children in schools
  - There were no detections of asbestos in Headstart and high school

Cancer risk for these exposures are below or within target range for cancer.



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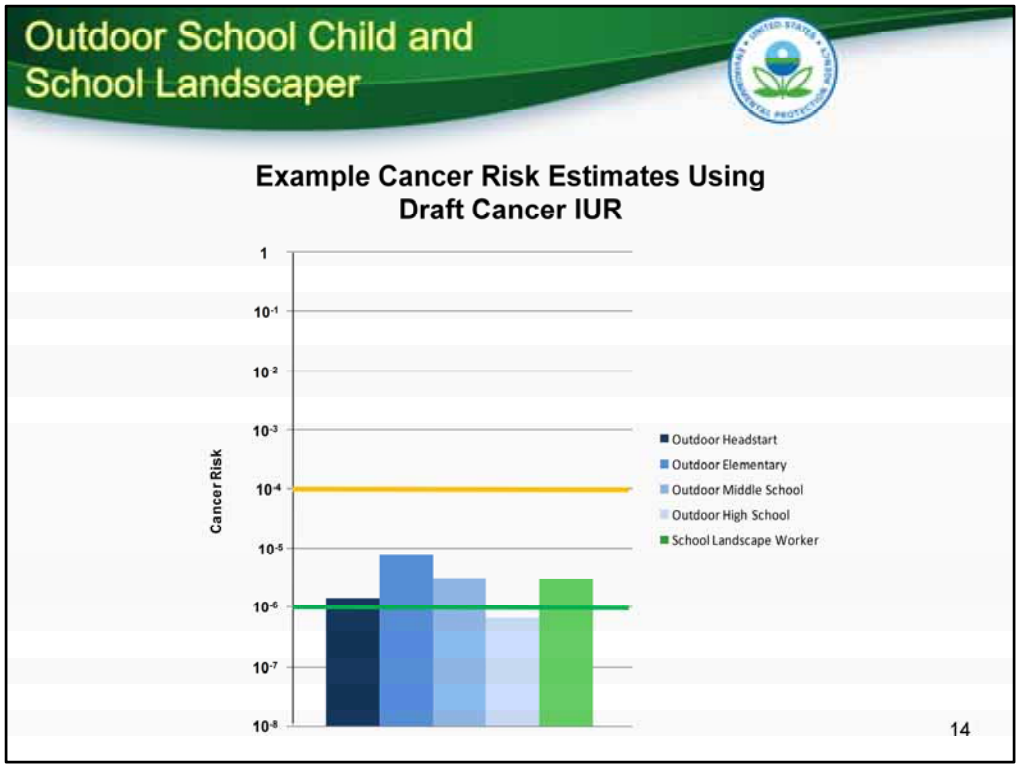
Noncancer hazard

- Indoor residential exposures at the target hazard
- School exposures below hazard target of 1.



Graphs representing outdoor exposures – Cancer risk.

- Blue bars = outdoor play in schools (exposures based on site-specific data reflecting school schedules (days per year, total years, etc.)
- Green bar = maintenance worker cutting grass at all schools (5 days a week, 8 hours a day, for 26 weeks a year, for 25 years.

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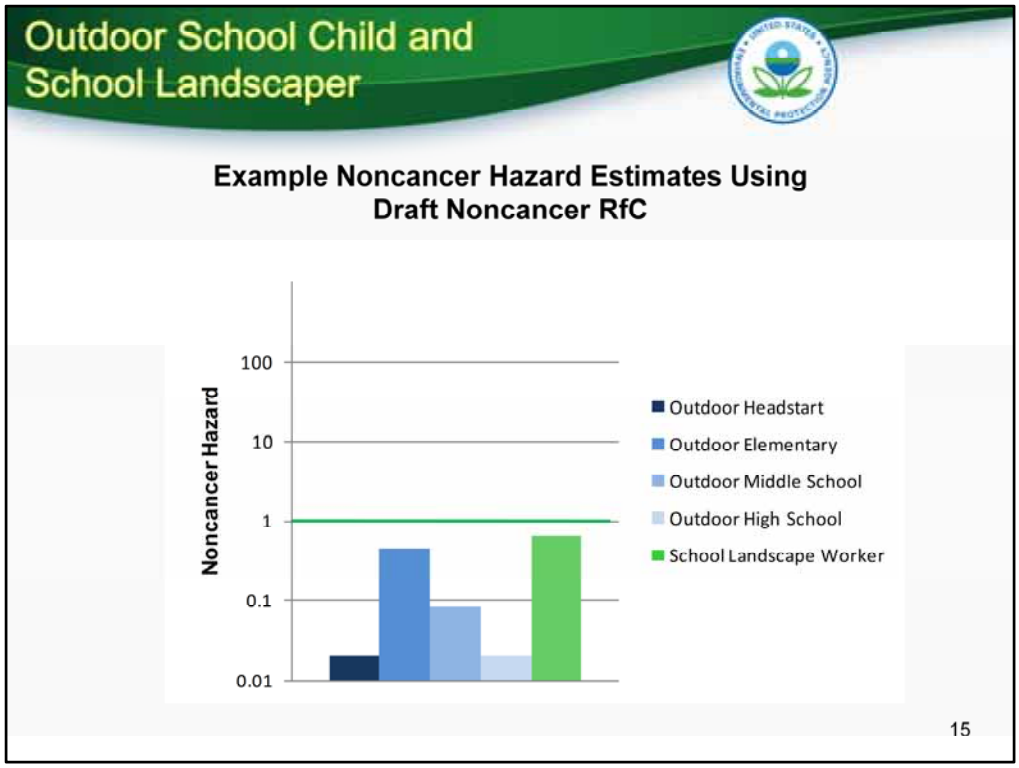

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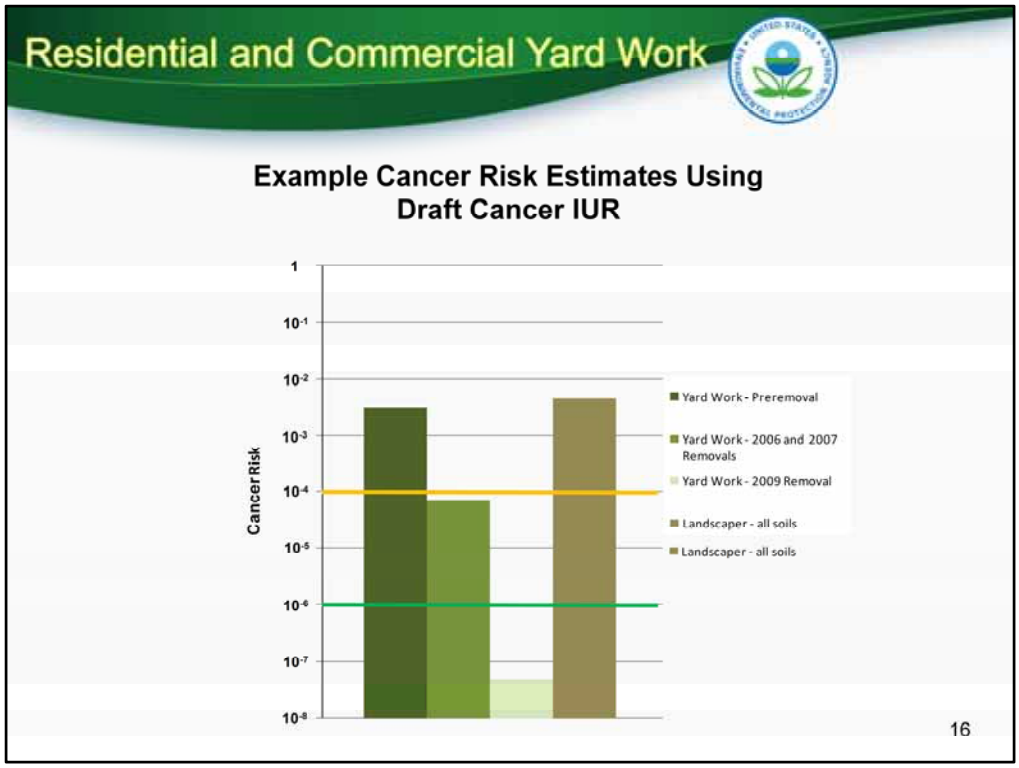
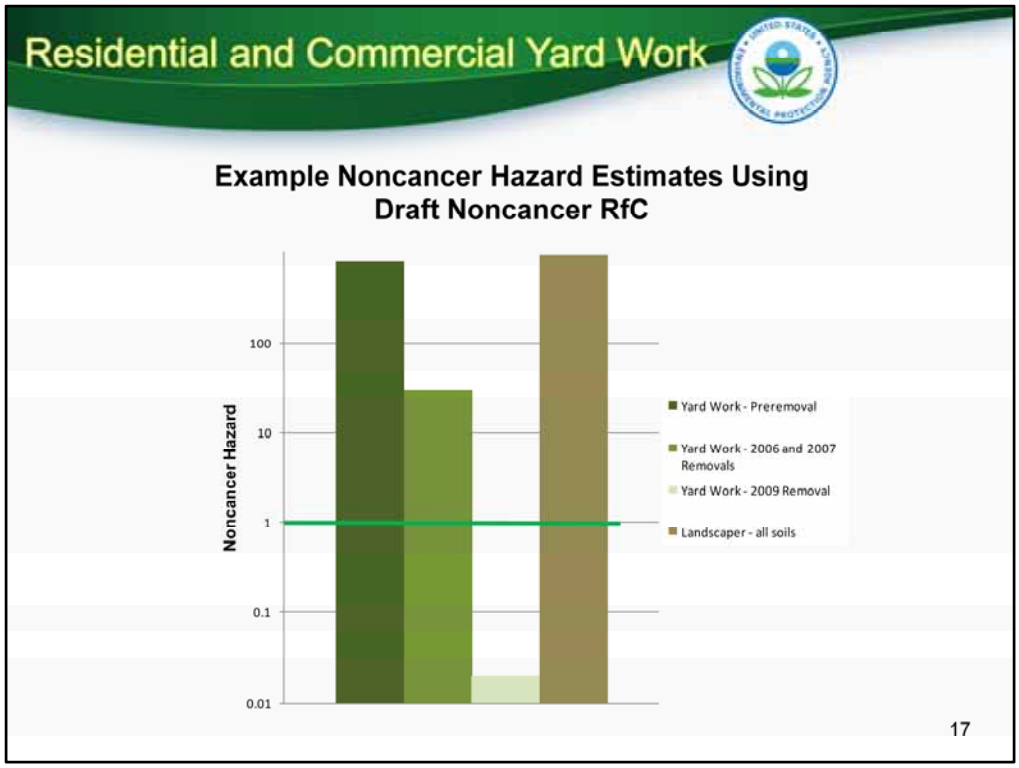
Noncancer hazard for these exposures are below target hazard of 1.



Graphs representing yard work (mowing, raking and digging) – cancer risk.

- Green bars = residential yard work
  - Dark green = yards that have not been cleaned – detectable levels of Libby amphibole and vermiculite
  - Medium green = yards cleaned in 2006/2007
  - Light green = yards cleaned in 2009
- Brown bar = commercial worker such as a landscaper doing yard work in types of yards (both cleaned and unclean) (5 days a week, 8 hours a day, for 26 weeks a year, for 25 years. Potential exposure to higher levels of Libby amphibole in yards that have not had an extensive removal.

Cancer risk for residential exposures to yards not cleaned and for commercial exposures to all types of yards are above 10^{-4} cancer target. Residential exposure to yards cleaned in 2006/2007 are below cancer risk of 10^{-4}. Residential exposure to yards cleaned in 2009 are below cancer risk of 10^{-6}.



Graphs representing yard work (mowing, raking and digging) – noncancer hazard.

- Green bars = residential yard work
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Hazard index for residential exposures to yards not cleaned, residential exposures to yards cleaned in 2006/2007 and for commercial exposures to all types of yards are above hazard target of 1. Residential exposure to yards cleaned in 2006/2007 are above target hazard of 1. Residential exposure to yards cleaned in 2009 are below target hazard of 1.

Factors Potentially Impacting Exposure Estimates

- Amount of soil removed
  - Removal of greater levels of Libby amphibole
  - Removal of visible vermiculite
- Source of backfill soil
  - Inside versus outside the Libby valley
- Soil moisture
  - Increased rainfall in 2009
  - Complete lawn cover at schools and some homes
- Sampling methods
  - Mowing in limited areas versus entire yard

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Studies Planned to Help Understand Factors Impacting Exposure Estimates

- Amount of soil removed
  - Repeat sampling of some yards cleaned in 2006/2007 and 2009
- Source of backfill soil
  - ABS on backfill sources
  - ABS at background locations
- Soil moisture
  - ABS mowing on dry versus wet yard
- Sampling methods
  - ABS mowing in limited areas versus entire yard
- Indoor air
  - Repeat sampling to evaluate previous estimates

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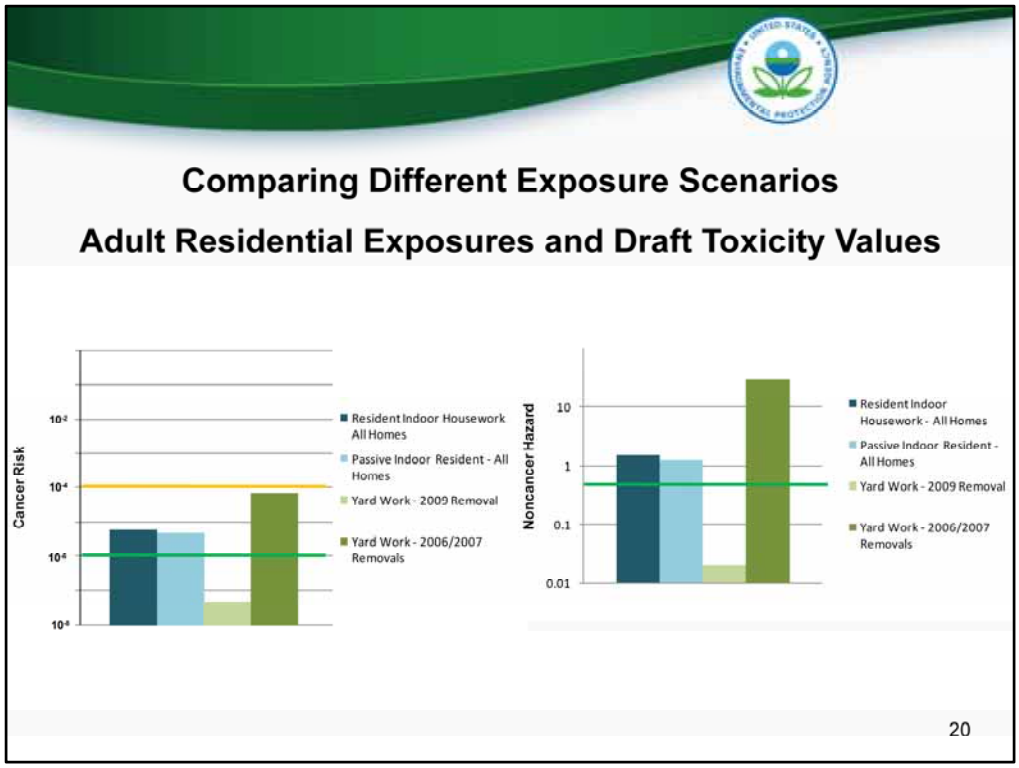
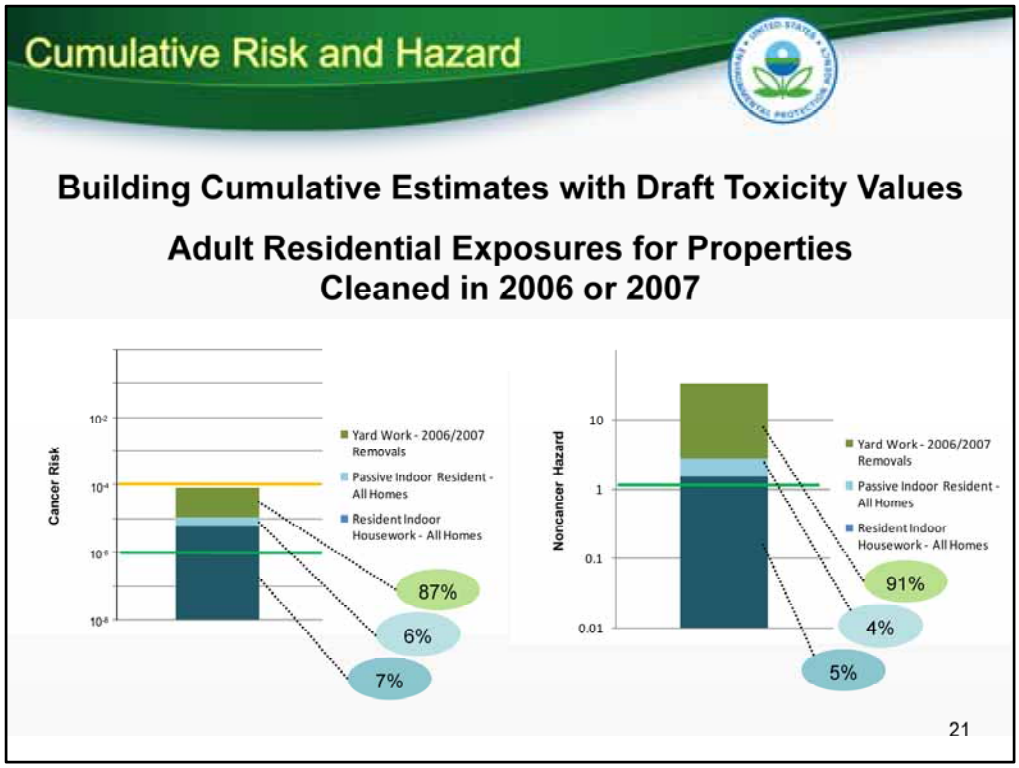


- Previous slides have shown preliminary cancer risk and noncancer hazard estimates for individual exposures (receptor such as an adult engaging in one activity such as housework).
- Next two slides will demonstrate an example of a cumulative risk estimate
- Above graphs show the individual exposures that will be included in the cumulative estimate
  - Indoor resident engaged in activities such as housework
  - Indoor resident engaged in quiet activities such as watching TV or sleeping
  - Outdoor resident engaged in yard work
    - comparing yard work for yards cleaned in 2006/2007 to yard work in yards cleaned in 2009

- Cumulative estimates for cancer risk as well as noncancer hazard will be shown



Cumulative estimates:

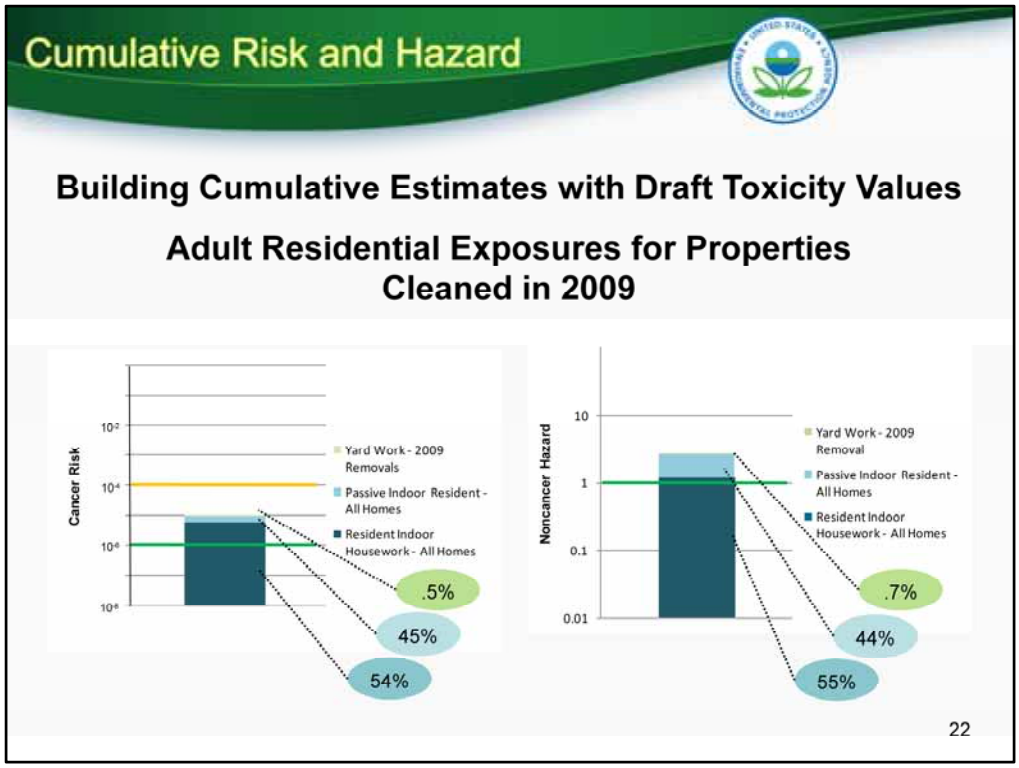
• Above graphs show the addition of cancer risk (on left) and noncancer hazard (on right) for the following exposures:

- Indoor resident engaged in activities such as housework
- Indoor resident engaged in quiet activities such as watching TV or sleeping
- Outdoor resident engaged in yard work in yards cleaned in 2006/2007

• Preliminary cumulative cancer estimate for these three exposures in less than 10^{-4}

• Preliminary cumulative noncancer hazard estimate for these three exposures is greater than 10

• The percent values in the small circles indicate the percent contribution of each exposure to the total risk. Here the yard work from the 2006/2007 removals is contributing the majority of the risk.



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- Outdoor resident engaged in yard work in yards cleaned in 2009

• Preliminary cumulative cancer estimate for these three exposures in less than 10^{-4}

• Preliminary cumulative noncancer hazard estimate for these three exposures is greater than 1 and less than 10

• The percent values in the small circles indicate the percent contribution of each exposure to the total risk. Here the yard work from the 2009 removals is contributing less that 1% of the total risk.

Summary

- At the present time outdoor activities that disturb soil appear to be the greatest source of Libby amphibole exposure.
- Indoor air quality may be of concern because of soil tracked inside.
- Draft toxicity values and exposure estimates may change pending scientific review and further data collection.
- A comprehensive cumulative risk assessment will be developed for a person who is a lifelong resident of Libby as the toxicity values are finalized and exposure assessments are refined.