

Council on Environmental Quality (CEQ) Comments on the Interagency Science Discussion Draft IRIS assessment of Libby Amphibole Asbestos (dated August 2014)

Date: August 13, 2014

CEQ Comments on the IRIS Assessment of Libby Amphibole Asbestos (Step 6B)

The Council on Environmental Quality (CEQ) appreciates the opportunity to review and comment on the final draft Integrated Risk Information System (IRIS) assessment of Libby Amphibole Asbestos. The assessment is clearly written and the analyses appear to be scientifically sound. The IRIS assessment of Libby Amphibole Asbestos supports a critical public health need and CEQ supports the timely completion and release of the final assessment.

We do not have any substantive comments on the content of this assessment. The derivation of the inhalation reference concentration (RfC), including the choice of principal study and critical effect (localized pleural thickening), and use of uncertainty factors, seems appropriate. Likewise, the derivation of the inhalation unit risk (IUR) seems appropriate. We also agree with EPA's conclusion that there are sufficient data to describe Libby Amphibole Asbestos as "carcinogenic to humans" by the inhalation route of exposure.

We understand that the IRIS assessment of Libby Amphibole Asbestos is one of the last assessments in Phase I of implementing the 2011 National Research Council recommendations, and as such, it does not use the new assessment template. We understand the assessment has been edited to be more concise and more transparent with respect to the literature search strategy and rationales for decisions.

We offer the following minor editorial suggestions with respect to the Toxicological Review:

Page 1-4, line 8: for clarity, suggest adding either "and" or a comma between "fibers" and "not."

Page 4-17, Text Box 4-1: suggest defining "LPT" in the definition of pleural thickening. It appeared once, but the abbreviation was used in a table. Defining it here in the text will provide some additional clarity.

Page 4-18, lines 34-36: suggest editing this sentence to be clearer. The sentence currently reads: "LPT is a change in tissue structure, and is not known to be an adaptive response to toxicity generally or to asbestos specifically." I think what this sentence means is scientists don't know whether LPT is an adaptive response to toxicity in general or to asbestos specifically. This would be clearer if the sentence were edited to read: "LPT is a change in tissue structure. It is not known if LPT is an adaptive response to toxicity in general or to asbestos specifically."

Page 4-20, lines 36-38: I think a word (maybe "and") is missing from the sentence after the semicolon (between "sites)" and "are"), which reads: "however, the results reported in the paper are for thickening on the chest wall only (rather than including other sites) are not equivalent to the 2000 ILO LPT classification."

Page 4-36, lines 8-10: the text reads "The risk of mortality related to asbestosis and other forms of nonmalignant respiratory disease is elevated in the Libby vermiculite mining and processing operations..." A few additional words would help with clarity in this sentence. The risk of mortality isn't elevated in the mining and processing operations, but in the population working in these operations.

Page 5-12, table 5-3: one row is labeled “time from first exposure,” whereas throughout the rest of the document, “time since first exposure” is used. Suggest remaining consistent with the terminology.

Page 5-19, line 27: a space is needed between “variables” and “should”

Page 5-20, line 12: should be “will likely result” instead of “will likely results”

We offer the following minor editorial suggestions with respect to the IRIS Summary:

Page 2, lines 3-4: Suggest putting the second sentence first (“an oral RfD was not derived”). Then follow up with the first sentence, though edited so it’s a complete sentence and not a phrase.

Page 8, line 35: Suggest defining “PCM” the first time the acronym is used.

Page 12, line 17: add “MOA” after “mode of action” to define that acronym (which is used later in the paragraph)

Page 13, first sentence after line number starts: missing the word “and” between “LAA” and “mesothelioma.”

Page 14, Section II.A.4, second paragraph: “ROS” should be defined since this is the first time the acronym is used.

Page 15, Section II.B. Was scientific information about oral exposure assessed and a slope factor not derived? Or was the oral route of exposure not assessed at all? Suggest being clear about that – perhaps by using language similar to what was used in the RfD section (...not assessed because inhalation exposure is the primary route of concern and there is a lack of oral data for LAA).

Page 15, Section II.C.1.1. Should the definition of inhalation unit risk include “at a concentration of 1 ug/L in water?”

Thank you again for the opportunity to review this assessment. I look forward to the interagency discussion.

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