## August 29, 2025

Cyrus Western, Administrator US EPA, Region 8 1595 Wynkoop Street Denver, CO 8020-1129

Re: Libby Asbestos Superfund Site Five Year Review and Delisting

#### Dear Sir:

This is a follow-up to the June 27 LASOC letter, which was developed not knowing that EPA had already made the protectiveness determination and finalized the Five-Year Review (FYR) report<sup>1</sup>. Presented are key elements, supported by additional discussion in attachments<sup>2</sup>.

We strongly disagree with the FYR report outcome and with suggestions of delisting OUs 4 & 7. Both your FYR process and determination are deeply flawed, and require re-examination and corrective action. This letter presents our rationale and expected outcomes<sup>3</sup>. Expected outcomes are:

- 1. Re-examination of the FYR
- 2. Revised determination: "Protectiveness cannot be determined until further information is obtained"
- 3. Addendum that memorializes the re-examination and sets out follow-up activities
- 4. A transparent and collaborative process
- 5. Indefinite postponement of discussing delisting of OUs 4 & 7

### 1. Re-examination of the FYR:

The FYR neither thoroughly examined relevant information related to human health impacts, nor acknowledged (or considered) submitted ecological resource information. Besides being an incomplete review, serious questions arise regarding professional due diligence and negligence. See Attachment 1.

# 2. Revised Protectiveness Determination:

<sup>&</sup>lt;sup>1</sup> LASOC Chairman, Brent Teske also provided a brief email on August 7 in response to the questions raised when you met with him during the week of July 18.

<sup>&</sup>lt;sup>2</sup> This letter supplements, not replaces, our June 27 letter.

<sup>&</sup>lt;sup>3</sup> Consistent with the intent of LASOC to provide a strong "local" voice and also to preserve the MT DEQ Director's role to independently voice DEQ opinions, this letter represents the position of LASOC's Lincoln Country representatives.

Based on an objective re-examination of the FYR the only justifiable protective determination is "*Protectiveness cannot be determined until further information is obtained.*" The current *carte blanche* determination is not justified or defendable given the lack of due diligence and omissions in the FYR. See Attachment 1 again.

# 3. Addendum to FYR:

An addendum to the FYR is essential to correct the deficiencies of the current FYR, and to memorialize follow-up activities that are required. Restating from our June letter: We are fully cognizant of the effort (funds and time) it will take to fully reexamine the more recent science, and to carry that forward with an updated risk assessment for both human health and the environment. To ignore this need is not protective and would be directly contradictory to the purpose of the FYR. It should be expected that the body of knowledge regarding LA is growing, and will continue. Long term planning for this Site (hindsight now) was deficient in not recognizing the inevitable reality of long-latency diseases, and making detailed provisions to address it with resources. That lack of foresight does not erase or diminish the need. See Attachment 2.

### 4. Process:

A transparent and collaborative process is necessary to help restore confidence in EPA's evaluation of Site protectiveness, and to establish a well thought out path to eventually answer the questions raised. The current scientific understanding of LA effects on human health and ecological resources is inadequate to assure protectiveness. See Attachment 3.

# 5. Efforts to Delist OUs 4 & 7:

As soon as the O&M phase began for these residential units we began hearing a repetitive desire from EPA to delist OUs 4 & 7. Again, as stated in our June letter, we are firmly opposed to delisting for the reasons then stated. Further, after considering this and our prior letters you should clearly understand our opposition. How could we possibly support delisting when we are no longer convinced that the remedy is protective? This continued delisting theme seems to be tone deaf to our concerns.

#### Summary:

This letter presents the rationale for our stance on the lack of known protectiveness and articulates our expected outcomes. We are prepared to work collaboratively to achieve these outcomes. Please consider this communication along with our June letter. We would appreciate a response by October 1 regarding whether you are willing to jointly pursue these outcomes, which is our preference rather than other options. Regardless, we need to be on a course to address these concerns. Thank you for your attention to this matter.

# Respectfully,

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## Cc:

Director, DEQ Sonja.Nowakowski@mt.gov (also LASOC member)
Lincoln County Commissioners
Lincoln County Board of Health
Lincoln County Health Department
City of Libby, Mayor
City of Troy, Mayor
Sen Daines
Sen Sheehy
Rep Zinke

# Attachment 1 Discussion- Re-examination of the FYR

- Updated scientific findings related to human health since the last FYR were provided in November 2024. As mentioned in our June 27 letter, among the concerns are correlation of LA exposure and autoimmune diseases that were not known or considered 10+ years ago. These comments were given mention in the FYR, but not thoroughly discussed or examined. Other concerns not addressed include recent findings of emphysema, coronary artery calcification, and other conditions detectable by the thoracic CT screening as part of the Libby screening program.
- These human health issues are not the basis of the current risk assessment and remediation. Protection of human health mandates a responsible pursuit of understanding these emerging trends.
- Only tacit recognition of pursuing the human health concerns has been given by EPA. Dismissive rationales have included lack of capability to get to answers, no funding, "it would take decades of research to answer concerns", etc.
- An early comment to EPA related to research of the human health concerns did result in EPA providing a contact with ATSDR as well as information about registries.
- The FYR does not follow the intent or wording of the FYR Guidance<sup>4</sup>.
  - a. Interviews and Community Responses- Summaries in the body of the FYR report show a bias toward understating the responses.
  - b. The Technical Assessment for the FYR is grounded mainly in the report's discussion of Question B. The Guidance discussion of this question focuses the review mainly on changed "standards." The human health concerns raised of course do not rise to the level of a new "standard" and should not be judged in the context of this Question.
  - c. The Technical Assessment inappropriately uses Question B's context and intent to be dismissive of the concerns raised as they relate to the protectiveness question. Page 22 states, "While these are legitimate concerns and have merit for consideration, decades of research would need to be conducted to satisfactorily address some of the concerns. Based on the best available data and the current Libby amphibole asbestos toxicity factor, the current remedy for the Libby Asbestos Site is protective." This statement admits that more information is needed to make a determination of protectiveness.
  - d. Setting these concerns aside in Question B is not appropriate, especially given that none of the concerns for human health or ecological resources is even mentioned in Question C.
  - e. Page 22 also includes this statement, "EPA plans to consult with the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention on the concerns listed above." Section VI (a table) lists no issues or recommendations for any of the

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<sup>&</sup>lt;sup>4</sup> Comprehensive Five-Year Review Guidance, USEPA, OSWER No. 9355.7-03B, June 2001

OUs, but repeats the "plan to consult" statement under Other Findings on page 23. The "consulting" effort is appreciated and may be ongoing, but "plans to consult" are no substitute for the elements of an Addendum that lays out obligations for specific goals, timelines, etc. Informal descriptions of the "plans to consult," as being "on our to-do list" or "to be looked into" are not memorialized commitments. These plans to consult clearly indicate that not enough information has been collected to make the determination of protectiveness, and are inconsistent with the "no" answer to Question C.

- f. The lack of formalized commitments to begin the decades long effort to address human health concerns is inconsistent with EPA's mandate to protect human health at this site, and is negligent in following the Guidance. Clearly the reason that it would take decades to address the legitimate concerns that have been raised is that we are only now approaching the time when long-latency diseases (all ARD) might start decreasing due to the remediation. Due to this latency problem with these health concerns, it is absolutely impossible and negligent to make the determination of protectiveness at this time. A new risk assessment that is consistent with the disease latency is absolutely essential. Yes, decades.
- g. Question C in the FYR is a broad question that is clearly, and appropriately, meant to prompt an examination of other relevant information that doesn't fit (nicely or otherwise) into Questions A or B, yet the FYR report answers Question C as "No other information has come to light that could call into question the protectiveness of the remedy."
- h. To name only two concerns that call into question the protectiveness of the remedy: the frequency of autoimmune disease diagnoses in the Libby/Troy area being almost triple the expected the US prevalence and some systemic autoimmune diseases being increased 5-10 fold over expected US prevalence values<sup>5</sup>.
- i. A researcher posed a question during EPA's July FYR public meeting that asked why "no information came to light" was the answer to Question C. The EPA toxicologist replied that new information must meet a certain threshold to be considered for that question, then cited that it is commonly a new Tier 1 EPA IRIS assessment. Confirmation of this threshold defining response has not been found in the Guidance. A new IRIS assessment would likely be a threshold for Question B, but there is no such threshold for Question C. By incorrectly imposing an unstated threshold criterion on the human health information in Question B, it eliminated it from consideration. Then it is conveniently ignored in Question C. This meeting response confirms that the analyses incorrectly focused on new standards only.
- The lack of consideration of ecological resource information as the second major element of "new information" since the last FYR alone is justification to reexamine the FYR.

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<sup>&</sup>lt;sup>5</sup> See Dr Jean Pfau FYR comments dated November 30, 2024.

- a. Per our June 27 letter, the ecological concerns revolve around the previously unpublished "Pre-Assessment Screen (PAS) Report for a Natural Resource Damage Assessment (NRDA)" conducted in 2021. That report was provided to EPA on March 3, 2025 by one of its co-authors as a "Further Comment on FYR". This report, completed for USGS/FWS, included review of the Baseline Ecological Risk Assessment (BERA) concluded for the Site, with emphasis on OU 3 (mine site) and concluded that the (then 10 year old) BERA "should not be considered due diligence in the evaluation of the potential ecologic impact of LA".
- b. Obviously, the PAS Report fits into Question C, yet as stated above the FYR report answers Question C as "No other information has come to light that could call into question the protectiveness of the remedy." This is especially troubling and negligent given that the FYR Guidance (on page 4-9) provides one of the "Situations to watch for" as "Ecological risks have not been adequately addressed at a site, and there is not a plan to address them through a future action."
- The public health and the ecological resource concerns, if diligently considered, would result in Question C being answered "Yes", followed by appropriate followup recommendations, an Addendum, etc.
- The spirit of the FYR Guidance and the EPA mandate to protect public health and the environment should encourage collaboration with the affected public, the scientific community, and other knowledge holders. Due diligence is essential to the FYR, but lacking in this instance. Both the human health and ecological concerns cited are not unknown to EPA staff, particularly at the toxicology/risk assessment level. One must wonder why there was no outreach to the outside scientific community who are known to the EPA technical staff. Why was an invitation not accepted to attend a meeting of the CARD Scientific Advisory Group in Libby on June 19 and 20 (even though the FYR Report was done by then unknowingly to us)? Why was there no feedback to make a first attempt to answer what should be done first to answer these compelling questions?
- The human health and ecological concerns are not new to EPA toxicology/risk assessment staff. Even without the input provided by the research and public communities, due diligence and a reasonable standard of care should have identified and addressed these concerns.
- Re-examining the FYR should proceed by reflection and auditing of the poor performance of this FYR.
  - a. When the Libby Asbestos Site came to national prominence about 25 years ago, the early responders, especially Dr Chris Weis, Dr Aubrey Miller and Paul Peronard, were highly focused on protection of human health and exhibited personal and professional courage to lead EPA and the community through uncharted waters. Then, like now, there were/are health questions to which there were no answers (quantifying risk). But they then and all of us going forward have an obligation to get answers.

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<sup>&</sup>lt;sup>6</sup> The report was submitted having been told comments could still be received, and is clearly within the Review Period ending on June 1 as stated on page 5 of the FYR report.

- b. The 25+ years of dealing with this Site can result in complacency and loss of focus. The robust and dynamic leadership that led the early activities at the site has deteriorated. EPA should be the leader in proactively maintaining a focus of the emerging LA related issues. The early culture and focus have been lost. We encourage EPA to make a critical examination of focus and performance.
- In this discussion of Questions B and C, the June letter should be referenced regarding concerns about Question A answers and its influence on increased uncertainty about protectiveness.

# Attachment 2 Discussion- Addendum to the FYR Report

- The purpose of the Addendum is to correct the shortfalls of the FYR, e.g. the
  ecological issues, and more importantly to memorialize activities needed to
  advance understanding of the human health and ecological concerns to
  eventually enable knowledgeably assessing:
  - o Critical and governing health outcomes and ecological impacts
  - Revisions to risk assessment parameters
  - Re-evaluation of the Remedial Action Objectives
  - Additional or revised remedial actions, if necessary
- Elements of the addendum should include
  - Recommendations/follow-up actions
  - Responsible parties
  - Oversight responsibilities, and
  - Milestone dates
- The most important and essential recommendations are preserving existing records and materials, and establishing a foundation support system for data sharing and research findings. Specifically the following:
  - Preservation of CARD records, data and biological samples
  - Continuation of grant support for CARD
  - An ATSDR registry for LA
- While EPA probably cannot directly effectuate these specific and other needs, they should be advocating for them as being essential to advancing understanding needed to provide protectiveness. EPA has a responsibility to articulate what in general they need to evaluate and provide protectiveness, as was done 25 yrs ago.
- The Addendum should include both short and long term goals, the latter which will likely span decades.
- The goals should reflect not just the long term latency of LA related impacts but recent findings that some autoimmune responses to LA may be rapid.
- Screening and evaluations of adolescent populations not previously part of screening should be a high priority. We need to know what effect, if any, we are seeing on the younger population.
- What research and clinical activities are needed to assess if there are measurable results from the remediation efforts?
- Recommendations should be developed interactively including expertise not organic to EPA.
- Funding is always an issue, and has been cited for years as an obstacle to
  establishing an ATSDR registry. While some of the goals and recommendations
  in the Addendum may not be completed due to funding issues, work should at
  least begin. Funding should not limit what is recommended. Recommendations
  should focus on what is needed. Alternatives for funding besides from Federal
  budgets should include Site designated funds and/or additional funding by PRPs.

- These concerns raised in the context of the FYR will undoubtedly be foremost in our future examination of the upcoming OU3 FS, which should be encouragement to proactively and collaboratively address them now.
- The concerns raised about the FYR are focused on the Libby Site, but it is important to remember that LA is scattered through the US and impacting human health. Advancing understanding and having a Registry would benefit public health, especially clinicians.

# Attachment 3 Discussion- Transparent and Collaborative Process

- The lack of transparency and collaboration in the current FYR has been a major contributor to an inadequate FYR, and loss of confidence and trust.
- Participation in the proposed re-evaluation by EPA staff who contributed to this flawed FYR and loss of confidence would be counterproductive. A fresh look is needed.
- It is recommended that an outside facilitator be retained to guide our mutual collaborative process.
- Key EPA risk/toxicology staff and LA researchers are known to each other, but yet no significant efforts were made to discuss the voiced concerns, including the ecological resource assessment shortfalls.
- Members of the research community, including selected ATSDR, NIH, CDC, etc staff are more well versed on LA science and clinical matters than EPA...as should be expected. Those resources should be actively consulted, if not delegated, to bring recommendations to EPA for inclusion in the Addendum.
- Participants in the Addendum process should also include Montana DEQ and members of the Lincoln County community.
- Both foregoing comments underscore the need for a permanent advisory group that could help move us past this current challenge and provide reliable and consistent oversight for decades.
- An organizational framework for initial consideration should be built around the Center of Excellence concept with an initial project for the planning phase with an advisory group. This concept has been the subject of significant effort and attention by CARD's Scientific Advisory Group (and others), and provides a significant head start to establishing a structure and other elements of a "Asbestos Related Disease Healthcare & Research Center of Excellence." It is encouraging that such efforts that have not come to fruition can now be a path forward.
- The recent EPA public meeting in July was frustrating by not being recorded for future reference, for recording being blocked, and for a cumbersome written question format that discouraged dialogue. We have asked for assurances that any future public meetings will be recorded, which was done at the more recent Groundwater Site FYR public meeting.
- It was striking to note the different tone of the Groundwater Site FYR and how it dealt with protectiveness issues in a more open and proactive manner. It was well done and encouraged confidence and trust.