Anticipated Public Health Questions from the Butte Community/CTEC

Talking Points

Confidential

The following talking points include questions that are anticipated to be asked at the CTEC meeting on Tues. April 8th and/or the Public Health Study meeting Wed. April 9th.

Misc. Public Health Questions:

1. Q: What are the Synergistic effects in Butte?

   A: When people are exposed simultaneously to multiple contaminants the response may be simply additive of their individual responses or may be greater or less than expected by addition of individual responses. An additive effect is the situation in which the combined effect of two chemicals is equal to the sum of the effect of each chemical given alone (e.g., 2+2=4). A synergistic effect is the situation in which the combined effect of two chemicals is much greater than the sum of the effect of each chemical given alone (e.g., 2+2=6). For example, both carbon tetrachloride and ethanol elicit liver toxicity, but together they produce much more liver injury than the mathematical sum of their individual effects on the liver would suggest. ~~Very few chemicals have been shown to be synergistic.~~ An antagonistic effect is when two chemicals interfere with each other's actions (e.g., 2+2= -3). Dimercaprol (a chelator) and lead are examples of antagonists. Most synergistic or antagonistic interactions can only be demonstrated at relatively high exposures where clear adverse effects are observed. Such interactions have not been observed or quantified at the relatively low rates of exposure typical of those associated with most environmental situations (NAS 1983; Krewski and Thomas, 1992). EPA uses a default approach that conservatively assumes that chemicals that induce the same effect by the same mechanism of action act in a additive manner. Several of the metals at Butte act on the same target organ. For example, arsenic, cadmium and mercury may elicit renal toxicity. However, it is important to remember that additivity is evaluated at the dose at which renal toxicity occurs. Not at the dose which EPA regulates the metal, which is based on the most sensitive effect in the most susceptible population. For example, the non-cancer toxicity value on EPA's IRIS database for arsenic is based hyperpigmentation of the skin. To assess additivity of renal effects, one would have to go back into the scientific literature and derive a non-cancer toxicity value specific to renal effects for arsenic. Other potential additive ~~effects~~combinations:

   - Methylmercury and lead – neurological toxicity
   - Lead and cadmium – cardiovascular toxicity
   - Lead and cadmium – hematological toxicity
   - Lead and cadmium – testicular toxicity

2. Q: Are Butte action levels protective/appropriate now that the CDC reference level is at 5 ug/dl?

   A: Yes, Butte action levels are protective and appropriate even though the reference level has changed.

   The draft Butte Public Health study shows that blood lead levels in Butte have declined dramatically since 2003 and are currently consistent with young children of similar demographics across the U.S. (e.g., mean blood lead levels of 1.5 ug/dl). This would suggest that the soil action levels derived for Butte have been protective and the RMAP program has been effective at identifying and reducing elevated blood lead levels.

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3. Q: Should the IEUBK model for BPSOU be revised and ran again?

A:When guidance is finalized, it will be determined if the if the 5ug/dl reference level warrants a re-run of the model. Every five years EPA re-evaluates the remedy established in the Record of Decision to determine if it is still effective. This re-evaluation considers any new information such as changes in land use, institutional controls or new EPA guidance's and policies. If EPA changes its policies regarding the exposure and toxicity assessment of lead, this will be evaluated in the next 5 year review.

4. Q: Is my garden safe if the sample result was 800 mg/kg?

In 1995 EPA conducted a study on the uptake of lead and arsenic by garden vegetables at the Kennecott NPL site in Utah. Over 20 different types of vegetables were grown in soil with lead concentrations ranging from 20 – 2290 ppm. Ingestion of the garden produce was modeled using EPA's IEUBK model. In typical cases the lead consumed from garden vegetables would not be a problem. However, for individual households with particularly high garden vegetable consumption, especially those of root vegetables, the level of lead exposure could become a concern.

For those with concerns about ingesting produce from their gardens

A: Under the Office of Solid Waste and Emergency Response (OSWER 9200.2-142 December 2013), the Technical Review Workgroup recommends that a range of soil lead Concentrations be used as guidelines to consider the associated Best Management Practices for Gardening in Lead Contaminated Areas to reduce lead exposure in contaminated soil. For example: the 800 mg/kg falls within the Potential Risk category and the recommended gardening practices are:

- Increased use of good gardening and housekeeping practices
- Relocate garden to lower risk garden areas
- Increasing use of soil amendments(e.g., compost, clean fill), barriers (e.g., mulch), and other remedial measures, including raised beds and containers
- Ensure gardeners wear gloves and use tools to reduce soil contact and ingestion

For further background information on lead risk assessment, refer to U.S. EPA Technical Review Workgroup for Lead website at: http://epa.gov/superfund/lead/trw.htm

5. Q: Are my children safe playing in dirt that sampled at 1,100 mg/kg.

A: Yes, EPA has produced 4 Baseline Human Risk Assessments for the BPSOU to ensure that people's health is not being affected by the heavy metals in the soils.

As mentioned above, EPA believes the soil action level for lead is protective of young children and their families. A study of the blood lead levels in Butte since the start of the RMAP program shows that blood lead levels in Butte have substantially declined and are consistent with those of other children in the U.S.

6. Q: What is the difference when comparing Anaconda and Butte action levels?

A: Basically they are different Remedies with different site characteristics. Butte has a comprehensive metals abatement program and a lower lead bioavailability.

See #8 below.

7. Q: Where do we go from here on the next Health Study?

   A: Phase II -- other issues raised by CTEC?

8. Q: Why is Arsenic action levels in Butte and Anaconda at 250 mg/kg and lead action levels are at 1200 mg/kg and 400 mg/kg respectively?

   A: The arsenic action levels are similar in Butte and Anaconda primarily because the bioavailability of the arsenic in soil was similar (approximately 13 -18%). The lead action level in Butte is 1200 ppm primarily because the bioavailability of lead in soil was very low (approximately 10%), whereas the bioavailability of lead in soil at Anaconda was much higher. Nikia, want to add anything about sources of lead differing in the two communities?

9. Q: CTEC members have asked for an external peer review to confirm or critique the methodology of the draft study prior to its finalization, to increase public confidence in the study's findings. What reasons can they think of for not doing this?

   A: An external peer review is entirely appropriate. It is critical that individuals with the appropriate training and experience in epidemiological and statistical sciences comprise the peer review panel to bring credibility to the assessment. Currently, a journal article of the public health study is being prepared for submission to a respected scientific journal for publication. This process requires review and critique of the article by several established professionals in the pertinent field of expertise. Completion of this process should satisfy any concerns regarding an external peer review.

10. Q: There are likely to be questions about how the study accounts for behavior modification if at all, as well as comparisons between uptown and downtown blood lead levels in Butte.

    A: Best for Roz and Dina

11. Q: There are concerns that the study will be presented as proof that RMAP is reducing the lead levels (cause and effect). Discussion on the 9th needs to help clarify what actual claims the study makes (if any) about the relationship between RMAP and the reduction in blood-lead levels.

    A: The public health study does not attempt to draw a direct correlation between the RMAP program and the reduction of blood lead levels in Butte. The purpose of the health study was to evaluate blood lead data collected in Butte from 2003 to 2011 to understand:

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    - How lead exposures in Butte have changed over time
    - How they compare to blood lead levels for areas outside of Butte
    - What factors in Butte might be contributing to differences in blood lead levels within Butte and between Butte and reference areas

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    The dramatic decline in blood lead levels since 2003 and the establishment of the RMAP program suggests that the RMAP program has been effective in identifying and reducing elevated blood lead exposures. The alternate conclusion is that blood lead levels are declining everywhere and nothing further needs to be done in Butte.

12. Q: Will the study be used to justify old blood-lead action levels (10mg/liter vs 5mg/liter) when new science might surface? There is concern that EPA will choose not to reopen a ROD even though the rest of the country is using a blood-lead risk number half of what we're using in Butte.

    A: It is not the goal of the public health study to justify regulatory action levels. The purpose of the health study was to evaluate blood lead data collected in Butte from 2003 to 2011 to understand:

    - How lead exposures in Butte have changed over time
    - How they compare to blood lead levels for areas outside of Butte
    - What factors in Butte might be contributing to differences in blood lead levels within Butte and between Butte and reference areas

    During its 5 year review of the Record of Decision, EPA will evaluate all new information and changes in policies or guidance's.

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13. Q: A presentation on the history of how we have gotten to where we are at will help both seasoned CTEC members and the general public. Show a summary of the studies: the Pig Study, University of ~~Cincinatti~~Cincinnati study (Walkerville study) and the Bornshine study. Explain how you get a blood lead level and deal with bioavailability numbers.

    A: Can response to individual questions at this time. A more formal presentation may be needed in the future.

14. Q: What thoughts do they have about future studies that will provide actionable information? What are we looking for in the next level of the health studies? If you were in our shoes, what would you be looking for?

    A: Non-Superfund concerns?

15. Q: Possibly look at other concerns?:

    A:

16. Q: Contaminants of Concern? Arsenic, Cadmium and Mercury.

    A:

17. Q: Arsenic: Is there some way to look at Arsenic? Is there an action level? Is there chronic exposure? Did the risk assessment take into account attic dust? What are the levels in attic dust?

    A:EPA conducted evaluations of the risks to arsenic exposure in both Butte (1997) and Walkerville (2003) using the framework outlined in EPA's Risk Assessment Guidance's for Superfund. Preliminary remediation goals were calculated using the risk assessment methodology and site-specific exposure inputs. In the Walkerville risk assessment, exposure to attic dust was evaluated. Concentrations of arsenic in attic dust ranged from 2 – 1220 ppm with an average of 377 ppm. The residents were queried as to what they used their attics for and how much time they spent in their attics. Based on this information, exposures from both long term use and short term re-modeling work were estimated. Exposures to arsenic in the attic dust were found to be within EPA's acceptable levels of concern.

18. Q: Areas of contaminated groundwater that is technically impracticable to clean up perceptions.

A:

19. Q: What would you recommend to help lay to rest the perceptions that have no basis in fact? What new dialogue could be opened about matters of concern?
A: I believe that the people who state the current cleanup levels are not protective should show evidence of how they are not. We have (1) a report from the Montana Department of Public Health and Human Services showing no differences in cancer incidence rates between Silver Bow county and the state of Montana or the U.S. and, (2) the current Public Health Study showing that blood lead levels in Butte have declined dramatically since the implementation of the RMAP program and are now consistent with those of similar children in the U.S. Where is the evidence that the programs in Butte are not protective?

20. Q: What can a health study do to help current, new and potential residents understand the potential risk? How can you differentiate rumor from fact? How can we give confidence to the public?

    A: The public health study was developed in collaboration with the Silver Bow County Health Department, the Montana Department of Environmental Quality, the USEPA, ARCO, and citizens of Butte (Nikia, do you want to elaborate). The study provides evidence of a dramatic decline in blood lead levels since 2003. Currently blood lead levels in Butte are consistent with those of similar children in the U.S. The structure of the RMAP program is clearly articulated and ensures that children can be tested and evaluated by the county health department, if necessary.

21. Q: What are the implications for public health with leaving waste in place—with known toxic constituents? This would include the Mt Pole Plant's dioxins left in place.

    A:

22. Q: What process does the EPA envision for determining the direction of future health studies in Butte?

    A: I think this is a decision for the citizen's of Butte, the county health department and the state of Montana, not just EPA.

John Ray Questions (04-06-14)

1. ~~1.~~ **Butte was promised an independent peer review of the study. This independent peer review was supposed to be part of the process of developing and conducting the health study, It was not supposed to be an after the fact endeavor that would have no impact on the design and conduct of the study. EPA appears to be reneging on that promise. Now all the agency promises us is that at some time after the process is finished some condensed version of the study will be submitted for possible publication. It was also stated by EPA that this review would not change the study. Such a review will have no impact on the design and conduct of the study as EPA originally promised. What good is it? Why is EPA afraid to have its work independently reviewed? Having a condensed article published is not the kind of independent peer review EPA promised. What the ~~pubic~~public is left with is that the EPA and its associates will be reviewing their own work. What assurances can the public have that this report was done in an unbiased manner and done correctly?**

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Without an independent peer review, the public can have NO such assurance. Why has EPA reneged on its promise? What is EPA afraid of discovering?

Response: See #9 above.

2. The purpose of the study is to demonstrate that the Residential Metals Abatement Program is working. I support the program but the methodology the study uses is faulty. It is an example of the "post hoc, ergo propter hoc" fallacy. On the one hand the study says the Residential Metals Abatement Program exists. On the other hand the study says that lead levels are dropping in Butte. The unproved assumption is that the first is the cause of the second. Yet, no methodology is utilized in the study to demonstrate this causal link.
How was this causality established?
Also, just because lead levels in Butte are approaching the national average, is the national average protective of human health? No data to warrant this conclusion is provided by the study.

Response: See #11 above.

2. ~~3.~~ By looking only at lead levels, the study does not give a big picture view of the entire toxics problem in Butte. We are told that the studies will be going on for some 30 plus years. By the time the studies are completed the point of the effectiveness of Superfund in Butte will be largely mute. We need some assurance for the residents of Butte currently alive that Superfund is working. This is just another example of the EPA dragging things out to the point that people either die or are no longer interested.

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Response: See #2 above

4. The study ignores environmental justice concerns. How is environmental justice incorporated into the design and execution of the health study?

5. Stacie Barry's peer reviewed study reached the conclusion that Superfund overall in Butte was not working and that public health was not being protected. We now have an EPA funded study that reaches the opposite conclusion. Why should we believe this EPA produced study? How is the EPA study better than the work that Stacie did? Is this EPA study simply a PR effort by EPA to refute Stacie's conclusions?

Response: The recent report from the Montana Department of Public Health and Human Services showed no differences in cancer incidence rates between residents of Silver Bow County and the State of Montana or the U.S. (http://www.dphhs.mt.gov/publichealth/cancer/documents/CancerIncidenceSilverBowCounty.pdf). This report was developed by experienced trained epidemiologists.

~~6.~~ The public health study was developed in collaboration with the Silver Bow County Health Department, the Montana Department of Environmental Quality, the USEPA, ARCO, and citizens of Butte (Nikia, do you want to elaborate). The study provides evidence of a dramatic decline in blood lead levels since 2003. Currently blood lead levels in Butte are consistent with those of similar children in the U.S. This would suggest that the RMAP program has been effective in Butte and the soil lead cleanup levels are protective.

Why has EPA refused to change its action levels on lead to be congruent with the CDC recommendations? Is this a one size fits all approach?

Response: EPA is currently re-evaluating its entire approach to assessing lead exposures, including, but not limited to the current reference level. During the 5 year review of the ROD, any and all new information will be considered when evaluating the effectiveness of the remedy. In the interim, EPA encourages the use of blood lead testing and public health approaches to identify and mitigate all potential sources of lead exposure.

7. What assurances can the public have that the toxics of concern have been properly characterized?

Response: EPA has conducted a number of risk assessments in Butte using the framework outlined in EPA's Risk Assessment Guidance's for Superfund. The use of site-specific environmental data and information allowed us to identify the contaminants of concern and more accurately assess exposure and risk. All involved stakeholders, including MDEQ, the citizens of Butte, and ARCO, had the opportunity to review and provide input to these assessments.