Midlothian, Texas Public Health Response Plan

Agency for Toxic Substances and Disease Registry

Response to Comments

May 2012

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Acronyms

AIHA	American Industrial Hygiene Association
ATSDR	Agency for Toxic Substances and Disease Registry
BLL	Blood Lead Level
BRFSS	CDC Behavior Risk Factor Surveillance System
CAA	Clean Air Act
CDC	Centers for Disease Control
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CrIII	Chromium 3 or trivalent chrome
CrVI	Chromium 6 or hexavalent chrome
DTHHS	ATSDR's Division of Toxicology and Human Health Sciences
EMEG	Environmental Media Evaluation Guide
EPA	US Environmental Protection Agency
ESL	Effects Screening Levels (TCEQ)
FDA	Food and Drug Administration
HWDF	Hazardous Waste Derived Fuel
IEUBK	Integrated Exposure Uptake and BioKinetic Model
MACT	Maximum Achievable Control Technology
MRL	Minimal Risk Level
MSDS	Material Safety Data Sheet
NAAQS	National Ambient Air Quality Standards
NCHS	CDC National Center for Health Statistics
NHANES	CDC National Health and Nutritional Survey
PAC	Protective Action Criteria
PAHAGV	Provisional Animal Health Assessment Guidance Value
PCB	Polychlorinated Bi-Phenols
PHAGM	Public Health Assessment Guidance Manual
PHA	Public Health Assessment

PHC	Public Health Consultation
PHRP	Public Health Response Plan
QA/QC	Quality Assurance/Quality Control
SCAPA	Subcommittee on Consequence Assessment and Protective Actions
STARS	State of Texas Air Reporting System
TCEQ	Texas Commission on Environmental Quality
TDSHS	Texas Department of State Health Services
TRI	Toxic Release Inventory
VOC	Volatile Organic Compound
WHO	World Health Organization
WONDER	CDCs Wide-Ranging Online Data for Epidemiologic Research

Several parties submitted comments, both written and verbal, in response to the Agency for Toxic Substances and Disease Registry's (ATSDR) Public Health Response Plan (PHRP) for the Midlothian site. ATSDR grouped these comments into similar topics, which are listed below along with the agency's responses.

Project 1: Response to Written PHRP Comments

Name of Project: Review and Analysis of Texas Commission on Environmental Quality (TCEQ) Air Monitoring and its' Applicability for Drawing Health Conclusions for the Surrounding Population

1. Comment: What technical guidance or peer-reviewed literature will be used to guide the analysis?

ATSDR Response: Overall, ATSDR will follow principles outlined in its Public Health Assessment Guidance Manual (PHAGM) [ATSDR 2005]. In addition, ATSDR is consulting numerous guidance documents from other agencies and peer-reviewed publications. For instance, when evaluating the ambient air monitoring methods used in Midlothian, ATSDR is comparing these methods to the US Environmental Protection Agency's (EPA) most current lists of reference and equivalent methods [EPA 2010] and EPA's peer-reviewed compendia of methods for measuring ambient air concentrations of inorganic and organic compounds [EPA 1999a,b]. Further, when evaluating data quality, ATSDR will consider specifications in other EPA guidance prepared specifically for assessing data quality of ambient air monitoring networks [EPA 2008]. The Public Health Consultation (PHC) for this project will provide a complete list of citations for all technical guidance and peer-reviewed literature that ATSDR used when reviewing the monitoring networks.

2. Comment: What tests, statistical or otherwise, will the data be subjected to in order to evaluate quality? We recommend that any correlation analysis have a basis in statistics. We request that we be allowed to review and comment on the methods and significance levels that will be used for such analyses when they are decided upon.

ATSDR Response: For each monitoring program conducted in the Midlothian area, ATSDR is systematically evaluating data quality. This evaluation involves many steps, which include obtaining and reviewing monitoring protocols or quality assurance project plans, evaluating whether a given program has met its data quality objectives, and verifying that measurements are of a known and high quality (see response to next comment for further details). In terms of quantitative tests to evaluate data quality, ATSDR is reviewing assessments of co-located measurements, in which case ATSDR will use standard metrics used in this field (e.g., relative percent differences). The PHC for this project might include additional statistical analyses for issues other than assessing data quality and if so, those analyses will be accompanied by detailed text explaining the statistical methodologies used. A comment period will be provided to the public before the document is finalized.

3. Comment: What are the metrics for determining if the data are of sufficient quality to be used for the intended purpose?

ATSDR Response: Chapter 5 of ATSDR's PHAGM lists examples of metrics typically used to evaluate data quality. These metrics include completeness of monitoring programs, precision assessed from co-located measurements, and accuracy gauged by analyses of audit samples and other methodologies. ATSDR will consider these metrics along with others (e.g., field and laboratory quality assurance and quality control (QA/QC) methods and results) in the PHC for this project.

4. Comment: What meteorological data will be used to evaluate air monitoring station siting?

ATSDR Response: Several meteorological monitoring stations have operated in the Midlothian area in the past few decades. ATSDR has already compiled some meteorological data from the National Climatic Data Center and TCEQ. The most appropriate data to use for a given analysis depends on the locations and time frames of interest. For general insights on prevailing wind patterns in the Midlothian area, ATSDR generated wind roses from 5 recent years of meteorological data collected at two monitoring stations in close proximity to the TXI and Gerdau-Ameristeel facilities. These wind roses and other information on local meteorological conditions will be fully documented in the PHC for Project 1.

5. Comment: Will air dispersion modeling be performed? If so:

- **Will a modeling protocol be prepared?**
- **What model will be used?**
- **What source terms will be used for the modeling?**
- **What emission rates will be used for the modeling?**
- **What meteorological data will be used for the modeling?**
- **What type of receptor grid will be used for the modeling?**
- **How will variability in emissions with respect to operations be addressed?**

We understand that ATSDR may conduct SCREEN3 modeling of emissions and may review the ISCST3 modeling conducted by the US EPA. If SCREEN3 analyses are performed, we recommend that ATSDR use the appropriate US EPA guidance to convert the 1-hr concentrations that are derived from SCREEN3 to other averaged times when assessing the output results for averaging times other than 1-hr averages. We also recommend that ATSDR consult additional sources of modeling including modeling performed by industry and TCEQ as part of the Clean Air Act (CAA) permitting process. (Ash Grove 3/19/10; TXI 3/19/10)

ATSDR Response: This comment raises several questions about dispersion modeling. The purpose of Project 1 is to assess the utility of the existing ambient air monitoring network for health assessment purposes. ATSDR will base its conclusions for this project primarily upon the available monitoring data and modeling studies that have already been completed. ATSDR currently does not envision conducting its own refined dispersion modeling analyses for this site. The Agency has already obtained and reviewed selected modeling studies conducted by EPA [EPA 1996] and performed in support of the air permitting process.

However, as the comment notes and as agency officials informed attendees at the February 22 public meeting announcing the PHRP, ATSDR will conduct screening analyses—using the SCREEN3 air model—for some limited insights on how ground-level concentrations of site-related pollutants are expected to vary with downwind distance under certain meteorological conditions. ATSDR is aware of the scaling factors referred to in the comment for estimating ambient air concentrations for averaging periods longer than 1 hour. The Agency will use those scaling factors where appropriate.

6. Comment: How will hot spots be addressed?

ATSDR Response: ATSDR is considering available modeling studies to assess how site-related air quality impacts are expected to vary with location. The PHC will document the most highly impacted areas by using worst case modeling results.

7. Comment: What data sources of "similar operations" will be considered for comparing Midlothian industry emissions to "similar operations"? There are no other similar operations – Midlothian has the largest concentration of cement kilns and steel mill in the nation!

We understand that ATSDR will consult the TCEQ State of Texas Air Reporting System (STARS) database, the US EPA National Emissions Inventory, the US EPA Toxic Release Inventory (TRI) and the US EPA Maximum Achievable Control Technology (MACT) database to determine emissions from the industries and from similar industrial facilities. We officially request that we be allowed to review and comment on emissions data derived from any other sources as soon as that source becomes known to ATSDR. We officially request that we be allowed to review any procedures to adjust these data to reflect averaging periods not reflected in the databases.

ATSDR Response: This comment addresses two different issues, which ATSDR addresses separately:

- The first paragraph in the comment refers to a statement in the PHRP indicating that ATSDR will review "similar operations to ensure that all chemicals of concern are evaluated." To clarify, ATSDR is conducting a full and thorough evaluation of all publicly available site-specific information for the Midlothian facilities. The Agency is also conducting a broader literature search primarily to ensure that the overall public health assessment process does not somehow overlook important issues that have been identified and reported at other cement kilns. ATSDR does not mean for this approach to imply that the nature and extent of cement and steel production in Midlothian are also observed at other locations.

- The second paragraph pertains to the specific information sources that ATSDR is accessing for facility-specific emission data. ATSDR has already accessed emission data from the sources listed in the comment, as well as measured emission data that the facilities have submitted to TCEQ. Those measured data include stack tests and

continuous emission monitoring results. ATSDR currently does not envision obtaining emission data from additional sources. The PHC will present emission data as documented in their original reports, and the agency does not plan to extrapolate those data to different averaging periods.

8. Comment: The concern about TCEQs air monitoring system being run periodically is only one of the community's concerns. The primary question regarding the air monitoring system is whether this system is fully capable of generating data upon which adequate public health determinations can be made. It is our expectation that all of the expressed concerns regarding the deficiencies will remain in focus and thoroughly be reviewed and considered in the final development of the PHRP for Midlothian.

ATSDR Response: ATSDR appreciates the fact that community members have expressed many concerns beyond those that could be readily captured in the one-page project summaries included in the PHRP. The PHC for Project 1 will attempt to address all comments received to date regarding the adequacy of the monitoring network. Please note that ATSDR has reviewed and compiled community concerns from numerous sources. These include, but are not limited to, community concerns (1) listed in the 2007 Draft PHC, (2) mentioned during the February 2010 meeting to discuss the PHRP, and (3) raised during numerous discussions with the petitioner and other Midlothian residents.

9. Comment: Under purpose, you need to include adequacy of monitoring techniques.

ATSDR Response: The PHC for Project 1 will comment on the adequacy of every ambient air monitoring method that has been used to date in the Midlothian area. The PHRP will be revised to address this comment.

10. Comment: References to "missing data" have been made in public meetings and from other interactions with the community. ATSDR should make every effort to investigate the existence of this "missing data" and address this issue in its report.

ATSDR Response: ATSDR has made an extensive effort to identify and obtain all publicly available data relevant to Project 1. The Agency takes very seriously any claims about "missing data." Given the importance and potential implications of this claim, ATSDR has contacted members from the public who attended this meeting to seek more specific information about claims regarding missing data, but have had very little additional information to follow up on. ATSDR continues to encourage anyone with more specific knowledge on missing data for this site to contact Agency officials, such that all relevant information will be considered and evaluated as part of Project 1 and the subsequent projects.

11. Comment: Are the air monitors in the right places? Monitors are located according to whether the land owner will allow. I do not believe monitors are located on the land where hazardous waste was being incinerated.

ATSDR Response: The comment is correct in stating that ambient air monitoring did not occur at the exact locations (i.e., the specific cement kilns) where hazardous waste was incinerated.

Rather, monitors were typically placed at off-site locations. The specific locations were selected based on various considerations—one of which being access to private property, as the comment states. The PHC for Project 1 will include ATSDR's judgments regarding what inferences can be drawn from the ambient air monitoring data based on the placement of the monitoring stations.

Project 1: Responses to Verbal Comments

On February 22, 2010, ATSDR hosted a public meeting in Midlothian to present the PHRP. Agency officials answered many of the questions during the meeting. ATSDR kept a log of questions that were asked such that more detailed written responses would be available to all interested parties, including those who did not attend the meeting. Following is a listing of the questions asked during the February 22 meeting along with the agency's responses.

12. Comment: Has chromium 6 (Cr VI) been identified in the soil or water?

ATSDR Response: ATSDR's review of soil and water data is not complete. Based on the data reviewed (incomplete at this point in time), soil samples have been analyzed for Cr VI - with results -so far- below detection limit. Based on the water data reviewed (incomplete at this point in time), it appears that only total chromium was reported - not Cr VI.

13. Comment: What types of test will be conducted to verify that the data you are using is good?

ATSDR Response: ATSDR received a very similar question in the written comments on the PHRP. Please refer to the responses to Written Comment (2) and Comment (3) (under Project 1) for more detailed information on this issue. ATSDR is conducting a very thorough data quality review for this site's ambient air monitoring data.

14. Comment: How many air monitors are being used for Midlothian study? Will this change?

ATSDR Response: As of the writing of this response, ATSDR has accessed data from 19 different ambient air monitoring stations that currently operate or previously operated in the Midlothian area. This number will change only, if ATSDR identifies additional data sources.

15. Comment: What about the air monitor on Wyatt Rd? Is the data it collected for 10 years being looked at?

ATSDR Response: ATSDR has already obtained the complete set of ambient air monitoring data that TCEQ collected at the monitoring station that was previously located on Wyatt Road. The earliest data available for this site are from 1999. The site continued operating into 2006.

16. Comment: Has TCEQ acknowledged the missing monitoring data that was gathered at the time the plant was burning hazardous waste and the volume of pollutants was the greatest?

ATSDR Response: Please refer to ATSDR's response to Written Comment (10), under Project 1, for more information on the issue of missing data.

17. Comment: Are the older kilns that previously burned hazardous wastes ever going to be allowed to do it again?

ATSDR Response: ATSDR does not have regulatory authority over which kilns operate at the Midlothian facilities. Residents should direct such questions to TCEQ—the agency that oversees the permits and operational status of Midlothian cement kilns.

18. Comment: Explain why dioxins and furans emissions have been omitted from this study?

ATSDR Response: Based on ATSDR's review of site-related documents, ambient air monitoring for dioxins and furans has never occurred in the Midlothian area. However, that does not mean that ATSDR will omit these chemicals from its evaluations. Rather, ATSDR will consider other sources of information (e.g., emission data) to determine if defensible conclusions can be reached on dioxins and furans or if actions should be taken to fill this information gap. The PHCs being prepared by ATSDR will document the Agency's final findings on this matter.

19. Comment: Which five years were you referring to when talking about the two monitoring data stations in the presentation?

ATSDR Response: This comment refers to meteorological data that ATSDR officials summarized during their presentations at the public meeting on February 22. During one particular presentation, an Agency official indicated that the PHC for Project 1 will include wind roses generated for a recent 5-year time frame. That time frame is 2002 to 2006. Please note that this time frame was selected simply to provide insights on local prevailing wind patterns; ATSDR is considering data from other time frames, as appropriate, to interpret ambient air monitoring data.

20. Comment: Explain why mercury emissions were not included in plan. Why are you not looking at those?

ATSDR Response: ATSDR is considering mercury emissions from the Midlothian facilities. In Project 1, ATSDR will comment on the adequacy of the existing ambient air monitoring data, and this evaluation will consider the fact that particulate mercury measurements do not characterize vapor-phase mercury. For mercury and numerous other pollutants, the PHC will conclude what inferences can be drawn from the existing monitoring data. The document will also make recommendations for how to evaluate the potential public health implications from exposure in cases where the existing monitoring data do not adequately characterize exposures.

21. Comment: When was "bio-medical" waste burned at the cement processing sites?

ATSDR Response: ATSDR's research on the operations at the Midlothian facilities has yet to reveal evidence of the facilities having burned biomedical wastes. Given the potential implications of this claim, ATSDR contacted community members who attended this meeting to seek more specific information about the issue (e.g., which facilities reportedly burned this waste and during what time frames), but have had very little additional information to follow up on.

ATSDR has asked TCEQ if the Agency has any documentation of biomedical waste being burned in the Midlothian area. The PHC for Project 1 will document the outcome of ATSDR's efforts to learn more about any past operations that may have burned biomedical wastes.

22. Comment: What methods will you use to ascertain if the data you are reviewing is accurate, reliable, and complete? Can you determine if the data has been compromised and/or is no longer reliable?

ATSDR Response: ATSDR received a very similar question in the written comments on the PHRP. Please refer to the responses to Written Comment (2) and Comment (3) (under Project 1) for more detailed information on this issue. In response to the second question, ATSDR will make determinations regarding whether specific data sets are reliable for health assessment purposes. The PHC for Project 1 will fully document Agency findings on this issue and also justify why certain conclusions were made.

23. Comment: Who collects the samples of emissions that you are looking at?

ATSDR Response: Many different parties conduct air emission testing and ambient air monitoring in the Midlothian area. These include state agencies, the industrial facilities, and contractors to the agencies and facilities. The PHC for Project 1 will identify the specific parties that have been responsible for collecting field samples and the specific laboratories that have been analyzing these samples.

24. Comment: What types of tests or analysis will be conducted to ensure the quality of the data?

ATSDR Response: ATSDR received a very similar question in the written comments on the PHRP. Please refer to the responses to Written Comment (2) and Comment (3) (under Project 1) for more detailed information on this issue.

25. Comment: How will you determine if the data monitoring points are good enough to provide good information?

ATSDR Response: ATSDR received a very similar question in the written comments on the PHRP. Please refer to the responses to Written Comment (2) and Comment (3) (under Project 1) for more detailed information on this issue.

26. Comment: Will effects screening levels that are being used be state of Texas levels or federal levels:

ATSDR Response: Appropriate screening values as derived from ATSDR, EPA, state agencies (e.g., TCEQ, California EPA), international sources (World Health Organization), and the toxicological literature, will be used. Where there is short-term exposure data reported, we may review Protective Action Criteria (PACs), derived by EPA, American Industrial Hygiene Association (AIHA), and Subcommittee on Consequence Assessment and Protective Actions (SCAPA). Generally, it is our practice to use the most appropriate conservative existing health

based guidelines for initial screening of data in our assessments. Where there is no health-based guideline or toxicological data for the compound of interest, we defer to toxicological/epidemiological literature for that compound or the guidance values and/or scientific literature of a surrogate compound that is likely to have similar pharmacodynamics/pharmacokinetics. Chemicals selected for further evaluation will be compared to appropriately averaged guidance values or epidemiologic studies with similar exposure scenarios.

27. Comment: How valuable is the 2008-2009 data considering it was collected during a period of reduced or no production as well as a period when no hazardous waste was being burned?

ATSDR Response: This comment correctly notes that a recent ambient air monitoring study was conducted during a time when facility operations were not necessarily representative of past conditions. The PHC for Project 1 will describe the utility of this particular set of ambient air monitoring data and what (if any) inferences can and should be drawn from these data.

28. Comment: How will you determine how much Cr VI is in the air as compared to total chromium?

ATSDR Response: For many sites that ATSDR evaluates, ambient air monitoring data are only available for total chromium, with no information on the relative quantities of the trivalent (Cr III) and hexavalent (Cr VI) forms. We understand that this is the case for the historical monitoring data for the Midlothian area. ATSDR will address the Cr VI issue as best as possible with the data we have to evaluate. Depending on the consistency of the fraction of Cr VI to Cr III in the speciated dataset and changes to or consistency of the operational status of area facilities, we may have the ability to make inferences to the potential past exposure of area residents to Cr VI from current data. Another option is to refer to other sources (e.g., peer-reviewed publications, recent EPA monitoring at other cement kilns) to identify the range of chromium speciation typically observed near cement kilns.

29. Comment: Will you test for dioxins, furans, and the more than ±129 chemicals tested by TCEQ? And will you look at them as they pertain to all viable pathways (water, soil, air, food, fish, etc.)?

ATSDR Response: The PHC for Project 1 is being prepared to assess the utility of all available ambient air monitoring data for reaching health conclusions—that includes data for every chemical that TCEQ (and other parties) have detected in the facilities' emissions and in Midlothian's ambient air. The other projects being conducted by ATSDR will address contamination levels in other environmental media. In cases where environmental data are not available for individual pollutants, the documents will either make conclusions based on other insights or make recommendations to fill the data gaps. Please note that ATSDR currently has not proposed conducting any testing of its own, though the PHCs might recommend that some additional sampling be conducted.

30. Comment: Has hexavalent chromium been discovered in soil or water?

ATSDR Response: ATSDR assumes that this question relates to hexavalent chromium in soil or water. Please see response to verbal comment #12 above.

31. Comment: How do you calculate the synergistic effects of various pollutants?

ATSDR Response: The Guidance Manual for the Assessment of Joint Toxic Action of Chemical Mixtures (Mixtures Guidance Manual) is intended to assist environmental health scientists and toxicologists of ATSDR's Division of Toxicology and Human Health Sciences (DTHHS) in determining whether exposure to chemical mixtures at hazardous waste sites may impact public health. It serves a basis for interaction profiles, as the basis for Public Health Assessments (PHA) and PHCs. The ATSDR approach outlined in the Mixtures Guidance Manual is consistent with the approach articulated by EPA in 1986 and used to some extent, formally or informally, by a number of agencies. The approach is grounded in the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Food Quality Protection Act), and affords greater assurance of protection against adverse health effects than does the assessment of each chemical separately. The Expert Peer Review Panel, assembled on May 30-31, 2000, strongly approved of ATSDR's efforts to provide guidance for assessing joint toxic action of chemical mixtures and endorsed the ATSDR approach presented herein, which incorporates their comments and recommendations. The Mixture Guidance Manual also underwent ATSDR Agency-wide review and incorporates comments received from these reviewers.

This guidance is designed to be used in conjunction with the ATSDR PHAGM, which provides the primary guidance for public health assessment, including aspects not covered in the Mixtures Guidance Manual. These additional aspects include exposure assessment guidance, recommended sources of health guideline values and toxicological information, and evaluation of health implications of other medical and toxicological factors, sensitive subpopulations, uncertainties, and community-specific health outcome data and community health concerns. The outcome of the PHA process is a determination of the category of public health hazard (ranging from "urgent public health hazard" to "not likely to result in harmful health effects"), and of follow-up actions including actions to protect public health, collection of additional health or site-characterization information, and community health education.

The systematic method outlined in the Mixtures Guidance Manual integrates ATSDR's interaction profiles, toxicological profiles, and research on chemical mixtures into a practical screening approach for potential health hazards. The conclusions from this exposure-based screening assessment of mixture hazard can then be taken into account along with biomedical judgment, the community-specific health outcome data, and community health concerns, to determine the public health implications and follow-up activities for a hazardous waste site.

The strategies for non-cancer and cancer effects are similar. Exposure data and toxicological information on the mixture of concern (or a similar mixture) are the preferred basis for an assessment. If available, toxicological information on mixtures of concern for hazardous waste sites are likely to be reviewed and evaluated in ATSDR documents, including interaction profiles and toxicological profiles. If specific ATSDR documents or comparable documents from other

agencies are not available, or do not provide Minimal Risk Levels (MRLs) or comparable health guideline values for the mixture or guidance regarding a health assessment approach, and if suitable whole mixture studies are not available, a components-based approach is undertaken.

Please refer to the following link for additional information regarding ATSDR's Guidance Manual for the Assessment of Joint Toxic Action of Chemical Mixtures: http://www.atsdr.cdc.gov/interactionprofiles/ipga.html.

32. Comment: How can residents expect to have faith in your recommendations, if those recommendations are based exclusively on TCEQ data?

ATSDR Response: ATSDR strives to issue documents that are fully transparent and based on the best available science. The Agency might determine that some ambient air monitoring data are not of sufficient quality to support health assessment activities, while other data might be found to be of a known and high quality. Whatever the case, the PHC for this project will fully document the thought process ATSDR used in reaching its conclusions. Moreover, ATSDR will actively seek community input on the draft PHC through public meetings and a public comment period. The public is encouraged to take advantage of those opportunities to provide feedback on the recommendations that ATSDR proposes.

33. Comment: Is there any power to get better data collected?

ATSDR Response: One of the purposes of Project 1 is to assess the quality of ambient air monitoring data that are currently available. Until that assessment is completed, ATSDR will not comment on the quality of the past data (and therefore, the need for collecting better data). The conclusions and recommendations of the first PHC will provide more insights on this matter.

34. Comment: What are your sources for metal data sets? Are there resources other than TCEQ?

ATSDR Response: The PHC for Project 1 will list who has been involved with the various ambient air monitoring projects completed in the Midlothian area. In response to this question, TCEQ (and its predecessor agencies) is the only party that has overseen ambient air monitoring projects for metals. However, TCEQ has enlisted the support of contractors (e.g., URS Corporation) and external laboratories (e.g., Desert Research Institute) to conduct field sampling and laboratory analysis for metals.

35. Comment: Is the information of how you reached a conclusion going to be shared with the community?

ATSDR Response: ATSDR strives to issue documents that are fully transparent and based on the best available science. The PHC for this project will fully document the thought process ATSDR used in reaching its conclusions. If the PHC is not clear in this regard, the public will be invited to submit comments to seek clarification on how the Agency reached specific conclusions.

36. Comment: Can you tell us if you have looked at someone else's samples? If you need more data can you use someone other than TCEQ to collect them?

ATSDR Response: For Project 1, ATSDR has obtained a large volume of ambient air monitoring data. The first PHC will document who was involved with the individual monitoring efforts. If ATSDR concludes that additional sampling should be conducted, one of the Agency's PHCs will include specific recommendations for filling those gaps. ATSDR will consider the concern that this comment raises if the Agency recommends that additional sampling take place.

37. Comment: I'm confused to what you are saying about data gaps. We already know there are data gaps. Does this mean that you are going to fire the kilns back up to re-create it?

ATSDR Response: ATSDR will not recommend changes in facility processes in order to fill gaps in the ambient air monitoring data. The PHCs for the various projects will identify important data gaps and make judgments as to whether and what additional study is warranted to fill these gaps.

38. Comment: Why are "emissions" not identified?

ATSDR Response: Unfortunately, ATSDR does not have an account of the original question that was asked, and the written question based on notes taken at the meeting is unclear. Therefore, it is difficult to provide a complete response.

Nonetheless, please note that the PHC for Project 1 will present extensive documentation of emissions from the Midlothian facilities. ATSDR hopes that this information will address the original concern expressed about emission data. Should that evaluation not address the question that was originally asked at the meeting, the public is encouraged to ask follow-up questions at future meetings or submit additional questions as public comments on the draft PHC, once it becomes available.

39. Comment: What pollutants are monitored for with the continuous emission monitors on the stacks?

ATSDR Response: The continuous emission monitoring requirements vary across the four industrial facilities of concern in the Midlothian area. The PHC for Project 1 will document these requirements. Briefly, monitoring is currently being conducted for some combination of the following parameters at selected kiln stacks: carbon monoxide, sulfur dioxide, nitrogen oxides, and total hydrocarbons. Opacity monitoring also occurs at the Midlothian facilities.

References

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[EPA] U.S. Environmental Protection Agency. 1996. Midlothian Cumulative Risk Assessment.

Project 2: Response to Written PHRP Comments

Name of Project: Review and Analysis of VOCs and Metal Exposures in Air

40. Comment: What technical guidance or peer-reviewed literature will be used to guide the analysis?

ATSDR Response: ATSDR uses the PHAGM as a reference for conducting PHA and PHC work. Epidemiological and toxicological literature referenced in our contaminant-specific toxicological profiles as well as those published since the release of our most recent draft of the toxicological profiles will also be reviewed to assess health implications of exposure. Refer to ATSDR's responses to Written Comments (2) and (3) in Project 1 for more information on how the agency will assess data quality.

41. Comment: What specific sources of data will be used to conduct the analysis?

ATSDR Response: ATSDR will evaluate all existing organic and inorganic data that we are aware of for this analysis (each PHC will list sources of datasets, including date ranges of samples collected and for which contaminants, in the appendix).

42. Comment: What statistical tests will the data be subjected to in order to evaluate trends and differentiate between concentrations relevant to long-term exposures as opposed to short-term exposures?

ATSDR Response: The purpose of ATSDR's evaluation of the data is to determine whether or not the existing data suggest that concentrations of airborne contaminants are present at levels of health concern. An initial screening of measured data against conservative health based guidance values will be used to identify contaminants for further evaluation. Part of the additional evaluation will include a review of the data distribution and time series analysis to identify both the magnitude of exposure and trends of exposure over time.

With regard to data distribution analyses and time-series assessment, the statistical approach depends on the number of observations, the number of non-detects, and relative data quality. Long-term and short-term exposures will be evaluated by comparison of average or geometric averaged concentrations (depending on the distribution of the dataset) to the relevant scientific literature and guidance values for chronic exposure assessment, and maximum/peak concentrations to the relevant scientific literature and guidance values for acute exposures. Descriptive statistical assessment may include calculation of location, scale, shape and distribution, and percentile/quantile statistics, as well as general counts of observations.

43. Comment: How will non-detect data be addressed in the trend analysis?

ATSDR Response: The approach we will use to assess non-detected data will depend on the duration of exposure we are evaluating. Non-detected data will not affect the ability of ATSDR

to assess acute exposures. For an evaluation of acute exposures, we will use maximum concentrations to represent worst-case short term exposure scenarios.

Non-detects will be evaluated using an appropriate approach for the dataset, such as non-parametric analysis for censored data. After contaminants of concern are selected based on comparison to screening criteria, we will evaluate each contaminant (and non-detects) on a case by case basis. This approach is necessary due to the variability of the dataset with regard to issues such as the averaging time for each sample, number of observations for each contaminant, its detection frequency, detection limit variability, etc.

44. Comment: What exposure metrics will be used in the analysis?

ATSDR Response: The exposure metric will vary by contaminant. Generally, peak concentrations will be evaluated to assess acute exposures and average concentrations will be evaluated to assess chronic exposures. As best as possible, health endpoints will be evaluated for contaminants of concern in our assessment of health outcome data. For this project, measured and modeled exposures will serve as the exposure metric.

45. Comment: What sources of toxicity screening values will be reviewed to select screening values for purposes of the work?

ATSDR Response: Appropriate screening values as derived from ATSDR, EPA, state agencies (e.g., TCEQ, California EPA), international sources (such as WHO), and the toxicological literature. Where there are acute data reported, we may also review PACs, derived by EPA, AIHA, and SCAPA[2].

46. Comment: If more than one guidance or literature sources has a toxicity screening value, what is the precedence for determining which toxicity value is the best?

ATSDR Response: Generally, it is our practice to use the most appropriate, updated, and conservative existing health-based guideline for screening of data in our assessments. Where there is no health-based guideline or toxicological data for the compound of interest, we defer to toxicological/epidemiological literature for that compound or the guidance values and/or scientific literature of a surrogate compound that is likely to have similar pharmacodynamics/pharmacokinetics. After ATSDR's screening process is complete, chemicals selected for further evaluation will undergo an in-depth analysis where the health assessor will review and integrate exposure and health effects data and use biomedical judgment to weigh what is known and unknown, including uncertainties and data limitations.

47. Comment: If the technical literature is used to develop toxicity screening values, what procedures will be used to determine if the literature source is relevant and appropriate for the purpose of the study?

ATSDR Response: The majority of contaminants sampled for in Midlothian have a health-based comparison value. In the instance where this is not the case, the robustness of the study, weight

[2] http://orise.orau.gov/emi/scapa/chem-pacs-teels/default.htm

of evidence assessment, scientific judgment, and consideration of site specific exposure scenarios will be evaluated. All methods used to assess public health implications will be documented in the PHC.

48. Comment: How will surrogate chemicals be selected if no toxicity screening value is available?

ATSDR Response: As stated previously, we don't anticipate that this type of analysis will be necessary for the majority of the contaminants detected. In the event that we do need to look for a surrogate for a particulate contaminant, we would use an assessment of the pharmacodynamics/pharmacokinetics and chemical structure of the surrogate. The process for selecting a surrogate will be documented in the PHC.

49. Comment: Will background chemical concentrations be addressed and if so, how?

ATSDR Response: As per ATSDR guidance, the PHC for this project will assess the public health implications of exposure to the measured air concentrations, regardless of the source. The document will also provide some perspective on the emission sources found throughout the Midlothian area. For example, should ATSDR find any chemicals to present a public health hazard, the PHC will acknowledge which sources emit the pollutant, if known and whether the measured concentrations in Midlothian differ from those found in similar settings nationwide. For more information on how ATSDR typically evaluates background concentrations, refer to Section 5.3 of ATSDR's PHAGM at: http://www.atsdr.cdc.gov/hac/phamanual/ch5.html#5.3

50. Comment: If background chemical concentrations are addressed, what sources of background data will be evaluated?

ATSDR Response: As the response to the previous comment notes, ATSDR will likely provide information on background concentrations only for certain chemicals. In these cases, the agency will consider various approaches to characterizing background. These may include upwind-downwind comparisons and citing information from the published literature (e.g., in ATSDR Toxicological Profiles, from EPA nationwide monitoring programs).

For more information on how ATSDR typically evaluates background concentrations, refer to Section 5.3 of ATSDR's PHAGM [ATSDR 2005].

51. Comment: We understand that ATSDR will rely on the Focused Sampling Study conducted by TCEQ to evaluate the percentage of Cr VI in all the chromium air sampling results that are part of the Project 1 database. ATSDR should consider that some members of the community have expressed concern that the recent TCEQ data set is not reflective of historical chromium air sampling results. ATSDR should be prepared to address this concern in its report.

ATSDR Response: For many sites that ATSDR evaluates, ambient air monitoring data are only available for total chromium, with no information on the relative quantities of the trivalent (Cr III) and hexavalent (Cr VI) forms. We understand that this is also the case for the historical

monitoring data for the Midlothian area. ATSDR will address the Cr VI issue as best as possible with the data we have to evaluate. Depending on the consistency of the fraction of Cr VI to Cr III in the speciated dataset and changes to or consistency of the operational status of area facilities, we may have the ability to make inferences to the potential past exposure of area residents to Cr VI from current data. Another option is to refer to other sources (e.g., peer-reviewed publications, recent EPA monitoring at other cement kilns) to identify the range of chromium speciation typically observed near cement kilns.

52. Comment: Please consider mercury, dioxin and polychlorinated biphenol (PCB) in your evaluation.

ATSDR Response: ATSDR will consider these chemicals in its evaluation. Based on ATSDR's review of site-related documents, ambient air monitoring for dioxins and PCBs has never occurred in the Midlothian area and the existing monitoring data for mercury is incomplete. However, that does not mean that ATSDR will omit these chemicals from its evaluations. Rather, ATSDR will consider other sources of information (e.g., emission data) to determine if defensible conclusions can be reached on these chemicals or if actions should be taken to fill this information gap. The PHC being prepared by ATSDR will document the agency's final findings on this matter.

53. Comment: ATSDR and Texas Department of State Health Services (TDSHS) will organize and evaluate VOC and metals data (peak vs. <u>average</u> concentrations)…. The human body does not average exposures!

ATSDR Response: A time series analysis of ambient air concentrations will be conducted to evaluate exposure concentrations, frequency, and duration. Average concentrations help to identify chronic exposure risks and peak concentrations help to assess acute exposure outcomes. Cancer risk is typically assessed by evaluating chronic exposures (assuming lifetime exposure), and generally cannot be assessed by using peak measurement data.

Project 3: Response to Written PHRP Comments

Name of Project: Review and Analysis of VOCs and Metal Exposures from Air Emissions in Media other than Air (e.g., vegetation, soil, slag, wheat, fish (Joe Pool Lake), and water samples)

54. Comment: What technical guidance or peer-reviewed literature will be used to guide the analysis?

ATSDR Response: ATSDR uses the PHAGM as a reference for conducting PHA and PHC work. Epidemiological and toxicological literature referenced in our contaminant-specific toxicological profiles, as well as those published since the release of our most recent draft of the toxicological profiles will, also, be reviewed to assess health implications of exposure. Data quality will be assessed through reviewing whether or not the data quality objectives of each dataset were met, correlation analyses with simultaneously collected data, as well as using EPA guidance documents for assessing data quality. Refer to the response to Written Comment (1) in Project 1 for specific examples of this EPA guidance that ATSDR will consider.

55. Comment: What specific sources of data will be used to conduct the analysis?

ATSDR Response: ATSDR will evaluate all existing organic and inorganic data that we are aware of for this analysis (each PHC will list sources of datasets, including date ranges of samples collected and for which contaminants, in the appendix).

56. Comment: What statistical tests will the data be subjected to in order to evaluate trends and differentiate between concentrations relevant to long-term exposures as opposed to short-term exposures?

ATSDR Response: The purpose of ATSDR's evaluation of the data is to determine whether or not the existing data suggest that concentrations of airborne contaminants are present at levels of health concern. An initial screening of measured data against conservative health based guidance values will be used to identify contaminants for further evaluation. Part of the additional evaluation will include a review of the data distribution and time series analysis to identify both the magnitude of exposure and trends of exposure over time.

With regard to data distribution analyses and time-series assessment, the statistical approach depends on the number of observations, the number of non-detects, and relative data quality. Long-term and short-term exposures will be evaluated by comparison of average or geometric averaged concentrations (depending on the distribution of the dataset) to the relevant scientific literature and guidance values for chronic exposure assessment, and maximum/peak concentrations to the relevant scientific literature and guidance values for acute exposures. Descriptive statistical assessment **may** include calculation of location, scale, shape and distribution, and percentile/quantile statistics, as well as general counts of observations.

57. Comment: How will non-detect data be addressed in the trend analysis?

ATSDR Response: The approach we will use to assess non-detected data will depend on the duration of exposure we are evaluating. Non-detected data will not affect the ability of ATSDR to assess acute exposures. For an evaluation of acute exposures, we will use maximum concentrations to represent worst-case short term exposure scenarios.

As mentioned previously, non-detects will be evaluated using an appropriate statistical method for the data set, which could vary greatly by number of observations. After contaminants of concern are selected based on comparison to screening criteria, we will evaluate each contaminant (and non-detects) on a case by case basis. This approach is necessary due to the variability of the dataset with regard to issues such as the averaging time for each sample, number of observations for each contaminant, its detection frequency, detection limit variability, etc.

58. Comment: What exposure metrics will be used in the analysis?

ATSDR Response: The exposure metric will vary by contaminant. It is influenced by concentration, duration and frequency dimensions, but for most exposures, even those which have been thoroughly investigated, the interactions of these different dimensions is not fully understood. Thus, a conclusive exposure metric may not be identified. As best as possible, health endpoints will be evaluated for contaminants of concern in our assessment of health outcome data. For this project, measured and modeled exposures and the location of populations within these areas of "maximum and moderate impact" will serve as the exposure metric.

59. Comment: What sources of toxicity screening values will be reviewed to select screening values for purposes of the work?

ATSDR Response: ATSDR will screen all available current chemical data to determine whether concentrations are above health-based comparison values. ATSDR will review relevant toxicological and epidemiologic data to obtain information about the toxicity of the chemicals to more completely understand the public health implications of exposure.

Comparing Environmental Concentrations to Comparison Values

ATSDR selects chemicals for further evaluation by comparing the maximum environmental concentrations against media-specific health-based comparison values. The maximum concentrations are used at this step of the screening process as a conservative measure even though we know that people are exposed to a range of concentrations and not just to the maximum reported levels. Comparison values are developed by ATSDR from available scientific literature concerning exposure and health effects. Comparison values are derived for soil/sediment, water, and air and reflect a concentration that is not expected to cause harmful health effects for a given contaminant, assuming a standard daily contact rate (for example, the amount of water or soil consumed or the amount of air breathed) and representative body weight (child or adult). Because they reflect concentrations that are much lower than those that have been observed to cause adverse health effects, comparison values are protective of public health in essentially all exposure situations. As a result, exposures to chemical concentrations detected

at or below ATSDR's comparison values are not expected to cause health effects in people. Therefore, levels below media-specific comparison values are not expected to pose a public health hazard and are not evaluated further for a given medium.

60. Comment: If more than one guidance or literature sources has a toxicity screening value, what is the precedence for determining which toxicity value is the best?

ATSDR Response: Typically, ATSDR selects the lowest environmental guideline consistent with the conditions at or near the site for screening purposes. However, be sure to use judgment in selecting the environmental guideline that best applies to site conditions in terms of time frames and populations that might be exposed. Consideration of the following issues will assist in identifying the most appropriate values for conducting screening:

- *Exposure duration.* Always consider exposure duration when selecting the most appropriate environmental guideline. A one-time exposure to a high contaminant concentration may result in different health effects than repeated exposure to a lower contaminant concentration. As noted, ATSDR has developed Environmental Media Evaluation Guides that apply to acute (14 days or less), intermediate (15–365 days) and chronic (366 days or more) exposures. Comparison values developed by other organizations may also account for acute, intermediate, and/or chronic exposures.

- *Site-specific exposure conditions*. In some instances, the most conservative environmental guideline may not be the most appropriate value to use in screening. Of critical importance in conducting public health assessments is selecting environmental guidelines that are most appropriate and applicable to site-specific conditions. Exposures identified at the site should closely approximate the exposure assumptions used to derive the environmental guideline. For example, including a soil contaminant for further evaluation based on a comparison value for a child would be inappropriate if the contaminant is found in a restricted industrial site where children are prohibited.

- When environmental guidelines listed in the ATSDR hierarchy are unavailable, those from other sources should be considered. For example, to meet their unique mandates, other government agencies, such as EPA, the Food and Drug Administration (FDA), and state and tribal environmental and health departments, have developed their own comparison values. These comparison values may address hazardous substances in water, soil, air, fish, or other biota.

- Possible sources of additional comparison values are listed in Table 7-1.

- Before choosing another environmental guideline, be sure to understand the derivation and use of that guideline to ensure that its use in screening is adequately protective of public health.

Because the mandates of different agencies may not always be strictly health-driven or consistent with the concerns of Superfund sites, fully understanding the derivation, uncertainties, and possible limitations of a comparison value is critical to determining its appropriateness for use in the PHA process. For example, some environmental guidelines are derived based on

environmental impacts rather than human health concerns. Selecting such guidelines would not necessarily aid in evaluating public health concerns.

Table 7-1. Additional Sources of Environmental Guidelines

- Department of Energy (DOE)
- EPA Federal Guidance 11 (*Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion*), 12 (*External Exposure to Radionuclide in Air, Water, and Soil*), and 13 (*Cancer Risk Coefficients for Environmental Exposure to Radionuclide*)
- EPA Region 3 Risk-based Concentrations (RBCs)
- EPA Region 9 Preliminary Remediation Goals (PRGs)
- EPA Soil Screening Levels (SSLs)
- EPA National Ambient Air Quality Standards (NAAQS)
- FDA guidelines and action levels
- Health Physics Society, American National Standards (ANS)
- International Commission on Radiological Protect (ICRP)
- National Council on Radiation Protection (NCRP) Radiation guidelines
- NCRP Soil Screening Limits
- Nuclear Regulatory Commission (NRC)
- Occupational standards/guidelines
- State-derived guidelines

61. Comment: If the technical literature is used to develop toxicity screening values, what procedures will be used to determine if the literature source is relevant and appropriate for the purpose of the study?

ATSDR Response: The majority of contaminants sampled for in Midlothian have a health-based comparison value. In the instance where this is not the case, the robustness of the study, weight of evidence assessment, scientific judgment, and consideration of site specific exposure scenarios will be evaluated. All methods used to assess public health implications will be documented in the PHC.

62. Comment: How will surrogate chemicals be selected if no toxicity screening value is available?

ATSDR Response: As stated previously, we don't anticipate that this type of analysis will be necessary for the majority of the contaminants detected. In the event that we do need to look for a surrogate for a particulate contaminant, we would use an assessment of the pharmacodynamics/pharmacokinetics and chemical structure of the surrogate. The process for selecting a surrogate will be documented in the PHC.

63. Comment: Will background chemical concentrations be addressed and if so, how?

ATSDR Response: As per ATSDR guidance, the PHC for this project will assess the public health implications of exposure to the measured air concentrations, regardless of the source. The document will also provide some perspective on the emission sources found throughout the Midlothian area. For example, should ATSDR find any chemicals to present a public health hazard, the PHC will acknowledge which sources emit the pollutant and whether the measured concentrations in Midlothian differ from those found in similar settings nationwide. For more information on how ATSDR typically evaluates background concentrations, refer to Section 5.3 of ATSDR's PHAGM at: http://www.atsdr.cdc.gov/hac/phamanual/ch5.html#5.3.

64. Comment: If background chemical concentrations are addressed, what sources of background data will be evaluated?

ATSDR Response: As the response to the previous comment notes, ATSDR will likely provide information on background concentrations only for certain chemicals. In these cases, the agency will consider various approaches to characterizing background. These may include upwind-downwind comparisons and citing information from the published literature (e.g., in ATSDR Toxicological Profiles, from EPA nationwide monitoring programs). For more information on how ATSDR typically evaluates background concentrations, refer to Section 5.3 of ATSDR's PHAGM [ATSDR 2005].

65. Comment: What analysis will be conducted to determine, if there is sufficient data of good quality to use it for its intended purpose?

ATSDR Response:

5.4 Identifying and Filling Critical Data Gaps

After reviewing environmental and modeled data, ATSDR still may be missing some information that will help us to understand what substances at what concentrations people could be exposed to. What we will do to decide is whether the missing information is critical and therefore should be highlighted as a data gap or whether the missing information is not essential for reaching public health conclusions.

Critical data gaps. In some cases, the available site documentation truly is insufficient for drawing public health conclusions on certain issues. Perhaps surface soil at a site of an unplanned release where the public has access was never sampled, or a drinking water well down gradient from a leaking underground storage tank was never sampled, or the well was sampled but not for the substance you have identified as a concern. These cases are examples of data gaps that must be filled to reach a defensible conclusion. In cases where sampling data are available, ATSDR may decide that the spatial and temporal extent of the sampling—or the quality of the sampling—do not form an adequate basis for drawing public health conclusions. ATSDR can address these critical data gaps by recommending future sampling efforts or by recommending additional sampling to confirm results from modeling studies that predict current and future levels of contamination. If the data gap pertains to past

exposure, which obviously cannot be characterized by sampling, modeling studies or exposure investigations may be warranted.

Data gaps that do not necessarily need to be filled. In other cases, however, ATSDR may recognize that the site has gaps in sampling data, but these gaps do not necessarily preclude reaching a defensible public health conclusion. An example of this is for sites with eliminated exposure pathways. If a site has an unplanned release to soil, but no one has access to the area where the spill took place, then sampling of the contaminated soils is unnecessary to answer public health questions. As another example, judgments could be made about levels of contamination in one medium based on other information available for the site. For instance, a site with metal-contaminated sediments might have fish tissue sampling data for species at higher trophic levels (i.e., at the top of the "food chain"), but not for species at lower trophic levels. Knowing that mercury biomagnifies in the food chain, exposures can be evaluated assuming that mercury concentration in the fish at lower trophic levels likely does not exceed that at higher trophic levels. Such an approach not only is scientifically defensible as a first approximation in most ecosystems, but would help ensure that the available resources are not spent collecting information that probably will not change public health conclusions. (Note: Any approach to assuming contaminant concentrations obviously vary among sites and with the contaminant(s) in question. For example, for organic compounds like PCBs or dioxins, species-specific lipid content typically influences the concentrations in fish more than trophic level hierarchies. It is critically important to consider the specific characteristics of contaminants of interest.)

Typically, when data gaps need to be filled, ATSDR will recommend that other agencies or organizations, such as EPA, tribal groups, state agencies, or site owners, conduct sampling. In a few cases, ATSDR will conduct additional sampling itself.

66. Comment: If data (e.g. analytical results of hair samples) is supplied by persons or entities other than ATSDR, EPA, TCEQ or TDSHS, how will the quality of this data be assessed?

ATSDR Response: Data quality is an important consideration to ATSDR, regardless of which party provides us data. For every data set, the agency carefully evaluates data quality by thoroughly reviewing all supporting documentation for the sampling effort. ATSDR follows recommendations outlined in its PHAGM when evaluating the quality of a given study.

67. Comment: Will contamination from cement kiln dust be addressed? Does water analysis of citizen's properties near the industrial facilities? Also, recommend analysis of water at Markwardt residence for high levels of hydrogen sulfide.

ATSDR Response: Yes, potential exposures regarding cement kiln dust will be evaluated. ATSDR will review relevant environmental data - recommendations may include additional sampling and analysis.

68. Comment: There is very little scientific value to comparing the Midlothian data set to data sets collected from areas that are not urbanized or do not contain significant transportation corridors. We recommend that if a comparison is made between the Midlothian data set and a set of background data, the background data set be reflective of an area similar to Midlothian.

ATSDR Response: ATSDR agrees. Please see "background" answers above for more information.

69. Comment: We understand that ATSDR has not ruled out additional sampling of environmental media to address concerns about some chemicals, including dioxins and furans. If you decide to conduct sampling activities, we request that we be notified of such plans at least 30 days in advance of the sampling activities and that we be allowed to review your sampling plan, observe the sampling activities, and be afforded the opportunity to split samples.

ATSDR Response: ATSDR's PHCs may include recommendations for additional sampling. If that is the case, we will encourage whatever party that conducts this sampling to notify stakeholders in advance, allow stakeholders to observe sampling activities, and provide the opportunity for split samples.

Project 4: Response to Written PHRP Comments

Name of project: Evaluation of the public health implications of National Ambient Air Quality Standards (NAAQS) and hydrogen sulfide ambient air pollutants in Midlothian.

70. Comment: What technical guidance or peer-reviewed literature will be used to guide the analysis?

ATSDR Response: ATSDR uses the PHAGM as a reference for conducting health assessment and Health Consultation work. Epidemiological and toxicological literature referenced in our contaminant-specific toxicological profiles as well as those published since the release of our most recent draft of the toxicological profiles will also be reviewed to assess health implications of exposure. Refer to ATSDR's responses to Written Comments (2) and (3) in Project 1 for more information on how the agency will assess data quality.

For the NAAQS constituents, we will rely on information synthesized by the EPA or WHO for their development of various standards or guidelines (e.g., EPA's Integrated Science Assessment).

71. Comment: What specific sources of data will be used to conduct the analysis?

ATSDR Response: ATSDR will evaluate all existing organic and inorganic data that we are aware of for this analysis (each PHC will list sources of datasets, including date ranges of samples collected and for which contaminants, in the appendix).

72. Comment: What statistical tests will the data be subjected to in order to evaluate trends and differentiate between concentrations relevant to long-term exposures as opposed to short-term exposures?

ATSDR Response: The purpose of ATSDR's evaluation of the data is to determine whether or not the existing data suggest that concentrations of airborne contaminants are present at levels of health concern. An initial screening of measured data against conservative health based guidance values will be used to identify contaminants for further evaluation. Part of the additional evaluation will include a review of the data distribution and time series analysis to identify both the magnitude of exposure and trends of exposure over time.

With regard to data distribution analyses and time-series assessment, the statistical approach depends on the number of observations, the number of non-detects, and relative data quality. Long-term and short-term exposures will be evaluated by comparison of average or geometric averaged concentrations (depending on the distribution of the dataset) to the relevant scientific literature and guidance values for chronic exposure assessment, and maximum/peak concentrations to the relevant scientific literature and guidance values for acute exposures. Descriptive statistical assessment **may** include calculation of location, scale, shape and distribution, and percentile/quantile statistics, as well as general counts of observations.

73. Comment: How will non-detect data be addressed in the trend analysis?

ATSDR Response: The approach we will use to assess non-detected data will depend on the duration of exposure we are evaluating. Non-detected data will not affect the ability of ATSDR to assess acute exposures. For an evaluation of acute exposures, we will use maximum concentrations to represent worst-case short term exposure scenarios.

Non-detects will be evaluated using an appropriate approach for the dataset, such as non-parametric analysis for censored data. After contaminants of concern are selected based on comparison to screening criteria, we will evaluate each contaminant (and non-detects) on a case by case basis. This approach is necessary due to the variability of the dataset with regard to issues such as the averaging time for each sample, number of observations for each contaminant, its detection frequency, detection limit variability, etc.

74. Comment: What exposure metrics will be used in the analysis?

ATSDR Response: The exposure metric will vary by contaminant. Generally, peak concentrations will be evaluated to assess acute exposures and average concentrations will be evaluated to assess chronic exposures. As best as possible, health endpoints will be evaluated for contaminants of concern in our assessment of health outcome data. For this project, measured and modeled exposures will serve as the exposure metric.

75. Comment: What sources of toxicity screening values will be reviewed to select screening values for purposes of the work?

ATSDR Response: For the NAAQS constituents, appropriate, health-protective screening values, as developed by the EPA, the WHO, and the epidemiological and toxicological literature will be used. For hydrogen sulfide, we will use protective screening values developed by ATSDR and the EPA.

76. Comment: If more than one guidance or literature sources has a toxicity screening value, what is the precedence for determining which toxicity value is the best?

ATSDR Response: Generally, it is our practice to use the most appropriate conservative existing health based guideline for initial screening of data in our assessments. For the NAAQS constituents and hydrogen sulfide, we will use the most conservative screening value from the EPA, WHO, or ATSDR, as applicable.

77. Comment: If the technical literature is used to develop toxicity screening values, what procedures will be used to determine if the literature source is relevant and appropriate for the purpose of the study?

ATSDR Response: For the NAAQS constituents and hydrogen sulfide, peer-reviewed, health-protective screenings values, are available for use by ATSDR. All methods used to assess public health implications of constituents above screening values will be documented in the PHC.

78. Comment: How will surrogate chemicals be selected if no toxicity screening value is available?

ATSDR Response: We do not anticipate that a screening value for a surrogate chemical will be needed in the evaluation of the NAAQS constituents or hydrogen sulfide because health-protective screening values already exist.

79. Comment: Will background chemical concentrations be addressed and if so, how?

ATSDR Response: See responses to Written Comment (49), Project 2 and Comment (63), Project 3. Moreover, for some of the NAAQS constituents (e.g., ozone), we will evaluate regional levels to assist in providing this context.

80. Comment: If background chemical concentrations are addressed, what sources of background data will be evaluated?

ATSDR Response: See responses to Comment (50), Project 2 and Comment (64), Project 3.

81. Comment: Will this project also address lead and PM2.5 and PM10?

ATSDR Response: This project will evaluate the public health implications of exposures to PM2.5 and 10; however, Project 2 will address metals, which includes lead.

82. Comment: The public health implications of NAAQS and hydrogen sulfide concentrations have been evaluated extensively by TCEQ and EPA as part of the CAA permitting process. ATSDR should consult these permitting actions as part of its analysis and be prepared to explain any differences in its opinions as compared to TCEQ and EPA in the event any differences exist.

ATSDR Response: As indicated above, we will rely heavily on the extensive scientific information gathered by the EPA in developing their standards for the NAAQS constituents. We will rely primarily on ATSDR's vast experience in evaluating the public health implication of hydrogen sulfide exposures at other sites. Although we will evaluate any important exposure information available from the permitting process, ATSDR's primary mandate is to evaluate the public health implications of exposures to the Midlothian community.

Project 5: Response to Written PHRP Comments

Name of project: Evaluation of Health Outcome Data for the Midlothian Area

83. Comment: What technical guidance or peer-reviewed literature will be used to guide the analysis?

ATSDR Response: Standard and accepted statistical and epidemiological methods will be used in analyzing cancer and birth defects registry data and other databases. For example, the Centers for Disease Control and Prevention (CDC)'s Wide-Ranging Online Data for Epidemiologic Research (WONDER) website (http://wonder.cdc.gov) provide information on epidemiological queries and methods, as well as multiple online databases.

84. Comment: What specific health outcome data will be evaluated and from where will it be obtained?

ATSDR Response: The Texas cancer registry, birth defects registry, hospital primary discharge data, and vital statistics are the major data bases that ATSDR will be evaluating. The information in these databases are maintained and collected by the DSHS. In addition, the CDC Behavior Risk Factor Surveillance System (BRFSS) data and other CDC National Center for Health Statistics (NCHS) data may be evaluated. ATSDR will obtain this health outcome data from the DSHS and CDC.

85. Comment: What asthma data will be evaluated and where will it be collected?

ATSDR Response: The primary asthma data that ATSDR will be evaluating is BRFSS and Texas hospital primary discharge data. These data will be obtained from DSHS and CDC.

86. Comment: Will health outcome data be compared to a control community, and if so, what is the community and how will it be selected?

ATSDR Response: For the health outcome data analysis, ATSDR will not be performing any randomized trial, cohort, or case-control study. Thus, there is no control community. There will be comparison communities that will vary depending upon the data analyses being performed or reviewed and the geographic unit evaluated in that analysis. Examples of comparison communities and populations include adjacent census tracts, neighboring zip-codes, neighboring towns (Venus, Cedar Hill), neighboring counties (Johnson, Tarrant), Health Region 3, the entire state of Texas, and the United States.

87. Comment: How will self-reported health symptoms be controlled to address other potential causes of respiratory health effects such as allergic reactions to cedar pollen?

ATSDR Response: The data bases that will be used to evaluate respiratory related issues (example hospital primary discharge data) generally do not provide contributing factors to the

diagnoses. Health concerns raised by community members will be addressed by both considering the known causes of the disease/condition, which may include allergic reactions to pollen, and exploring the chemicals of concern to determine the diseases associated with exposure. The analyses that ATSDR is proposing is primarily descriptive in nature. The results of our initial investigations will help us determine if more rigorous investigations are needed. Any subsequent studies would include a more complete consideration of potential confounders in our analyses of exposure disease relationships.

88. Comment: Will the technical veracity of the Legator study be evaluated given that TCEQ toxicologists provided comment to the Journal editor post publication of the Legator study disputing the study's methods and findings?

ATSDR Response: No formal critique of the 1998 Legator paper (Toxicology and Industrial Health 14(6):829-942) will be included in the health outcome consultation. The concerns raised in this paper are similar to the respiratory health concerns raised by community members. As such, hospital primary discharge data and peer-reviewed literature, including the Legator paper will be used to discuss the concerns.

89. Comment: How will the cancer registry data be used to address community concerns? For example, will cancer incidence and mortality rates in the community be compared to incidence and mortality rates across the state of Texas or to a control community? If so, what is the definition of the community for this purpose? What statistical tests will be used to make the comparison?

ATSDR Response: Previous reports from the DSHS cancer registry group will be reviewed and a request will be made for them to evaluate the incidence of multiple types of cancer with the latest complete data set. Standard epidemiological and statistical methods are employed by the DSHS. The comparison community and population rates will include multiple geographic units, but typically includes adjacent zip codes or census tracts, the state and the United States rates.

90. Comment: How will the birth defect registry data be used to address community concerns? For example, will birth defect rates in the community be compared to the birth defect rates across the state of Texas or to a control community? If so, what is the definition of the community for this purpose? What statistical tests will be used to make the comparison?

ATSDR Response: Previous reports from the DSHS birth defects registry group will be reviewed. ATSDR will request that DSHS update those reports for all birth defects reported and use geographic coding that more closely aligns with the exposure plume area of interest that will be determined by the environmental sub-team. Standard epidemiological and statistical methods are employed by the DSHS. The comparison birth rates will most likely compare rates within the plume area to those outside of the plume.

91. Comment: How will the feasibility of obtaining and using alternative health outcome or indicator data be assessed?

ATSDR Response: The data bases that are planned on being used for evaluation of the health outcomes related to the site are all available from the state of Texas and/or CDC. While some of the databases are less typically incorporated into ATSDR health consultations (such as BRFSS and primary hospital discharge data), they are validated, well-maintained databases by the CDC and state.

92. Comment: To what extent has using alternative outcome or indicator data been accepted by the scientific community as a whole?

ATSDR Response: The data bases that ATSDR primarily will be using have been widely accepted and are the basis for many peer-reviewed investigations and journal articles.

93. Comment: How will the existence of immune diseases and acute health effects in the community be verified?

ATSDR Response: Individual medical records will not be requested to verify the existence of immune diseases or other health effects. These issues are considered health concerns of the community and will be addressed. If there is no readily available data base in existence for the condition (such as for immune diseases), ATSDR will not be able to estimate the amount of the disease in the community; however, we will consider both the known causes of the disease/condition and explore the chemicals of concern to determine the diseases associated with exposure. This analysis would be more descriptive in nature.

94. Comment: What journals or databases will be consulted in the literature search to assess the relationship between immune diseases and acute health effects?

ATSDR Response: The National Institute of Health's National Library of Medicine PubMed database will be the primary database for any literature review. For specific conditions, information from nationally recognized governmental and non-governmental organizations may also be reviewed.

95. Comment: We understand that the public health evaluation will rely on publicly available data bases of health effects outcomes rather than on self-reported health symptoms. We request that you notify us immediately if this approach changes as you proceed with the study and allow us the opportunity to review and comment on your methodology.

ATSDR Response: Self-reported health symptoms constitute community health concerns and will be addressed in the health consultation. For health concerns without a readily available data base, a literature review for the known causes of the disease/condition will be made.

96. Comment: Please work with Midlothian Independent School District to determine number of special ed students, how many asthma inhalers are kept in the nurses' offices and how many serious diseases are affecting students. Speak with school nurses – find out how many students and athletes rely on inhalers. Check out the number of juvenile diabetes and cancer victims attending school or deceased. Contact MISD Special Education 972/775-4317 and see how many disabled students are enrolled.

ATSDR Response: These childhood health concerns are noted. ATSDR will review the scientific literature to determine how these types of alternative data sources have been used to address similar questions posed by a community and will evaluate the feasibility, availability, and appropriateness for answering some community concerns in Midlothian. For several of these conditions, even knowing the number of cases within the Midlothian School District will not allow for any comparison with a base line rate in other school districts, the county or the state to draw meaningful conclusions about the numbers. Childhood cancer and asthma will be evaluated in the health outcome data using available data bases. Data from the birth defects registry will capture some, but not all students who may be disabled. ATSDR will use the information we have in the best possible way to present information on these childhood health concerns to the community.

Project 5: Response to Verbal Comments

97. Comment: What steps need to be made to include co-morbidity in this study?

ATSDR Response: For the two primary health outcomes of concern which have registry data available (cancer and birth defects), co-morbidity is not included in the analysis, although age, gender, race, and other available risk factors will be accounted for in the analyses. For other health outcomes, ATSDR will evaluate the chemicals of concern in relation to the multiple health effects that may be attributed to them. Unfortunately, there is no health outcome database available that can be used to directly address co-morbid conditions for the community.

98. Comment: What is the prevalence of degenerative spinal disc disease?

ATSDR Response: Degenerative disk disease is a common condition that is related to changes that occur with age. By age 60, over two-thirds of adults in the United States will have radiographic evidence of degenerative disk disease, fortunately most of those will not be symptomatic.

99. Comment: Have you noticed an excessive number of cases of spinal degeneration as a whole (in this general region) as compared to the rest of the country?

ATSDR Response: The rate of spinal degeneration (degenerative disk disease) has not been assessed in this population. The national rate for radiographic evidence of degenerative disk disease is discussed above.

100. Comment: Can this diagnosis be included in the study? Or other possible diagnosis elevated in this region?

ATSDR Response: Degenerative disk disease, since it is related to aging and lifestyle, will not be included in the analyses. ATSDR will review hospital primary discharge diagnosis as reported to the state of Texas to see if there are any elevations in chemically-associated diagnoses.

101. Comment: Will hospitals outside of the county be contacted? Many use Fort Worth and Dallas medical facilities?

ATSDR Response: For our Project 5 PHC, we will review reported hospital primary discharge diagnoses for the state including hospitals in Fort Worth and Dallas. We will not be making direct contact with any hospital to obtain medical information.

102. Comment: Will you compare asthma rates for Midlothian ISD to other comparable size school districts without so much industry in the community?

ATSDR Response: Asthma rates will be reviewed from the BRFSS data and Texas hospital primary discharge data. Neither database uses school districts as a geographic unit. Other Texas communities will be used as a comparison.

103. Comment: How will anecdotal data be considered as compared to registry data?

ATSDR Response: ATSDR's intention is to address the health concerns raised by community members even if no readily available database exists for the condition. While these concerns cannot be addressed using a statistical or epidemiological evaluation, ATSDR will consider both the known causes of the disease/condition and explore the chemicals of concern to determine the diseases associated with exposure.

104. Comment: What things will you do that are different that what have been done by the State Health Department?

ATSDR Response: The DSHS is ATSDR's cooperative agreement partner in the evaluation of health issues related to the Midlothian site. Their previous documents from the birth defect and cancer registry were prepared using standard epidemiological and statistical methods and their registries are maintained consistent with national standards. ATSDR will be reviewing those documents previously prepared related to the site. For this PHC, we will be expanding the work that had previously been performed on health outcomes. ATSDR will request the DSHS birth defect and cancer registry groups to use the latest data to update those reports, expand the scope of conditions reviewed, and when possible use geographic coding that more closely aligns with the exposure plume area of interest that will be determined by the environmental sub-team. ATSDR will evaluate BRFSS data, hospital discharge data and other vital statistics information. For health conditions of concern that do not have a database, we will review the known causes of those conditions and the chemicals of concern from the site.

105. Comment: What "questionnaire" data will be evaluated?

ATSDR Response: Questionnaires and other surveys will be treated as anecdotal information, if they provide no basis for a statistical evaluation. As such, we will consider both the known causes of the health concerns that are raised and explore the chemicals of concern to determine the diseases associated with exposure.

106. Comment: What is the typical latency period for chemicals associated with hazardous wastes?

ATSDR Response: Latency, or the period of time from exposure to the development of a disease, will vary depending upon the concentration of the chemical, the timing of exposure (e.g., developing fetus vs. late adulthood), the length of time exposed, and the type of chemical. For the Midlothian health outcomes, we will be looking at acute and chronic diseases and cancer. Acute effects may be experience immediately or within days of exposure (e.g. asthma attack) and they typically require fairly high concentrations to elicit a response. Chronic effects may take several to many years of lower level exposure before the development of a disease (e.g., cardiovascular changes). Exposure to carcinogens increases the probability of developing a cancer. Most solid cancers have a latency period of twenty years or more after exposure occurs.

107. Comment: Since mercury and other pollutants attack the immune system and the immune system is one of the body's defenses against developing cancer, would not pollution be capable of speeding the development of a cancer lump?

ATSDR Response: Chemicals are considered carcinogens when they either initiate and/or promote the development of a malignant tumor or cell line. Cancer risk assessment is based on those genetic and epigenetic (something that indirectly influences a cell without directly affecting its DNA) effects. Some chemicals may impact some part of the immune system. The immune system has many components, only some of which contribute to the defense against tumor cells (e.g., Natural Killer cells, cytotoxic T cells, helper T cells, etc.). Cancer research often focuses on different aspects of our body's immune response to cancer in an effort to find ways to boost our immune defenses. Given the extent of the health outcome data available, it will not be possible to evaluate the possible interaction between carcinogens and impact on immunological cell lines involved in cancer defense. ATSDR will evaluate the chemicals of concern to determine if there are known links to immunological dysfunction.

108. Comment: I've heard the word "limitations" used a lot tonight. Can you tell me how good of a document you can produce if there are so many limitations? Best case scenario with the information you have or are that impossible?

ATSDR Response: In evaluating the health outcome data for the site, it is important to understand the limitations of the databases being used. The purpose the database was created, assumptions that were made, and information that was not included or completed will influence the extent we can use the database to address the health questions being asked. ATSDR will need to identify what is a suitable and appropriate comparison population for evaluating epidemiological information. By acknowledging these limitations, ATSDR can better recognize when failure to demonstrate a positive association does not mean an association does not exist but there are a variety of shortcomings that do not allow the analysis. We will use the data available in the best possible way to present information on health incomes in the community.

Project 6: Response to Written PHRP Comments

Name of project: Evaluation of Reported Health Issues in Animals in the Midlothian Area

109. Comment: What technical guidance or peer reviewed literature will be used to guide the analysis?

ATSDR Response: Technical guidance includes consultations with veterinary toxicologists and scientists both inside and outside of the federal government. Peer reviewed literature from veterinary, toxicology, environmental health, and epidemiological journals, will be reviewed, as well as EPA documents, ATSDR toxicological profiles, and Material Safety Data Sheets (MSDS).

110. Comment: What health related data will be collected from local and state veterinarians?

ATSDR Response: The State Veterinarian's office deals exclusively with infectious disease issues in livestock and does not have data pertinent to the project. Veterinary records of animals (as made available by individual owners) in the Midlothian area will be reviewed.

111. Comment: Which veterinarians will be contacted to request data?

ATSDR Response: ATSDR will contact veterinarians for animals, whose owners give us permission to do so.

112. Comment: How will the list of symptoms of concern for various organ systems are developed?

ATSDR Response: The list of signs of concern for various organ systems will be developed based on a review of the literature, consultations with veterinary toxicologists and other scientists, and issues raised by the community

113. Comment: What TCEQ Report will be assessed to determine the extent to which data can be used to estimate exposures of companion animals and livestock in the Midlothian area?

ATSDR Response: Existing TCEQ reports will be one source of information that will be taken into consideration.

114. Comment: What is the definition of the Midlothian area for purposes of estimating exposures?

ATSDR Response: The exact area has not been defined as of now, but it will include the areas within air dispersion contaminant plume model results from all facilities, as well as downstream and downwind from all facilities.

115. Comment: How will exposures be estimated and what metrics will be used for this purpose?

ATSDR Response: Multiple environmental pathways are under consideration. When possible, point source and data indicating average exposures will be supplemented by additional veterinary clinical samples and samples from agricultural and residential surfaces and sediments.

116. Comment: What journals or databases will be consulted in the literature search to assess the toxicity of chemicals to companion animals and livestock?

ATSDR Response: Peer reviewed literature will be obtained from veterinary, toxicology, environmental health, and epidemiological journals.

117. Comment: How will differences in animal species be addressed when evaluating toxicity data from peer reviewed literature?

ATSDR Response: This will be determined after the preliminary assessment.

118. Comment: How will route specific Provisional Animal Health Guidance Values (PAHGV) be developed?

ATSDR Response: Following the assessment, whether or not PAHGVs need to be developed will be determined.

119. Comment: How will causes of health effects from environmental exposure be evaluated against health effects and symptoms known to be common in specific animal species from genetic or animal husbandry issues?

ATSDR Response: Comparison data and experience of clinical veterinarians will be used to establish the health effects and signs known to be common in specific animal species from genetic or animal husbandry issues. A thorough literature review will be used to evaluate health effects from potential environmental exposures.

120. Comment: The community's concern goes far beyond veterinary issues. The concern expressed by the petitioner and the public is that animals are manifesting excessive illnesses that appear to parallel human illnesses occurring in the community. There is no doubt that these illnesses are occurring in the animals. The concern is that these animals are acting as sentinels to human health.

ATSDR Response: Animals can experience health effects from exposure to environmental contaminants, which is why we have undertaken this assessment and will consider human exposure in light of our findings.

121. Comment: We understand that you may submit biological samples from animals that have been frozen for some period of time to a laboratory for analysis. We are interested in learning how you will verify that the animals submitted for analysis are from the Midlothian area and how you will know whether or not the samples have been tampered with before they come into you possession.

If you decide to conduct sampling activities, we request that we be notified of such plans at least 30 days in advance of the sampling activities and that we be allowed to review your sampling plan, observe the sampling activities and be afforded the opportunity to split samples. (Ash Grove 3/19/10; TXI 3/19/10)

ATSDR Response: Retrospective testing will not be performed. If prospective testing is conducted, protocols including appropriate chain of custody procedures will be developed. ATSDR understands the concern and will address it as we develop protocols.

122. Comment: We understand that you will consider other factors that can cause health effects in animals such as diet and breeding, as part of your analysis. We are interested to learn how these issues will be considered if there are no records describing them provided by the community.

ATSDR Response: Comparison data, review of the literature, and experience of clinical veterinarians will be used to establish the health effects and signs known to be common in specific animal species from genetic or animal husbandry issues. The records that are available will be taken into consideration.

123. Comment: The essence of concern regarding the animal issues (as expressed in the PHRP) seems to have been lost or not adequately reflected in both the summarized concerns and in Project 6.

ATSDR Response: Animals can experience health effects from exposure to environmental contaminants. ATSDR has recruited veterinarians to more fully address the animal issues.

124. Comment: Are there any discrepancies between instances of animal health issues, PAHGV's applied and TCEQ data?

ATSDR Response: ATSDR will be determining whether animal health issues parallel with environmental contaminant exposures. The initial analysis will not involve PAHGVs, since they have not yet been created.

125. Comment: It is most unfortunate that Dr. Dennis Jones will not be available to participate in this study as previously planned. He demonstrated considerable knowledge of dioxin and furan exposure in relation to animals during our interview. Veterinary knowledge of both large and small animals is essential.

ATSDR Response: ATSDR agrees and hope to involve him to the extent that his other duties allow.

General/Non-Project Specific

126. Comment: The PHRP should be upgraded to a Study Protocol and the Protocol should be peer reviewed.

ATSDR Response: ATSDR does not consider the PHRP to be a health study protocol and does not plan to have the PHRP peer reviewed. All completed evaluations will be peer reviewed after the community has had an opportunity to comment.

127. Comment: If decision made not to peer review the PHRP, then the PHRP should provide more detail regarding how the work will address the most contentious aspects of the work previously conducted by TDSHS and other government agencies.

ATSDR Response: A discussion of methods for evaluating existing data and responding to community concerns was held in a community meeting in February 2010. The projects proposed in this PHRP reflect a new evaluation of existing data to respond to community concerns and are not intended to respond to comments of work previously completed by other governmental agencies.

129. Comment: "There are very few data on the impact of incinerator emissions on the health of nearby communities. Epidemiological investigations have rarely been conducted and few studies of disease and illness patterns have been undertaken" (Barry Johnson). The same holds true today. Studies and sufficient data are still lacking. This is a concern that has plagued not only this community, but communities through the world where incineration is taking place, especially incineration of hazardous waste.

ATSDR Response: The quote cited in the comment is taken from Congressional testimony that an ATSDR employee gave in 1994 during a House of Representatives sub-committee session on "Health Impacts of Incineration." As part of its health assessment activities for Midlothian, ATSDR is conducting a literature search to identify relevant studies that have been conducted in the years since this testimony was issued. This literature search will focus on individual studies as well as reviews, such as those published by ATSDR [ATSDR 2002] and the National Research Council [NRC 2000]. ATSDR will document findings from the literature search in one of its PHCs and comment on the relevance of the findings to the Midlothian facilities.

130. Comment: In reference to statement: "TXI continues to obtain permit approval without public input (recent news). I believe the following statement more adequately addresses the gist of the news article: "According to EPA, TCEQs standard permitting program does not meet federal requirements and the TXI tire-burning plan fell under a state program that is inadequate (recent news)." [http://www.dallasnews.com/sharedcontent/dws/news/city/ellis/stories/100309dnmetcement.41ee106.html]

ATSDR response: Comment noted.

131. Comment: Confounding circumstance should be considered (i.e. Ellis County is an ozone non-attainment area, kilns not designed to burn hazardous waste allowed to operate under less protective MACT standards, etc.) [This would reflect that you acknowledge there is more than one confounding circumstance.]

ATSDR Response: ATSDR acknowledges that "confounding circumstances" exist within the Midlothian study area. We will attempt to explain our evaluation process in a clear and concise manner (e.g., how does exposure to higher levels of ozone along with concurrent exposure to VOCs affect health).

132. Comment: Comments to the draft PHC should have been one of the greatest sources of community concerns. Was there a special reason for not listing community concerns expressed in these comments? Our comments to the Midlothian draft PHC (TDSHS document) regarding the concerns we have with the air monitoring system are extensively expressed. It puzzles me that all these concerns would be summarized and truncated into a statement, "Effectiveness of air monitoring system concerns expressed by Dr. Stuart Batterman, Dr. Neil Carmen and Dr. Al Armendariz. Some examples are listed.

ATSDR response: This list of community concerns in the PHRP specifically came from concerns that ATSDR heard when we conducted various communities outreach activities. It was not intended to incorporate the public comments that were received on DSHS's draft PHC (released 12/2007). These comments will be taken into account as data is evaluated.

133. Comment: The following need to be added to the list (Concerns Voiced During Interviews in July 2009):
-Data collected during period of reduced production, suspension of hazardous waste burning, etc. should not be used to evaluate past or future levels of toxic emissions.
-Data collected during suspension of hazardous waste burning, etc. will not give an adequate picture of Cr VI emissions.
-Need to address cement kiln dust.
-Public needs to understand the difference between how a regulatory agency and a public health agency addresses public health issues.

ATSDR response: These concerns will be added to PHRP.

134. Comment: Page 4. Under "Contractual Support" last sentence is confusing. Did you mean to say"…how the data will be interpreted from the contractor's work."?

ATSDR Response: Yes, we will make the correction in the revised PHRP.

135. Comment: Could you add a space between the bulleted items? Without spacing, they are very difficult to read.

ATSDR response: Yes, correction will be made in the revised PHRP.

136. Comment: When evaluating the air monitoring data, how will upset events be factored in? Will there be an official and unofficial documentation related to the "reported" upsets by the 4 major industries? How will the upsets that have occurred throughout the years that have never been reported and documented be factored in?

ATSDR Response: The comment asks how ATSDR will evaluate potential air quality impacts associated with emissions resulting from process upsets, startups, shutdowns, and other short-term events. ATSDR is considering multiple information sources to address the issue. First, for emission events that facilities reported to TCEQ, ATSDR has already accessed summary information on individual events and will document these in its PHCs. Second, regarding the possibility that additional emission events occurred that were not reported to state officials, ATSDR will review continuous emission monitoring data and continuous ambient air monitoring data, both of which should provide some indication of times when emissions were considerably elevated above typical levels. The PHCs will fully document the data ATSDR considered when evaluating this issue.

137. Comment: Please consider: Holcim violated their air permit for several years emitting more than twice its permit allowed amount of nitrogen oxide. They were fined by TCEQ. This in itself was an extremely unusual step. What could have been the potential public health implications of the basis for this penalty?

ATSDR Response: We will specifically look at this time period to determine if adequate data are available to evaluate what potential public health implications may have been to exposures from nitrogen oxide from Holcim and other sources.

138. Comment: Please consider: Ash Grove burned hazardous waste derived fuel (HWDF) from 1986-1992. It was not until after the 'trial burn' in 1992 that it was determined that this facility could not safely burn HWDF. What were the potential public health implications to the community as a result of this?

ATSDR Response: Although it is outside of ATSDR's purview to evaluate the compliance issues leading to this decision, we can assess health implications through the evaluation of ambient air data collected during that period of time. The PHC for Project 1 will specify whether ambient air monitoring data from this particular time frame are sufficient for evaluating this issue.

139. Comment: Please consider: EPA issued citations to TXI for violations involving hazardous waste burning – and what were the potential public health implications?

ATSDR Response: See response above to comments (137) and (138).

140. Comment: Can you explain the difference between the phrases "Could there be a relationship…" or "Is their a relationship…" when considering a potential impact of air emission? To me "is there" would indicate a need for proof positive while "could be" is based on the preponderance of evidence.

ATSDR Response: For PHAs, ATSDR is not generally able to determine a cause and effect relationship, so we rely on, as indicated in the comment, a preponderance of evidence from exposure, toxicological, and epidemiological information to determine if (or could) harmful effects occur. We will make sure our language is clear in the revised PHRP.

141. Comment: When you look back to assess health impacts, will you be using screening levels deemed to be protective at that time or levels as you know them now? How will you incorporate the evolving science that has not been assimilated to your health assessment guidelines?

ATSDR Response: ATSDR will use the best and most current science to assess exposures in Midlothian. A toxicological review of contaminants of concern follows our initial screening process, which includes a literature review of the current toxicological and epidemiologic research.

142. Comment: The science of epigenetics has proven that chemical changes occur to DNA and the proteins that organize it is a factor in many human illnesses. Science has established that these changes alter gene expression – whether genes are turned on or off. Altering gene expression can have huge repercussions on normal cell function and, in turn, health outcomes (short and long term). What tools do you have available to assess the epigenetic effect of the various chemicals to which the community is exposed?

ATSDR Response: By its very nature, epidemiological investigations addressing environmental exposures incorporate the concept of epigenetics. Results from epidemiological investigations have been the impetus for much epigenetic and toxicological research. Thus, epidemiological methods are the tools that are available to ATSDR that will be used for this site.

We recommend that ATSDR consider this concern and try to address it to the extent practicable.

ATSDR Response: While it is beyond the mandate of this agency to engage in molecular and genetic research on epigenetics, ATSDR focuses on hazardous chemicals and the toxicological effects attributable to them for the development of cancer and adverse birth outcomes. However, we embrace the concept of epigenetic and the role of genetic-environmental interactions in disease causation.

143. Comment: Do you have the tools to evaluate the synergistic effects of – not only of multiple, but all simultaneous chemical exposures? The community has always expressed a concern that a holistic approach has not been taken when assessing toxic exposures. Will this produce a separate independent analysis or will this data be incorporated into and be a factor in the overall toxicological assessment? Will lead also be addressed?

ATSDR Response: Please refer to verbal response to comment (32) (under Project 1) for more detailed information on this issue.

144. Comment: Who does ATSDR perceive as their "stakeholders" and why?

ATSDR Response: ATSDR defines a stakeholder as a person, group, or community who has an interest in activities at a hazardous waste site (taken from ATSDR's Glossary of Terms).

145. Comment: The statement below by Dr. Frumkin in his March 2009 congressional testimony gives rise to the questions: 1) To what extent will the published toxicological profiles be relied upon? And, 2) Have web-based updates been made available or will the "book publication" be the resource?

Dr. Frumkin's statement: ***Since its inception, ATSDR has produced Toxicological Profiles by reviewing the accumulated literature at a particular point in time, culminating in publication of a monograph that promptly commenced to go out of date. The Profile would be updated some years later with a next edition, which would rather soon become stale. ATSDR is replacing this "book publication" model with a more contemporary model based on ongoing, web-based updates of relevant sections as new material becomes available.***

ATSDR Response: As ATSDR evaluates a site and uses the Toxicological Profile and applicable addendums to gain information, we will use the most up-to-date version of the document (that has been finalized and released).

146. Comment: What progress has been made in this analysis: ***In the PHC released for comment in December 2007, TDSHS indicated: Currently, TDSHS staff are analyzing the hourly NAAQS data (sulfur dioxide, hydrogen sulfide, nitric oxide, nitrogen dioxide, nitrogen oxides, ozone, and particulates) and preparing a health consultation to address these compounds.***

ATSDR Response: Activities in response to the Midlothian environmental community concerns are being undertaken by the ATSDR and are outlined in the PHRP. Activities identified in the 2007 draft health consultation have been superseded by the PHRP and corresponding health consultations.

147. Comment: In our review of ATSDR toxicological profiles, publications, and PHAs, ATSDR seems to skirt the impact of lower lead levels and bioaccumulation. Lead is a poison to human health at any level. It appears that ATSDR is advocating a blood lead level (BLL) of 10 ug/dL, as an acceptable level of lead poisoning. It is understandable that a zero blood level of lead may not be achievable; however, achievable levels should not be a factor in explaining health impact. We hope that ATSDR analysis and educational processes stress that there is no acceptable level of lead poisoning and explains the impact of bioaccumulation.

ATSDR Response: CDC has established recommendations for medical procedures and clinical follow-up of children with various BLLs. For example, CDC recommends

- emergency hospitalization of children with BLLs $\geq$ 70 ug/dL
- chelation therapy for children with BLLs $\geq$ 45 ug/dL
- case management for those with BLLs $\geq$ 15 ug/dL or as low as 10 ug/dL (if resources allow).

Thus there is no single "CDC blood lead level." The CDC level of concern (i.e., 10 ug/dL) was not established to be a safe or normal level although it has frequently been misinterpreted as a toxicological threshold.

As early as 1991, CDC stated that harmful effects of lead occurred at BLLs <70 ug/dL. In 2005, CDC and the Advisory Committee on Childhood Lead Poisoning reviewed the scientific evidence of adverse health effects in children with BLLs <10 ug/dL and concluded that evidence of adverse health effects in children with BLLs <10 ug/dL and concluded that

- no "safe" BLL for children has been identified and
- children with BLLs <10 ug/dL should not be considered lead poisoned as the term is used in the clinical setting.

CDC/ATSDR recognizes that the available data for health endpoints other than cognitive function are consistent with an association between BLLs <10 ug/dL and poorer health outcomes. Thus, any assessment of adverse effects focusing solely on the effect of cognitive function or IQ underestimates the negative consequences of children's exposure to lead.

Rather than arbitrarily setting a "level of concern," CDC recommends institutionalizing primary prevention through a systematic and society wide effort to control or eliminate lead hazards in children's environments before they are exposed. This is because BLLs should not be used to trigger exposure prevention. Exposure should be eliminated before harm occurs. As a result, CDC recommends that federal agencies continue to monitor and measure the amount of lead in environmental media, including air, water, and soil. CDC also recommends that regulatory agencies develop new mathematical models of exposure or modify existing models (e.g., the Integrated Exposure Uptake and BioKinetic Model (IEUBK)). The models should predict the magnitude of a child's increase in BLL given a range of potential exposures rather than the probability of a BLL $\leq$ 10 ug/dL.

ATSDR will address these concerns related to lead in the health outcome document and will provide some data on blood lead levels from the Texas Childhood Lead Prevention Program.

148. Comment: Summarized community concerns may not reflect true meaning of concerns. Suggested wording changes are made.

ATSDR Response: ATSDR appreciates the fact that community members have expressed many concerns beyond those that could be readily captured in the summaries included in the PHRP. While these concerns are not detailed in the summaries, they are part of the overall evaluation and will be included.

149. Comment: The environmental sampling has the potential to underestimate the actual airborne concentrations of mercury. The issue of mercury exposure was raised as a concern by some members of the public even though both TCEQ and EPA-6 have previously determined that risks associated with mercury exposure are below regulatory levels of concern. If ATSDR conducts some type of modeling analysis to evaluate the health

impacts of mercury exposure, that analysis should consider the loss of mercury to the global cycle as part of the modeling procedure.

ATSDR Response: The comment pertains to approaches and assumptions ATSDR will use when evaluating potential exposures to mercury. As suggested by the comment, the existing ambient air monitoring data for mercury may understate actual airborne concentrations. That is because airborne mercury is often found in the vapor phase. All mercury measurements for the Midlothian area quantified mercury bound to particulate matter. ATSDR's PHC will describe this issue in greater detail and offer alternate approaches for evaluating the total airborne levels of mercury. Use of a screening dispersion model will be one option. The PHC will fully document the final approach that ATSDR takes and comment, uncertainties associated with estimates of ambient air concentrations of mercury, and whether the agency recommends that monitoring of vapor-phase mercury be conducted in the future.

150. Comment: TRI is "self reported by industry". There is a significant variation in what industries report to the State and what is reported in TRI.

ATSDR Response: ATSDR is aware of at least one published report highlighting inconsistencies between (1) emission data that the Midlothian facilities reported to TRI and (2) emission data that these facilities reported to the Texas environmental agencies. This published report focuses on inconsistencies in emission data for mercury and lead. It should be noted that changes in TRI reporting requirements for mercury and lead became effective in reporting years 2000 and 2001, respectively. Starting in these years, EPA dramatically lowered the reporting thresholds for these (and other) chemicals, which resulted in a sharp increase in the number of facilities that were required to report to TRI. The apparent inconsistencies between emission data for lead and mercury likely result, at least in part, from these changes in the TRI reporting requirements (and no similar changes occurred in the state's emission reporting systems). ATSDR will comment more thoroughly on the limitations of emission data in its PHCs

Users of TRI data should be aware that TRI emission calculations reflect disposal or other releases and other waste management of chemicals, not whether (or to what degree) the public has been exposed to them. Both the toxicity of a chemical and exposure considerations should be taken into account when using the data.

• TRI chemicals vary widely in toxicity and in their capacity to produce toxic effects. Some high-volume releases of less toxic chemicals may appear to be more serious than lower-volume releases of highly toxic chemicals, when just the opposite may be true.

• The potential for exposure may be greater the longer the chemical remains unchanged in the environment. Sunlight, heat, or microorganisms may or may not decompose the chemical. Smaller releases of a persistent, highly toxic chemical may create a more serious problem than larger releases of a chemical that is rapidly converted to a less toxic form.

151. Comment: In reference to the use of the 2008-2009 follow-up environmental sampling TCEQ performed in response to the TDSHS Midlothian PHC, please consider the Dr. Al Armendariz's comments. Although we know ATSDR did not contract with TCEQ to do

the follow-up sampling, TCEQs intent was to fill the "data gaps" outlined in the PHC; hence, the conflict of interest still exists.

ATSDR Response: ATSDR will consider these comments.

152. Comment: Reviewing previous environmental data will give an incomplete picture of the impact of 40 something years of industrial activity in the area. The agencies must take into consideration that there is absolutely no emissions data from either EPA or the state for the first 30 years of industrial operations in Midlothian – including the first 4 years of hazardous waste burning. Omissions such as these ensure that this analysis only gives a glimpse into the actual pollution burden inflicted.

ATSDR Response: It is true that there are no data for the entire operational history of each of the facilities of concern. This is a common limitation of making health conclusions regarding historical exposures. However, ATSDR will make some inferences about past exposure by reviewing operational changes (processes, fuels, installation of controls, etc.). When feasible, we can compare data collected before and after major operational changes occurred to assist us in our consideration of past exposures.

153. Comment: Any air data and modeling should take into account whether the plants are operating at full capacity, what is being incinerated or used as fuel and compared to historical operating practices. We fail to see the importance of current air data and modeling because of the nature of current emissions. All plants are not operating at full capacity; none are incinerating hazardous waste and are not indicative of historical activity.

ATSDR Response: As mentioned previously, ATSDR will consider facility operational status in our assessment of historical data trends. We have many years of data to evaluate, some of which was collected during periods of greatest concern to area residents.

154. Comment: The Role of the Community section – Scheduling of meetings should be made without local community conflicts.

ATSDR Response: ATSDR makes every effort to schedule around community events. We check the city and school district calendars prior to considering any meeting dates. ATSDR will do our best to take previously scheduled events into consideration when planning a meeting.

155. Comment: Within the study, there appears to be a failure to consider food chain pathway of exposure. At the time hazardous waste incineration began, Midlothian was home to five operating dairies, countless beef cattle operations and local crop farming. In addition to small animals, it is important that livestock be considered also, i.e. the Kemp Ranch incidence.

ATSDR Response: ATSDR agrees that multiple pathways of exposure need to be considered. At this time we will not be examining food animal issues. However, if the investigations performed for the health consultations reveal that animals may have excess exposure to

environmental contaminants, the ATSDR will consider the issue of human risk from consumption of locally grown livestock and make appropriate recommendations.

156. Comment: Community Concerns section - Rates of health problems – This should include diabetes due to dioxin exposure and endocrine disruption.

ATSDR Response: ATSDR will include diabetes as a community health concern in the Project 5 PHC. According to the National Health and Nutritional Survey (NHANES) and BRFSS data, diabetes rates in Texas are higher than that of the United States. We will not be able to separate contributions to diabetes from dioxin exposure from the major risk factors such as hereditary and obesity.

157. Comment: Community Concerns section – Rates of health problems – Autism rates for the community should be explored due to the fact large amounts of neurotoxins are continually emitted.

ATSDR Response: Autism will be addressed as a community health concern. Since there is no registry for autism spectrum disorders, no rates can be calculated; however, the literature will be reviewed for possible chemical causes that may have any relationship to the site.

158. Comment: Community concerns section – A study by TDSHS of a Down Syndrome cluster in Ellis Co. was conducted but not designed to consider environmental factors. According to parents of these babies, the state failed to conduct any personal interviews, observations or laboratory analyses. Interestingly, all of the children were the twenty-first trisomy and not the twenty-third. To intentionally exclude environmental factors under the circumstances is inexcusable and misleading.

ATSDR Response: ATSDR will review the study prepared in 1996 by the DSHS on the Down Syndrome Cluster. In that study, in an effort to identify risk factors associated with the cluster, DSHS performed face to face interviews of case mothers of the children who were born between 1992 and 1994 and diagnosed with Down Syndrome. ATSDR will request that the DSHS birth defects registry group provide an updated report on all birth defects using geographic coding corresponding to the exposure plume area of interest. Down Syndrome (Trisomy 21, translocations, and mosaics) is included in the birth defects registry. Trisomy 23 (Klinefelter's Syndrome – 47, XXY or Triple X Syndrome – 47, XXX) is typically not detected until puberty, or at all, and would be underreported in the birth defects registry which primarily covers the first year of life.

159. Comment: According to the Public Health Region 3 data, Midlothian's overall birth-defect rate is 50% higher that the States.

ATSDR Response: ATSDR will review reports prepared by the DSHS birth defects registry group that pertain to Midlothian. In our preliminary review of these reports, while some specific birth defects were higher than expected (e.g., hypospadias), the rates of most types of birth defects were similar to other comparison communities. ATSDR will request that the birth defects

registry group provide an updated report on all birth defects for the area and compare them to neighboring areas, regional, and state rates.

160. Comment: Community concerns voiced in Dec 2005):

-Cars are dusty all the time – thick/white dust. Many residents of Cement Valley have to have their cars washed with vinegar to remove the deposits of dust.
-Air Quality Problems – Please add "Unidentifiable odors and extreme fatigue" coupled with respiratory problems.

ATSDR Response: Comment noted and will be addressed in evaluations.

161. Comment: Concerns voiced during interviews in July 2009-Need to add: Concern for number of disabled children in the community – appx 800. (This is documented by "Problem Solvers Project to retrofit playground park equipment for disabled children to play".)

ATSDR Response: This will be noted in the revised PHRP.

162. Comment: Protectiveness of the regulatory health-based screening guidelines: ESLs utilized by the regulatory agency differ greatly from those a health-based agency with which to assess and assure public health. A conflict of interest exists in that TCEQ has granted a permit; and is therefore reluctant to concede their decisions could be harming the public. Each industry is evaluated as if it stands alone in a pristine world. This defies logic and makes a further mockery of the TCEQ's Effects Screening Levels (ESLs) or any other agency's minimal risk level.

ATSDR Response: ATSDR will be considering all health guidance values in our assessment, and using the most conservative values for our initial screening of environmental media. All of the sources for health guidance values are peer reviewed. While we understand the concern that arises from evaluating impacts from a single source when others are in close proximity, ATSDR feels that environmental samples collected from the community reflects the aggregated impact of all facilities in the area.

164. Comment: Under Summarized Community Concern's section, please add:

a. TCEQs repeated denial of public participation with regard to Permit Applications and Renewals.

ATSDR Response: ATSDR is not involved in the regulatory/enforcement/permitting process.

b. Ellis County is non-attainment for ozone emissions which extremely exacerbate respiratory problems.

ATSDR Response: Project 4 will evaluate the health effects of ozone exposures in the Midlothian community and to the extent possible, how these exposures may exacerbate exposures to other NAAQS constituents and other respiratory irritants like hydrogen sulfide.

165. Comment: Appendix A – Area of Investigation: The subdivision of Kingswood (technically Cedar Hill) just north of Ash Grove was the first neighborhood to be exposed to incineration of hazardous waste, i.e. Gifford Hill – North Texas Cement – now Ash Grove started in 1986. This community has an extreme amount of cancer incidence and mortality and the longest latency period.

ATSDR Response: ATSDR will be requesting that the DSHS cancer registry group update their cancer incidence report and include multiple types of cancers. We will ask DSHS to perform the evaluation using census tracts that most closely correspond to the exposure plume area of interest determined by the environmental sub-team. Areas north of the Ash Grove Cement facility are included in this plume area.

166. Comment: Appendix B – Subteams: For the past eighteen years, Dr. Beauchamp has failed to see or acknowledge any medical problems in the Midlothian community regardless of the facts presented to him and I strongly feel his involvement is not in the best interest of the study.

ATSDR Response: While ATSDR has the lead for Midlothian activities, Dr. Beauchamp is part of the ATSDR/DSHS team. All products produced by ATSDR are based on conclusions cleared through the ATSDR clearance process.

167. Comment: Appendix C – Peer Review: "Be reviewed by no fewer than three or more than seven reviewers who a) are selected by the Administrator, ATSDR" – who is the current Administrator of ATSDR? (Pope 3/19/10) "The panel…should be made up of disinterested scientific experts in the fields of study appropriate to the scope of the protocol." "…that scientists and engineers who have been involved in the Midlothian issues in any previous capacity…should be excluded from the panel because their objectivity may be subject to criticism by groups."

ATSDR Response: Concern noted and all efforts will be made to obtain impartial peer reviewers. The community will have the opportunity to recommend peer reviewers.

References:

[ATSDR] Agency for Toxic Substances and Disease Registry. 2002. Public Health Reviews of Hazardous Waste Thermal Treatment Technologies: A Guidance Manual for Public Health Assessors.

[NRC] National Research Council, Committee on Health Effects of Waste Incineration. 2000. Waste Incineration and Public Health. Washington, DC: National Academy Press.