

Dragon, Karen E. (CDC/NIOSH/EID)

From:
Sent: Sunday, July 29, 2007 9:33 AM
To: sbongiorno@stny.rr.com; FRoma@aol.com; glabare@stny.rr.com; lauffer@frontiernet.net; nlabare@stny.rr.com; SDavis2908@aol.com; rwhite3@stny.rr.com; TOXICSPILLENDNY@aol.com; WBESCwhudak@aol.com; jkeough3@stny.rr.com; lupardd@assembly.state.ny.us; dan.lamb@mail.house.gov; NIOSH Docket Office (CDC); endmayor@pronetisp.net; clinton@clinton.senate.gov; senator@schumer.senate.gov; Amanda_Pasquale@schumer.senate.gov; taelter@gw.dec.state.ny.us
Subject: Comments for Dr. Lynne Pinkerton: (Frank: Let me know if receive this,
Attachments: Comments for Dr. Lynne Pinkerton on Endicott

I feel it's important that WBESC formally endorse Dr. Clapps recommendations on the feasibility NIOSH report:
(Someone please send this to: I suspect AOL may be blocking my emails as spam. It's a huge problem many activists are running into every where.

Comments from Dr. Clapp on NIOSH IBM Endicott Feasibility report:

1. It will be important to compare the cancer mortality experience to a reference group of workers and not just the "general population" as described on p. i-ii of the Executive Summary. The NIOSH reference group of workers would be a way to do this, if it is available for the relevant time period. There are several other options that should also be considered, such as SMOR or PCMR for mortality analyses.
2. The ECHOES database was started earlier than 1987, so it is unclear why it could only be useful for the years 1987-1992. For example, the Appendix I, line 172-3 cites an article by Hillman in JOM dated 1982. Mr. Hillman was the developer of ECHOES, and he is now retired and would be an invaluable resource for the NIOSH study.
3. The cancers of interest, and for which power calculations were done, are limited. There is good evidence that non-Hodgkin lymphoma is associated with several chemicals to which Endicott workers were exposed. Furthermore, brain and central nervous system cancer have been shown to be elevated in maintenance and repair workers in the IBM Burlington plant (Beall, et al., 2005) and in IBM manufacturing workers (Clapp, 2006). It would be worth including power calculations for these, as well.
4. The input of former IBM Endicott employees is vital to the success of the cohort study. A formal mechanism for including them in the study as advisors should be developed; the feasibility study has already benefited from their involvement as have other studies of IBM workers.
5. The protocol for the cohort study should include a specific decision process for going further with a nested case-control study.

End of Dr. Clapp recommendations

This announcement posted in today's Binghamton press newspaper:

News Tip: Cancer from chemicals in IBM workers

Boston University Dr. Richard Clapp

Time Warner channel 4 Sun. 7/29 10AM www.cdc.gov/niosh/review/public/103/

Confirmed:

Lenny Siegel will also speak on TCE in Endicott NY 8/2

More details to follow soon such as place and time.

TCE Activist-Author Lenny Siegel to Speak in Ithaca August 1st Lenny Siegel, a nationally-known TCE activist and author from Mountain View, CA will be in Ithaca August 1st to speak, answer questions, and entertain discussion on the industrial

solvent TCE (trichloroethene). **The public meeting with Siegel will be on Wednesday August 1, at 7:00 p.m., in the Livesay Conference Room at the Tompkins County Social Services Building, 320 W. State St., across from the City Health Club in downtown Ithaca.** (Press Release) (Photo of Lenny Siegel)

<http://www.ithaca-ship.org/news.htm>

Confirmed:

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More details to follow soon such as place and time.

Here's some interesting info from Congressmen Hinchey's office about EPA

DEVELOPMENT OF EPA'S HUMAN HEALTH ASSESSMENT OF TRICHLOROETHYLENE (TCE)

Hinchey Question 8 What is EPA's timeline for completing the TCE risk assessment? Has it begun the meta-analysis (analysis of data combined from multiple original studies) recommended by the NRC? What role are federal responsible parties (polluters) playing in EPA's internal process of updating the risk assessment?

Answer: EPA completed a 2001 draft TCE assessment that underwent public comment and peer review by the Agency's Science Advisory Board (SAB) in 2002. After the peer review, it was clear that a number of significant science issues remained and that potentially important scientific literature had been published since the 2001 draft assessment that EPA needed to consider and characterize in the assessment.

EPA, along with the Department of Defense (DOD), the Department of Energy (DOE), and the National Aeronautics and Space Administration (NASA), sponsored a National Academies of Science/National Research Council (NAS/NRC) consultation to provide technical advice on four specific key and complex scientific issues that are critical to the TCE health risk assessment. On July 27, 2006, the NAS/NRC publicly released its technical consultation report on these science issues, providing advice to EPA. EPA is proceeding with the development of its TCE health assessment.

As you noted in your question, one of the NAS's recommendations was to conduct a meta-analysis of the available human epidemiology studies, which the panel felt was important to assessing the weight of evidence as to the carcinogenicity of trichloroethylene. EPA has started on that epidemiology meta-analysis by assembling a multidisciplinary scientific team that is addressing the recommendations and comments received from all sources. We have completed initial drafts of the qualitative review of the epidemiology studies and compilation of information as to study design characteristics, the analysis of study exposure assessments, and the tabulation of study results by cancer site and exposure metric. Our next steps in this review and meta-analysis include detailed calculations of study power, quantitative analysis of results across studies to assess heterogeneity and possible reasons for heterogeneity, and integration of the results of these analyses into the overall weight of evidence. It should also be noted that the meta-analysis is not intended to provide quantitative estimates of cancer potency, but rather for a dose response assessment.

It is expected that a review draft will be ready for independent external expert review and public comment no later than 2008. At this time, it is difficult to forecast how long the external peer review will take and when this complex scientific health assessment will be completed.

TCE RISK ASSESSMENT - CONTAMINATED SITES

Hinchey Question 9 TCE is found in the subsurface at thousands of contaminated sites throughout the U.S., including at least hundreds where there is federal jurisdiction. To what degree have those federal sites been screened for vapor intrusion?

Answer: For the federal sites where EPA has an oversight responsibility (i.e., NPL sites), the areas of those sites

that have known volatile organic compound (VOC) plumes overlain by buildings are typically the sites where trichloroethylene (TCE) vapor intrusion screening has been conducted, is being planned, or screening has been requested. The degree of such vapor intrusion screening is site-specific. Residential areas, particularly where there is a basement or crawlspace overlying the VOC contamination, would be a priority area for screening. Non-residential areas, such as schools, libraries, hospitals, hotels, and retail establishments, that are overlying the VOC plume, or would be expected to be impacted by a nearby shallow ground water VOC plume, also would be priority areas for screening. Those areas with buildings that are rarely occupied, for example a storage shed, generally would have fewer actual samples taken for screening, but instead may be subject to some form of land use control to address potential future risks, if warranted.

Typically, federal facilities prioritize screening evaluations at sites with shallow ground water, high concentrations of volatile chemicals in the ground water or subsurface soil, and the presence of potential receptors. Sites that meet these criteria are prioritized for evaluation and are screened to determine whether a more immediate cleanup is needed to address a vapor intrusion problem.

Hinchey Question 10 What screening or action levels are each EPA region using to evaluate those sites?

Answer: Typically, once EPA regions have identified that there is a potential for vapor intrusion to occur, additional samples are taken to compare with a screening level to further evaluate the potential risk associated with vapor intrusion. Screening levels have varied somewhat depending on when the screening activities began and the status of the trichloroethylene (TCE) cancer slope factor at the time. For example, EPA's Office of Research and Development is developing a revised Health Risk Assessment document for trichloroethylene. Generally, regions are using a bracketing approach to evaluate the risks to exposure when bracketed between the more stringent cancer slope factors (i.e., the 2001 draft TCE risk assessment) and the less stringent cancer slope factor (e.g., California EPA). The bracketed ranges that are within the acceptable protective risk ranges are then considered to evaluate exposure risks. It is also common practice to evaluate background levels (or reference levels) from nearby locations, but not overlying the plume, to estimate whether some contributions are site-related or due to confounding sources (e.g., background contamination, indoor solvent storage and use). Some regions compare contaminant concentrations in air, both indoors and immediately below the building slab foundation. This data helps confirm that indoor air contamination is related to subsurface contamination rather than indoor sources.

Action levels for remedial actions generally take into account site-specific considerations, as well as the risk management expectations from the states and affected communities. Typical considerations that impact action levels include background concentration levels, detection and quantization levels, depth of the contamination, land use, building construction and heating, ventilation, air conditioning (HVAC) operations.

TCE RISK ASSESSMENT - VAPOR INTRUSION GUIDANCE

Hinchey Question 11 EPA circulated a draft Vapor Intrusion Guidance in 2002. When will the next draft of this document be available for public review?

Answer: At this time, we do not have an estimated date for the next public draft of the guidance document, however, we should know more by fall 2007. We have been working on the underlying science and have made significant technical improvements, including the development of a national database of vapor intrusion observations that has changed the field from one dominated by predictive models to one that can be based on observed measurements. The national database currently includes over 2,500 paired samples of environmental and indoor air concentrations to improve the understanding of the factors influencing vapor intrusion and could be used to help regulators establish reasonable (evidence-based) screening levels. We are considering making this national database available to the states for their use. In making the database available, we would also provide training and instruction to the states on the use of the database. We have also held four public workshops on the improved understanding and scientific evidence for vapor intrusion and we are developing responses to comments from the 2002 document that are updated and based on the most current understanding of vapor intrusion. In addition, the Interstate Technology and Regulatory Council has recently issued technical guidance on vapor intrusion (ITRC, 2007), which can be used in the interim.

Hinchey Question 12 The draft Guidance included risk numbers for TCE based upon the 2001 draft Human Health Risk Assessment. What will be the basis of the risk levels in the next version?

Answer: The EPA's Office of Research and Development is developing a revised Health Risk Assessment

document for TCE (trichloroethylene) and a resulting IRIS toxicity value that should be available in 2008.

TCE RISK ASSESSMENT - GUIDANCE

Hinchey Question 13 New homes, schools, and other structures are being constructed at sites throughout the country where there is an evident potential for vapor intrusion. When will EPA publish guidance on the level of investigation and remediation necessary before construction?

Answer: EPA does not have plans to develop formal guidance on the level of investigation and remediation necessary before construction of new buildings. However, we have held numerous public workshops highlighting the difficulty of predicting the influence of new buildings on vapor flow and how investigation costs can exceed those for exposure controls (see <http://iavi.rti.org>). We have also discussed how this is true for new construction, where a simpler solution might be to install inexpensive pro-active passive venting systems that can be converted to active depressurization systems with the addition of a fan, if needed, after building construction.

Hinchey Question 14 When will EPA publish guidance on design standards for engineering controls to be built into these structures?

Answer: EPA does not have plans to develop formal guidance on the design standards for engineering controls installed in newly constructed buildings. However, Agency personnel have contributed to a volunteer consensus-based document, published in 2007, by the Interstate Technology and Regulatory Council (ITRC) that is the most current vapor intrusion guidance document available (http://www.itrcweb.org/gd_VI.asp). We specifically support the Remediation chapter as it is the only publicly-available guidance document on this topic to date, and addresses both design standards and implementation issues for engineering controls in both new and existing buildings.

Hinchey Question 15 When will EPA publish guidance on protocols for the long-term operation and maintenance of those measures, as well as monitoring of their effectiveness?

Answer: EPA does not have plans to develop formal guidance on the protocols for the long-term operation and maintenance of engineering controls installed in newly constructed buildings. However, EPA has contributed to and supports the flexible recommendations and rationale in the Operation, Maintenance, and Monitoring chapter of the Interstate Technology and Regulatory Council (ITRC) vapor intrusion guidance document. The ITRC document was written with the objective of obtaining 50-state regulator concurrence. In addition to EPA Headquarters and regional staff, the ITRC vapor intrusion guidance team has included nearly 40 state regulators, including 19 active state contributors to the document, as well as contributions by numerous industry, consultant, academia, and community stakeholders. EPA or the state also monitors the long-term operation and maintenance of all remedial systems, including vapor intrusion systems, at Superfund and Resource Conservation and Recovery Act (RCRA) corrective action sites as part of the remedy oversight.

DEVELOPMENT OF EPA'S HUMAN HEALTH ASSESSMENT OF TRICHLOROETHYLENE (TCE)

Hinchey Question 16 Please provide a timeline showing any and all progress EPA is making to follow the National Academy of Sciences July 2006 report on the need to develop a new risk assessment for TCE.

Answer: The reply to an earlier TCE question provides a more detailed timeline. EPA has assembled a multidisciplinary scientific team that is addressing the recommendations and comments received from all sources. Because of the complexity of this assessment there are several sections of the assessment that are being developed simultaneously.

As part of our review and meta-analysis of the epidemiologic data on TCE, we have completed initial drafts of the qualitative review of the epidemiology studies and compilation of information as to study design characteristics, the analysis of study exposure assessments, and the tabulation of study results by cancer site and exposure metric. Our next steps in this review and meta-analysis include detailed calculations of study power, quantitative analysis of results across studies to assess heterogeneity and possible reasons for heterogeneity, and integration of the results of these analyses into the overall weight of evidence.

With respect to the physiologically-based pharmacokinetic (PBPK) modeling, we have completed initial drafts of the review of TCE metabolism, conducted additional runs of the "harmonized model" reviewed by the National

Research Council (NRC) so as to obtain better statistical convergence, and reviewed and extracted data from many additional studies of TCE pharmacokinetics that were not used in the "harmonized model." Our next steps in PBPK modeling include the evaluation of the "harmonized model" with respect to the enlarged set of TCE pharmacokinetic data, testing of any changes to the model structures motivated by this evaluation, and running of model simulations to use in dose-response assessment.

As to other aspects of the assessment, we have obtained most of the relevant studies for review in our assessment, and are currently analyzing these data, taking into account the advice of the NRC, previous comments by the Science Advisory Board (SAB) peer review panel and the public, and recently published scientific literature. After completing the hazard evaluations for each potential toxic endpoint (for which the meta-analysis will be a key input with respect to cancer endpoints), and pending completion of the PBPK modeling evaluation, we will conduct the dose-response assessments.

TCE RISK ASSESSMENT - VAPOR INTRUSION PROCESS

Hinchey Question 17 EPA's Vapor Intrusion Guidance provides help to Agency personnel investigating and responding to vapor intrusion. It doesn't impose any new legal obligations. While New York has solid state guidance, many states - such as Pennsylvania and Michigan - do not. Inside EPA reports that Congress is considering ways to block implementation of the Guidance on Good Guidance. Please provide an explanation of this process and estimates on the time it will take additionally to adhere to OMB's policy.

Answer: We are still assessing the impact of the Office of Management and Budget's (OMB) recent Bulletin for Agency Good Guidance Practices. EPA's existing processes for finalizing scientific guidance documents, like those which would be considered significant under The Bulletin for Agency Good Guidance Practices, include peer review and approval by the Science Policy Council. Additionally, we note that one of the main tenets of the Bulletin is that agencies have adequate procedures for public comment on significant guidance documents. Typically, we take comment on major guidelines, thus we do not expect that this process will delay the issuance of this guidance in any way.

Hinchey Question 18 When do you expect EPA's 2002 draft Vapor Intrusion guidance to be finalized?

Answer: As discussed in a previous answer, regarding the next public draft, we do not have a scheduled date for the finalization of EPA's 2002 draft Vapor Intrusion guidance. However, we are continuing to improve the modeling and science underlying the draft guidance. An IRIS value [for TCE] is expected in 2010, and this value will be used in assessing vapor intrusion at that time.

AMBIENT STANDARD FOR TRICHLOROETHYLENE

Hinchey Question 19 Is EPA considering a National Ambient Air Quality standard for trichloroethylene (TCE)?

Answer: No. Trichloroethylene is considered a Hazardous Air Pollutant (HAP) under section 112 of the Clean Air Act, and, as such, its emissions are regulated through a series of source category-specific emission standards. Pollutant emissions regulated under this section of the Clean Air Act cannot also be regulated through the use of National Ambient Air Quality Standards.

I wonder if tree testing would help in Endicott?

**Samples from trees could help Hillcrest
cancer probe**


Researchers may find connection to metal pollution

 Zoom CHUCK HAUPT / Press & Sun-Bulletin

Trees are shown near Nowlan Road in Hillcrest near one of the manufacturing sites. A scientist will collect samples from trees in the area to try to map previous levels of pollution.

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HILLCREST -- Researchers from the University of Arizona plan to collect tree ring samples in August in an effort to determine what was in the air when a cluster of neighborhood children developed cancer in the 1990s.

<http://www.pressconnects.com/apps/pbcs.dll/article?AID=/20070728/NEWS01/707280336>

Court: VA must pay Agent Orange victims

By SCOTT LINDLAW, Associated Press Writer Thu Jul 19, 10:56 PM ET

SAN FRANCISCO - An appeals court chastised the Department of Veterans Affairs on Thursday and ordered the agency to pay retroactive benefits to Vietnam War veterans who were exposed to Agent Orange and contracted a form of leukemia.

"The performance of the United States Department of Veterans Affairs has contributed substantially to our sense of national shame," the opinion from the 9th U.S. Circuit Court of Appeals read.

http://news.yahoo.com/s/ap/20070720/ap_on_re_us/veterans_e

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James Little
RD#1 Endicott, NY 13760
Phone: 607-725-3846
Email: Jli2533838@aol.com

Get a sneak peek of the all-new AOL at <http://discover.aol.com/memed/aolcom30tour>

Dragon, Karen E. (CDC/NIOSH/EID)

From: Richard Clapp [richard.clapp@gmail.com]
Sent: Thursday, June 28, 2007 4:02 PM
To: NIOSH Docket Office (CDC)
Cc: jli2533838@aol.com
Subject: Comments for Dr. Lynne Pinkerton on Endicott

Attachments: Comments on Endicott



Comments on
Endicott (32 KB)

Dear NIOSH Folks,

Please forward these comments on "A Assessment of the Feasibility of a Study of Cancer among Former Employees of the IBM Facility in Endicott, New York" to Dr. Lynne Pinkerton.

Thank you,
Richard Clapp, Professor
Boston University School of Public Health
Boston, MA 02118

Comments on Endicott Feasibility report:

1. It will be important to compare the cancer mortality experience to a reference group of workers and not just the "general population" as described on p. i-ii of the Executive Summary. The NIOSH reference group of workers would be a way to do this, if it is available for the relevant time period. There are several other options that should also be considered, such as SMOR or PCMR for mortality analyses.
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