# REPORT OF THE DISTRICT OF COLUMBIA MAYOR'S SPRING VALLEY SCIENTIFIC ADVISORY PANEL

## INTRODUCTION

The second meeting of the Spring Valley Scientific Advisory Panel was held on December 7, 2001 in Washington, DC under the authority of the District of Columbia Mayor's Order 2001-32 (March 1, 2001).

The objective of the meeting was to review the progress of the District of Columbia Department of Health and the U.S. Army Corps of Engineers in characterizing and ameliorating the risk of potential adverse health effects resulting from human exposure to contaminants from World War I chemical weapons testing in the Spring Valley neighborhood located in the northwestern quadrant of the District of Columbia.

At it first meeting held in April 2001, the panel made several recommendations designed to expand the base of data/information on potential exposure to contaminants of interest, and evidence of health effects based on comparative epidemiological analysis (exposed versus unexposed population). The effect of concern was cancers for which there is evidence of arsenic as a risk factor. The panel also recommended that attention be given to risk communication including activities designed to enhance the Spring Valley residents' knowledge of process and procedures for assessing potential health impacts of exposure to chemicals released in the environment. The panel's recommendations provided the frame of reference for the presentations given at the December 7, 2001 meeting as listed in the agenda, which is attached. The detailed text of each presentation is on record, and available for public review in the Office of the Executive Director of the Mayor's Spring Valley Scientific Advisory Panel. In summary, the agencies have made substantial progress in "complying" with the panel's recommendation.

### Potential Exposure Assessment

In determining the potential exposure, the U.S. Army Corps of Engineers has identified over 130 properties/lots for grid sampling and to date have sampled over 50 of these sites beginning in September of 2001. Given the trigger rate for additional sampling of 12%, the U.S. Army Corps of Engineers expects to have a grid-sample for nearly 200 properties.

### Risk Management

Looking toward remediation of contaminated properties the U.S. Army Corps of Engineers discussed three different approaches to developing site wide remediation goals.

***Option 1 – Hazard Based Remediation***

0-2' feet of surface soil would be removed if:

(a) Exposure Point Concentration (EPC) ≥ 23.5ppm, the U.S. Army Corps of Engineers will clean the entire lot to background.

(b) Exposure Point Concentration (EPC) ≤ 23.5ppm, the U.S. Army Corps of Engineers will remove grid points ≥ 23.5.

Below 2' feet of subsurface soil would be removed if:

(a) Exposure Point Concentration (EPC) ≥ 41.4ppm, the U.S. Army Corps of Engineers will remove subsurface soil

***Option 2 – Bioavailability-Based Remediation***

0-2' feet of surface soil would be removed if:

(a) Exposure Point Concentration (EPC) ≥ 47ppm, the U.S. Army Corps of Engineers will clean the entire lot to background.

(b) Exposure Point Concentration (EPC) ≤ 47ppm, the U.S. Army Corps of Engineers will remove grid points ≥ 26.

Below 2' feet of subsurface soil would be removed if:

(a) Exposure Point Concentration (EPC) ≥ 56ppm (SPLP derived soil-to-groundwater protection level), the U.S. Army Corps of Engineers will remove subsurface soil

***Option 3 -- Background-Based Remediation***

0-2' feet of surface soil would be removed if:

(a) Exposure Point Concentration (EPC) ≥ 20ppm, the U.S. Army Corps of Engineers will remove all grid points

Below 2' feet of subsurface soil would be removed if:

(a) Exposure Point Concentration (EPC) ≥ 41.4ppm, the U.S. Army Corps of Engineers will remove subsurface soil

The Environmental Protection Agency's proposed arsenic cleanup level for soil is 20ppm, with no depth limitation. The cleanup level considers such factors as:

- 20ppm is slightly below the non-carcinogenic health effects level of 23.5ppm (HI = 1)
- It is within the EPA's cancer risk range (.43 to 43ppm)
- It is above background, so the U.S. Army Corps of Engineers wouldn't be cleaning up background arsenic
- 20ppm has been used as cleanup level in other states

## Epidemiological Analysis

Responding to the panel's recommendation concerning epidemiological analysis of cancers for which exposure to arsenic is a risk factor, the District of Columbia Department of Health presented data that showed no excess cancer incidence and mortality in the Spring Valley neighborhood during 1987–1998 compared with U.S. populations in the Surveillance, Epidemiology and End Results (SEER) Program. SEER is an ongoing contract-supported program of the National Cancer Institute of the National Institutes of Health. It coordinates the collection of cancer data in population-based cancer registries located throughout the United States.

Comparing the Spring Valley ("exposed") neighborhood with Potomac, Maryland ("unexposed"), a community with a similar demographic profile, the analysis found no difference in cancer incidence and mortality rates. Limitations of the analysis – small number of cases – were reported.

Dr. Steven Lamm, an epidemiology and occupational health consultant for the U.S. Army Corps of Engineers, presented an epidemiological analysis of the health effects of arsenic. It included a basic overview of arsenic (chemistry and biology) and a recitation of known health effects. Dr. Lamm concluded that based on a hypothesized exposure levels to arsenic in the Spring Valley neighborhood the risk of adverse health effects is "low to zero". Dr. Lamm made a similar presentation to the members of the Spring Valley community, and his report was made available to the Spring Valley Scientific Advisory Panel for review.

## Exposure Assessment

As indicated earlier, the U.S. Army Corps of Engineers' soil sampling and analysis program is underway. These measurements will define potential exposure. Actual exposure measurements, testing biological materials, specifically hair and urine, will be conducted by the Agency for Toxic Substance and Disease Registry (ATSDR). The draft protocol for this assessment was presented to the panel.

## PANEL COMMENTS AND RECOMMENDATIONS

The panel commends the efforts underway to address some of the scientific and health-related questions raised by the "discovery" of World War I chemical warfare agents in the Spring Valley neighborhood. The panel is also aware of the challenges in assessing the potential adverse effects of environmental chemicals and materials on human health.

A fundamental challenge in environmental health is relating the presence of a chemical or other contaminant with a valid prediction of ensuing hazards to potential biological (human) receptors. Adverse health effects in humans begin with exposure. No matter how hazardous an environmental toxicant is, without exposure there is no risk. Exposure can occur as a result of contact with a variety of elements (i.e., air, water, soil) that in turn influences the pathways of exposure (i.e., inhalation, ingestion, dermal) and may progress to damage of, or alteration in, the function of organs (i.e., lung, bladder, liver). Individuals' interactions with these elements are complex; and therefore it is not surprising that exposure assessment and dose estimation are formidable challenges to those investigating the health effects of environmental contaminants.

It bears repeating that individuals' exposure may be modified by factors such as activity patterns, which determine encounters with the sources of exposure; and the bioavailability of the agent in time and place (only a portion of the total quantity of a chemical or contaminant present in the environment is potentially available for uptake by individuals. This concept is referred to as biological availability or bioavailability.). The rate at which exposure occurs may also be a modifying factor. From a given exposure, a person's resultant dose – the amount of contaminant transferred to the exposed individual – will depend on host characteristics such as age, gender, occupation and proximity to source (time spent indoors versus out).

In summary, many types of variabilities enter into the risk assessment process: variability within individuals, among individuals, and among population groups. Types of variability include the nature and the intensity of exposure and susceptibility to toxic insults, related to age, gender and other factors. Infants and children are often considered more susceptible to the adverse effects of toxic contaminants. Referring to exposure to arsenic (a chemical of concern to the Spring Valley residents) in the drinking water, the Subcommittee on Arsenic in the Drinking Water for the National Research Council, National Academy of Sciences, concludes that it is unclear whether infants and young children might be more susceptible to arsenic-induced health effects, particularly those effects for non-cancer endpoints where less-than-lifetime exposures are important, and where children's greater water consumption per unit of body weight might put them at relatively greater risk. The Subcommittee states that more data are needed to better understand the susceptibility of children to arsenic-induced toxicity, particularly for non-cancer effects.

There are also issues of uncertainty – the lack of knowledge of the underlying science. There are numerous gaps in scientific knowledge regarding arsenic and other contaminants. Hence, there may be uncertainties in risk assessment. For instance, there is little evidence of the level and species of arsenic consumed by different individuals and populations, and the role of arsenic in food remains somewhat uncertain.

In assessing the risk of arsenic and numerous other environmental contaminants, it is difficult, if not impossible, to entirely rule out the possibility that genetics, lifestyle differences such as smoking, food preference, cooking habits, and exposure to other environmental factors might play a role in explaining variability in the risks. In addition, human populations are exposed to multiple pollutants whose individual, let alone, joint effects are not known. To date, toxicology has remained primarily the science of individual toxicants, even though people are rarely, if ever, affected by a single agent in isolation from other agents that might influence risk. Understanding risks from simultaneous or sequential exposure to multiple agents, particularly at low levels of exposure, is a challenge to the health sciences (i.e., toxicology, epidemiology).

The sum vector of the challenges cited in the preceding paragraphs is a clear indication that risk characterization should present the state of knowledge, uncertainty and disagreements about the risk situation to reflect the range of relevant knowledge and perspectives. An accurate and balanced synthesis must treat the limits of scientific knowledge with an appropriate analytic process.

## The Lamm Report

It is in this setting that the panel acknowledges and commends the progressive efforts of Dr. Lamm to enhance the awareness of the Spring Valley residents of the health effects of exposure to arsenic and related risk assessment parameters. Dr. Lamm's report attempts to address significant concerns of members of the community and to make the information understandable. However, the review inadequately describes the risks (and their accompanying uncertainties) that have been linked with exposure to inorganic arsenic in several populations. Findings of the report could well lead to the mistaken conclusion that some populations with demonstrated exposure may be at low or minimal risk.

The panel commends Dr. Lamm for the inclusion in his review of most of the important, well documented affects of arsenic. In addition, two important health effects of arsenic with highly suggestive, but preliminary information should also be included. These, specifically, are cardiovascular effects and diabetes. There is reference made to 'blackfoot disease', which results from effects of arsenic on the vascular system, but more information is available on other, related cardiovascular effects such as blood pressure (Rahman et al, 1999). Two suggestive studies of excess diabetes from southwest Taiwan are available and should be cited (Tsai et al, 1999; Tseng et al, 2000).

A general weakness of the report is the omission of data on dose-response relationships. In fact, it is this type of data that provides the basis for concluding that arsenic is a carcinogen of the skin, bladder, lung, and possibly other organs. The Lamm report indicated studies in the United States have not demonstrated a cancer risk from exposure to drinking water. This is not accurate. Studies by Lewis (1999), Karagas (2001), and Bates (1995) have found elevated risk for one or another cancers either in the full study population or important subgroups. In addition, this statement must be carefully qualified. In fact, there have been no well conducted, large scale studies conducted in the US of populations exposed to arsenic in drinking water, and therefore it would not be surprising if none of the completed studies had observed elevated cancer risks. The studies cited above either were small or have other important methodological limitations. There are no data available from large, well-conducted studies in the United States that address the question of arsenic in drinking water and cancer risk. There is no reason to believe that the United States population differs in its susceptibility profile from populations in Chile, Argentina, or Taiwan where excess risk for several cancers has been observed after long-term exposure to waterborne arsenic at higher levels than are typical in the United States.

In addressing the risk of lung cancer from arsenic exposure, the Lamm review indicates, “There are some recent studies that relate lung cancer to arsenic absorbed from the ingestion of arsenic-containing water.” In fact, several studies, from Taiwan, Chile, and Argentina have demonstrated a dose-response link between water-borne arsenic and lung cancer. The recent NAS Subcommittee to Update the 1999 Arsenic in Drinking Water Report (2001) concluded, “the database of epidemiological studies linking arsenic in drinking water with increased risk of skin, bladder, and lung cancer provides a sound and adequate basis for quantitative assessment of cancer risk.”

The report is correct in stating, “... with bladder cancer, most of the associated arsenic exposure are with water containing one-half to one milligram of arsenic per liter and daily dosages measured in milligrams”. The exposures in many high-arsenic/high risk areas of the world that have been studied average about ½ mg/L (500 micrograms/L). What isn’t mentioned is that risk of bladder cancer has been observed in a dose-dependent fashion down to arsenic exposures much lower than ½ mg/L (eg. Chiou et al. 2001).

While arsenic below 150 micrograms/L may not cause skin cancer, there is but a thin data base currently available to demonstrate this. The report cites a study from Inner Mongolia in this regard. Dr Lamm’s Inner Mongolia study involved a cross-sectional examination of 3,228 individuals, and observed 8 skin cancers, all among persons with “peak” arsenic exposures greater than 150 micrograms/liter. With only eight observed cases of skin cancer, the lack of statistical stability in this study severely limits the conclusions that can be based on its findings. In addition, the use of “peak” arsenic levels to define exposure can result in an underestimate of risk.

Other panel concerns about the report include the lack of an association in the U.S. observed “between bladder or lung cancer and drinking waters with arsenic levels between 3 and 60 ppb (ug/L).” This may be as much a consequence of inadequate study methods or study size as of a true lack of association. Again, it would be premature to draw the conclusion that there is no risk of arsenic exposure at these levels, given the limitations of studies that have been completed to date.

In summary, the Lamm review of the health effects of arsenic covers many important and relevant aspects of the chemical's toxicity, both with respect to inhalation and ingestion. But the review is incomplete and does not present a balanced picture of what is known and what is unknown about the effects of arsenic exposure. The report would be much stronger, useful and interpretable if it were fully referenced *(the references are cited at the end of this report*).

## RECOMMENDATIONS

Based on the presentations, the panel's discussion, its experience, and desire for a comprehensive database on which to base conclusions, the following recommendations are made:

### Recommendation One

The panel recommends that the Environmental Protection Agency provide the scientific underpinning, or health-risk rationale, for the recommended remediation level of 20ppm. The panel believes that risk assessment and risk management decisions should be conducted on a site-specific, not-one-size-fits-all, basis and should incorporate all available and relevant scientific information to achieve this objective. The paramount consideration for the remediation of the Spring Valley neighborhood should be the management of overall risk to human health, present and future.

### Recommendation Two

The panel recommends that the agencies collect information on arsenic and related contaminants in household dust/debris in a selected number of Spring Valley homes.

The objective is to determine the extent to which household dust/debris may contain arsenic or other contaminants of concern. In other words, is household dust/debris a potential pathway for chronic exposure to environmental toxicant of concern to Spring Valley residents.

There are a number of strategies that may be employed, including the collection of vacuum cleaner content, to get a "clue" as to the potential contribution of household dust to the overall exposure. The panel is aware of the potential for selection bias in this voluntary self-selection approach to exposure assessment.

The panel emphasizes that this recommendation should not be interpreted as suggesting a comprehensive home audit, the tools for which have been developed by environmental health specialists to assist in the assessment of exposure. Rather the focus here is on a simple "indicator" of potential exposures in well-selected samples of living quarters.

**Recommendation Three**

The panel recommends a revision in the Agency for Toxic Substance and Disease Registry (ATSDR) protocol for biomonitoring of the potentially exposed population. The panel's primary concern is that the monitoring be conducted when the "study cohort" is likely to have maximum exposure such as outdoor activities (i.e. children playing the yard), which is usually in the warmer months. Evidence abounds that a person's activity pattern is the single most important determinant of environmental exposure to most pollutants.

The panel also suggests that the selection of individuals for biological monitoring of exposure be accomplished according to the following scheme:

1. Top 10 homes with children and a high level of arsenic on the property as identified by the U.S. Army Corps of Engineers' soil sampling and testing programs.

2. Top 10 homes without children and a high level of arsenic as identified by the U.S. Army Corps of Engineers' soil sampling and testing programs.

3. A 5-10% random sample of individuals in the remaining homes.

The panel believes that this scheme will provide data/information on a range of exposure scenarios and may enhance efforts to address questions and issues of concern to interested and affected parties, or decision makers.

This scheme along with other data should facilitate analysis, for risk characterization, which includes various ways of reasoning and drawing conclusions by systematically applying theories and methods from the relevant sciences.

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