



CALIFORNIA ASSOCIATION of SANITATION AGENCIES

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April 21, 2010

To: EPA Docket ID No. EPA-HQ-ORD-2010-0123

Subject: Proposed IRIS Inorganic Arsenic Cancer Slope Factor

The California Association of Sanitation Agencies (CASA) appreciates this opportunity to comment on the proposed new cancer slope factor (CSF) for inorganic arsenic to be used in the Integrated Risk Information System (IRIS). CASA represents more than 90 percent of the sewered population of California and has long been a proactive leader on wastewater, recycled water, and biosolids management issues.

CASA is extremely concerned with respect to the science on which the proposed seventeen fold increase in the CSF is based and on the catastrophic impacts such an increase could have on wastewater treatment and the environmentally successful and necessary recycling programs for treated water and biosolids.

Water is an increasingly scarce and valued resource throughout the western United States and in California specifically. As such there has been an ever increasing effort to reuse vast quantities of tertiary treated wastewater rather than discharging it to the ocean or other water bodies. Similarly, there are 750,000 dry tons of biosolids managed in California alone each year. Some 85 percent of this is recycled on agricultural land, city parks, golf courses, home and community gardens, in landscaping activities, or other beneficial uses. Both of these critical recycling activities will likely be severely curtailed by the proposed CSF. Thus it is imperative that EPA correctly and accurately interprets the science and ensures the proper science is utilized in establishing the CSF.

CASA is concerned that southwest Taiwan is so heavily relied upon as the source of most of its scientific basis. Comparative studies (Lamm et al., 2004) found no correlation between the Taiwanese studies and US population studies, and strong evidence that a threshold model should be used in ingested As risk assessment. Dietary inorganic arsenic intake is much lower in the United States as documented by Schoof et al. (1999) and Europe by Baeyens et al. (2009) than in Southeast Asia. EPA should verify that study results are valid and appropriate for the protected population of the United States.

The comparison population used is inappropriate as it represents all of southwest Taiwan with a population of 2 million people, compared to the study area of 18 villages with a population of less than 1,000 people each. As demonstrated by Dr. Lamm's presentation to the Science Advisory Board (SAB) on April 6th, the whole of southwest Taiwan is treated as a 19th village in the analysis and thus skews all results. Dr. Lamm demonstrates that without the comparison "village" all exposure outcomes are negatively sloped for cancer incidence compared with how EPA handled the data in finding positively sloped outcomes. Moreover, the comparison population is incorrectly assumed to consume zero ug/l arsenic from their drinking water. As both Dr. Lamm and Dr. Schoof pointed out to the SAB, Lewis et al., (2000) described that the comparison and study population both lie above the

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Chianan plain and likely have the same water supply sources. Also of critical concern is the fact that a number of study area villages are presented as low dose drinking well supplies but actually had high concentration drinking wells. EPA's use of median concentrations for all villages likely underestimates the exposures, and cancer effects are likely to be more attributable to water consumption from the high concentration wells even though all populations are presented as having low dose exposure from water supplies. See Dr. Lamm's and Dr. Schoof's comments to the SAB on April 6th.

EPA utilizes a background dietary intake of 10 µg/d for non-water intake of inorganic arsenic. The literature is replete with documentation to the contrary that dietary intake should be significantly higher. Schoof et al. (1998) provided evidence to use 50 ug/d as background dietary intake for Taiwanese populations. Subsequent studies by Kile et al. (2007) have confirmed that high rice consumption rates will be associated with high inorganic arsenic intake regardless of location throughout Southeast Asia.

The IRIS document also fails to cite recent epidemiological work by Mink et al. (2008), which conducted a meta analysis to evaluate a causal relationship between low level arsenic exposure via drinking water and bladder cancer. The meta analysis found the summary relative risk estimate (SRRE) for those who never smoked to be less than 1.0 and a SRRE for the combination of never smokers and ever smokers to be only slightly elevated. Moreover there are a number of recent updated studies (Chen et al., 2009, 2010) which better evaluate low dose exposures which were not reviewed by EPA. It is imperative that low dose exposure data be thoroughly evaluated to ensure a scientifically defensible CSF is utilized.

In summary, since the toxicological review is purportedly to allow EPA to quantify incremental risk above background it is of paramount importance that appropriate background dietary intake values are used. This was not the case for non-water dietary intake, nor for water intake, or for assessing the comparative population's intake. In fact the data shows no cancer correlation at the low dose exposure level when the comparative population is omitted (Lamm et al., poster 2010). As further evidence, the SAB in 2007 concluded that assumptions of arsenic levels in food and water have a substantial impact on the assessment of risk from arsenic in drinking water.

EPA should consider more thoroughly the implications of the proposed CSF change regarding the limits that would subsequently be imposed on As in soil, water and food. With the present CSF, nearly 100% of US soils are above the Soil Screening Level of As, and some have expressed concern for consumers of rice, the staple food with highest inorganic As levels in the US diet. With the proposed CSF, all US food, water and soil would violate guidelines for recommended limits to As exposures. All soil would be hazardous. No rice and some other foods would be deemed safe for human consumption, and the MCLG is already zero. EPA has argued that these are policy concerns that cannot be considered in the dose-response evaluation; however, it is only due to policy that the dose-response assessment is being extrapolated to exposure levels far below those experienced by any living human. Research has suggested that As could be an essential element at low levels of intake, similar to present background from water and food in the US.. Consequently, EPA should consider the possibility of a hormetic dose-response model for inorganic arsenic. Hormetic or threshold models for As cancer risk appear likely from the US data on moderately exposed individuals, a population more appropriate for establishing the CSF for US citizens than the flawed Taiwan dataset.

Given the enormity of impacts to wastewater treatment and water supply facilities throughout the United States and specifically in California, CASA respectfully requests a thorough evaluation of these and other issues raised related to the science on which the CSF is based. Please contact Greg Kester, the CASA Biosolids Program Manager with

questions at gkester@casaweb.org or at 916-844-5262 with questions or for further clarification on any of these issues.

Sincerely,



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