

March 29, 2010

Science Advisory Board Staff Office  
US Environmental Protection Agency  
(Mailcode 1400F)  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

**RE: Toxicological Review of Inorganic Arsenic (CASRN 7440-38-2)]**

The American Farm Bureau Federation (AFBF) submits these comments on behalf of its farming and ranching members nationwide. AFBF is the country's largest general farm organization, representing farmers and ranchers in all 50 states and Puerto Rico. Farm Bureau members grow, produce and raise the food, fiber and energy sources that feed, clothe and fuel the U.S. and the world. Our membership includes producers of every size and scale of operation.

In early 2009, the U.S. food industry became aware of the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) evaluation of the cancer risk of inorganic arsenic risk from oral exposure [Toxicological Review of Inorganic Arsenic (CASRN 7440-38-2)].

A March 2009 draft of that document proposes a dramatic increase in the assumed risk per unit arsenic dose from the current cancer slope factor--nearly a 17-fold increase. EPA Office of Research and Development (ORD) has been updating the IRIS section on cancer risks from inorganic arsenic since 2003, including a partial review of some of the underlying issues by an EPA Science Advisory Board (SAB) in 2005. According to numerous scientists, both inside and outside the government, the revised value will have huge implications with no clear public health benefit. Essentially, the proposed revision indicates a need to reduce or warn the public about arsenic concentrations below the unavoidable levels that occur naturally in background soil, water or diet.

Arsenic is a naturally occurring element to which everyone is exposed, primarily through diet, water and secondarily soil. Such low-level exposures are ubiquitous and without evidence of adverse effects. Nevertheless, EPA assumes that ingesting any amount of arsenic has a risk of cancer and has revised its estimates of risk upward by 17 times. The agency's draft oral cancer slope factor predicts lifetime cancer risks at a given exposure level and thus will be used to assess the need for regulation of inorganic arsenic exposures in water, soil, pesticides, or products. Because EPA's current estimates of arsenic risk already predict hypothetical risks at the upper end of their acceptable risk range, this increase will have profound impacts on implied public health threats from arsenic exposures, even from naturally occurring background sources.

The proposed change in the cancer slope factor for arsenic is 25.7 per mg/kg-day for women, that being the more sensitive population. This number appears to be approximately 17.1 fold more sensitive than the previous number EPA used which was 1.5 per mg/kg-day.

A change of this magnitude clearly could have serious and far-reaching implications for agriculture and the food industry in the United States. Therefore, we firmly believe that the SAB has a responsibility to conduct a careful review of the proposed numbers and keep in mind the potential economic issues and public reactions to which the cancer slope factor numbers may lead.

While we understand that the numbers presented by EPA may be correct using one analysis, the resulting cancer slope factor flies in the face of observable data of the people currently consuming food products and in contact with soil containing what could suddenly be construed as toxic levels of arsenic. We believe that the cancer slope factor is the result of an overly conservative process and that the resulting numbers will lead to illogical conclusions respecting interactions with food, soil and water. Issuing hazard analysis numbers that will, by virtue of the background levels of arsenic in food and soil, create the impression that these ingredients in our everyday lives are toxins is not good science; on the contrary, such a course would lead to overly precautionary regulatory and consumer decisions that only tend to stifle sound policy and sound science. The proposed risk value would lead to serious concerns about the safety and wholesomeness of the U.S. food supply from a naturally-occurring and uncontrollable factor.

While EPA ORD has told industry that these numbers are not standards, it is inconceivable that the agency does not realize that this new slope factor will have to be used by other program areas within EPA and other agencies to set new regulatory standards. If nothing else, once these numbers become public they will be enforced as a standard through lawsuits by third parties pursuing their own agendas.

We therefore ask that the SAB undertake a careful review of the cancer slope factor and any relevant calculations or data leading to that slope factor to make sure that it is correct and scientifically justified to the best of your abilities before the numbers are finalized and published. This is too important an issue to the agriculture and food industry, with too many potential negative consequences to our industry in particular and the U.S. economy in general, for the EPA to make a mistake in their final analysis.

Thank you for consideration of our comments and please don't hesitate to contact us if you have any questions.

Sincerely, 

Mark Maslyn  
Executive Director  
Public Policy