

December 19, 2022

The Honorable Tom Vilsack  
Secretary of Agriculture  
1400 Independence Ave, NW  
Washington, D.C. 20250

Subject: EPA Integrated Risk Information System Draft Inorganic Arsenic Assessment

Dear Secretary Vilsack:

The undersigned agricultural related trade associations are writing to you to express our concerns with the current schedule for review of the Environmental Protection Agency (EPA) Integrated Risk Information System's (IRIS) draft assessment of inorganic arsenic. We urge you to request that EPA extend the deadlines for interagency review and other IRIS process deadlines to ensure the integrity of the final assessment. The Department is included as one of the agencies reviewing this draft as part of IRIS Step 3.

While we do not know what the draft contains, we understand that the draft may not have adequately considered the latest scientific developments. It is critical that the arsenic risk assessment reflect the best available science, since IRIS assessments are regularly used by EPA, states and other federal agencies to establish regulatory standards, including for agricultural production. Any exaggeration of actual health risks would create unnecessary costs and burdens for government, industry and the public, without concomitant benefit to human health. We are likewise concerned with EPA's lack of compliance with critical IRIS public and federal agency process steps. It is critically important that other Federal agencies, including USDA, have adequate time to ask questions and provide comments to EPA regarding this draft.

According to the EPA IRIS Program Website, the program uses a seven-step process to develop each assessment.<sup>1</sup> Interagency review is part of Step 3. Under the current schedule, USDA and other agencies have until December 30 to provide comments to EPA. That permits only 46 calendar days for development and submission of comments from the date received, including two Federal holiday periods. Given the complexity of the assessment, the significant potential impact on agricultural production and the sheer magnitude of material to be reviewed, the amount of time allowed by EPA is simply insufficient.

Further, according to the posted schedule on the EPA IRIS website, the draft assessment will be released for comment to the public in March 2023 and then forwarded to the EPA Science Advisory Board (SAB) for peer review in April 2023 (IRIS Step 4). Review of hundreds of pages of documentation, including complex epidemiological issues and related study selection and quality concerns warrants at least a 60 day public comment period which was the amount of time EPA provided for the 2010 arsenic assessment. In addition, EPA apparently is allowing no

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<sup>1</sup> <https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system>

additional time for internal consideration of these public comments, nor to revise the draft assessment in response to such comments prior to submission to the SAB, raising questions about EPA's commitment to transparency.

The enhanced IRIS procedures set out by EPA in 2013 were established in order to allow robust public comments and facilitate necessary improvements to the assessment process in response to the highly critical 2011 National Academy of Science's Review of the 2010 Arsenic IRIS Assessment. Unfortunately, EPA does not appear to be abiding by the IRIS procedures that it agreed to implement in 2013.

We urge USDA to ask EPA to (1) add additional time to the Step 3 interagency review and (2) add additional time to the Step 4 (combined public comment and peer review by EPA SAB) process to allow EPA to respond to comments and revise the draft, as appropriate.

Given the immediacy of the December 30th deadline, we urge you to convey your concerns to EPA Administrator Regan as soon as possible. We are happy to discuss this further with you or other appropriate USDA officials. Please contact Steve Hensley (National Cotton Council) at 703-475-7716 with any questions or for further information about this urgent request.

Sincerely,

Agricultural Retailers Association

California Specialty Crops Council

Dairy Producers of Utah

The Fertilizer Institute

National Association of State Departments of Agriculture

National Cotton Council

Northwest Horticultural Council

Oregon Cattlemen's Association

USA Rice Federation

Cc: Linda Abbott, OCE  
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