



# PPC

## PESTICIDE POLICY COALITION

A Coalition Working for Sound Pest Management Policies

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*Submitted via regulations.gov*

**Re: Comments on Draft Integrated Risk Information System (IRIS) Toxicological Review of Inorganic Arsenic, Docket EPA–HQ–ORD–2012–0830**

The Pesticide Policy Coalition (PPC) respectfully submits comments on the Environmental Protection Agency’s (EPA or the Agency) Draft Integrated Risk Information System (IRIS) Toxicological Review of Inorganic Arsenic.

The PPC represents agriculture, food, fiber, public health, pest management, landscape, environmental, and related industries, including small businesses/entities, which are dependent on the availability of pesticides. Our coalition supports the development and implementation of public policies and laws that utilize the best available science and technology to ensure protection of human health and the environment.

PPC members include national and regional trade associations; commodity, specialty crop, and silviculture organizations; cooperatives; food processors and marketers; pesticide manufacturers, formulators, and distributors; pest and vector-control applicators and operators; research organizations; state departments of agriculture; equipment manufacturers, and other interested stakeholders. The PPC serves as the unifying voice for the review, discussion, development and advocacy on pest management regulation and policy that is based on the best available science.

The public is increasingly confronted with pest pressure, resistance management concerns and disease threats introduced into the United States via trade, weather, and other factors. It is through pest control products, used by farmers, ranchers, public health officials, and other pesticide applicators; and produced by pesticide manufacturers, that we can address and mitigate these threats. These products are essential tools for users to protect not only America’s food, fiber, and biofuel; but also, to protect public health from vector-borne disease, safeguard our

infrastructure from the damage caused by pests, and mitigate the increasing threat to the environment from invasive species.

The PPC has identified serious concerns with the EPA Draft IRIS Toxicological Review of Inorganic Arsenic which we summarize in the following five areas:

**Lack of Transparency.**

- During the 13-year development process for the Draft Arsenic Assessment, IRIS has failed to engage the public in any meaningful way through webinars, conferences, reviews, or other stakeholder fora. The public has been kept in the dark, other than the publication of the draft protocol in 2019.
- Evidence tables and other scientific documentation has not been provided, denying the public the ability to fully understand the science upon which the Draft Arsenic Assessment is based.
- The 60-day comment period was far too brief to afford the public time to adequately comment on a technical, 600-page science document.

**Failure to Integrate All the Lines of Scientific Evidence.**

- Contrary to NAS recommendation for integration of all the lines of scientific evidence (see Chapter 7 of the 2013 Formaldehyde Report), IRIS relies on epidemiology and ignores human biology.
- Utilization of mode of action information would lead to the conclusion that a threshold exists for exposure to inorganic arsenic---below which there is no observation of adverse impacts on humans.
- Study selection does not reflect the current body of scientific evidence. Few, if any, studies published after the adoption of the protocol in 2019 are included, ignoring four years of recent arsenic studies.

**Reliance on Modeling and Not on Actual Data.**

- Human health effects, including cancer, can be found from exposure to elevated levels of arsenic, while there is uncertainty about exposure of arsenic at lower levels. IRIS relies upon epidemiology studies of populations exposed to high levels of arsenic and then uses simplistic modeling to draw conclusions of effects at low exposures.
- While it is important to study vulnerable sub-populations, IRIS over relies on studies with populations that are not representative of the U.S. population. IRIS should better account for risks to the U.S. general population.

### **The IRIS Draft Arsenic Assessment is Not Aligned with Other Scientific Entities.**

- Risks at 1 part per billion (ppb) is a focus of the Draft Arsenic Assessment, which is lower than the exposure of most Americans.
- The regulatory consequences from this assessment if finalized as-is will present staggering costs for water and soil remediation since the levels are largely below naturally occurring levels of arsenic in the U.S.
- If finalized in its current form, the safety of much of the U.S. food supply will be called into question based on the scientific assumptions used in the Draft Arsenic Assessment.
- The Draft Arsenic Assessment is far more stringent than other risk assessments in the U.S. (e.g., the U.S. Food and Drug Administration) and by international health organizations (e.g., European Food Safety Authority).

### **Biased Peer Review.**

- The Science Advisory Board panel fails to meet the objective and balanced requirements of the Federal Advisory Committee Act (FACA). Five of the 14 panel members have authored arsenic publications and two of them have published extensively with one authoring 31 publications and another 21 publications. There are serious questions about how panel members can objectively review the Draft Arsenic Assessment when their work forms the basis of some of the findings. Panel members are being asked to grade their own papers.

In 2010, the IRIS Draft Arsenic Assessment was roundly criticized by the public and by National Academy of Science (NAS) peer reviewers. IRIS has taken 13 years to develop this 2023 revised draft, but many of the same science policy and process concerns remain today.

Thank you for your serious consideration of these comments. If PPC members can be of assistance in any way, or if you have questions, please do not hesitate to contact me at [shensley@cotton.org](mailto:shensley@cotton.org) or (703) 475-7716.



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