

January 27, 2025

The Honorable Lee Zeldin
Administrator-nominee
Environmental Protection Agency

Dear Administrator-nominee Zeldin:

America's economic competitiveness and national security depend on a supply chain that is dependable and resilient. At the start of virtually every supply chain are chemistries needed to manufacture a wide range of critical products. Chemical management policies that are both predictable and based on findings supported by high quality information are fundamental to promoting American innovation and strengthening our economy.

The Environmental Protection Agency's (EPA's) risk evaluations and risk management policies for chemicals must be based on the best available science. That's why we write to bring to your attention an important issue impacting American jobs and economic competitiveness that fails to meet that standard. The EPA's Integrated Risk Information System (IRIS) program has been increasingly used to develop overly burdensome regulations on critical chemistries essential for products we use every day.

IRIS has often fallen short of scientific standards required of EPA and is out of step with global health agencies and regulators. IRIS fails to adequately incorporate high quality and relevant science and does not consistently utilize a "weight of the scientific evidence" approach. Also, the process IRIS uses to prioritize and select chemicals for assessment lacks transparency.

Controversy over EPA's IRIS process, the resulting hazard values, and the use of those values is not a new phenomenon. Specific concerns include: a lack of impartiality in accurately reporting scientific information, scientific inaccuracy, lack of transparency, limited peer review, and slow progress in producing assessments - these issues and others have been raised by Congress on many occasions. Moreover, Congress has never authorized IRIS and since 2009 the program has been flagged as a "high risk" program vulnerable to waste, fraud, abuse, or mismanagement by the U.S. Government Accountability Office (GAO).

EPA's IRIS values fail to go through regular rulemaking checks related to notice-and-comment, interagency review, and engagement with stakeholders. These assessments are not valid for use in regulatory settings and often omit key information. For example, IRIS toxicity values are often set below naturally occurring background levels, detection limits, or levels of the chemical produced by the human body. Nearly all recent assessments have established toxicity values that are also well below existing standards set by EPA, OSHA, or the European Union.

Despite these concerns, EPA has relied on IRIS assessments in regulatory contexts, particularly for critical building block chemicals. These actions could result in bans, unachievable standards, enforcement actions, and litigation.

Some recent examples of agencies using IRIS include:

- **Final Formaldehyde Risk Evaluation:** EPA recently issued its final risk evaluation under the Toxic Substances Control Act (TSCA) that was based on a flawed IRIS assessment. EPA's final risk evaluation concludes that virtually all occupational conditions of use contribute to "unreasonable risk" under TSCA. The TSCA risk evaluation for formaldehyde relies on a faulty IRIS value to propose workplace limits that are significantly lower than the recently updated European Union occupational limits and could result in potential bans or difficult-to-meet standards for some uses. EPA has received fundamental criticism from multiple peer review bodies and public comments provided by hundreds of experts, stakeholders, and other agencies. Members of the EPA's own Science Advisory Committee on Chemicals (SACC) have raised serious concerns over EPA's reliance on IRIS.
- **EPA Air Rules on Ethylene Oxide:** These rules affect critical industries like electric vehicles, semiconductor manufacturing, and health care. The rules rely on a deeply flawed IRIS value for ethylene oxide that is 23,000 times lower than naturally occurring levels in the human body.
- **Biden Administration DOJ Action:** An IRIS value was used to justify emergency action seeking to shut down a manufacturing facility under Section 303 of the Clean Air Act.
- **IRIS Toxicological Review of Inorganic Arsenic:** Proposes a controversial cancer risk value that is 21 times more stringent than the current value. The values from IRIS assessments could be used to drive new regulatory levels for inorganic arsenic that are significantly lower than the background levels of arsenic in soil and water in many states with impacts to soil remediation programs, drinking water standards, crops and other food supplies.
- **Final IRIS Review of Hexavalent Chromium:** EPA's recent IRIS assessment disregarded the weight of evidence and may lead to a new drinking water standard far lower than the average background levels of naturally occurring hexavalent chromium in groundwater. This could impose massive costs to water systems nationwide with little to no public health benefit.

We urge you and your team to take steps quickly to address problems with the IRIS program, including:

- Prohibiting the use of IRIS assessments to develop, finalize, or issue a rule or regulation;
- Disbanding the IRIS program and returning responsibilities to program offices;
- Being responsive to Information Quality Act requests for correction for recent IRIS assessments; and
- Appointing and empowering a Science Advisor reporting to the Administrator and with authority for streamlining duplicative risk assessment activities.

We thank you for your attention to this important issue and look forward to working with you.

Sincerely,

American Chemistry Council
Adhesive and Sealant Council
Agricultural Retailers Association
Alliance for Chemical Distribution
American Cleaning Institute
American Coatings Association
American Composites Manufacturers Association
American Feed Industry Association
American Foundry Society
American Fuel and Petrochemical Manufacturers
American Home Furnishings Alliance
American Petroleum Institute
AmericanHort
Arsenic Science Task Force
Arsenical Wood Preservatives Task Force
Asphalt Roofing Manufacturers Association
Battery Council International
Can Manufacturers Institute
Catfish Farmers of America
Chlorine Panel of the American Chemistry Council
Color Pigments Manufacturers Association, Inc.
Communications Cable and Connectivity Association
Decorative Hardwoods Association
Essential Minerals Association
Ethylene Oxide Panel of the American Chemistry Council
Ethylene Oxide Sterilization Association
Extruded Polystyrene Foam Association (XPSA)
Far West Agribusiness Association
Florida Tropical Fish Farms Association
Hawaii Aquaculture and Aquaponics Association
Illinois Farm Bureau
INDA, Association of the Nonwoven Fabrics Industry
Independent Lubricant Manufacturers Association
Institute of Makers of Explosives
International Sleep Products Council
International Wood Products Association
Iowa Farm Bureau
Kitchen Cabinet Manufacturers Association
Louisiana Chemical Association
Metal Construction Association
National Aquaculture Association
National Asphalt Pavement Association
National Association for Surface Finishing
National Association of Manufacturers

National Association of Printing Ink Manufacturers
National Cotton Council
National Electrical Manufacturers Association
National Funeral Directors Association
National Mining Association
National Wood Flooring Association
Non-Ferrous Founders' Society
North American Metals Council
North Carolina Manufacturers Alliance
Northwest Aquaculture Alliance
Ohio AgriBusiness Association
Ohio Chemistry Technology Council
Organic Arsenical Products Task Force
Performance Racing Industry (PRI)
Pine Chemicals Association International
Plastics Industry Association (PLASTICS)
Plumbing Manufacturers International
Polyisocyanurate Insulation Manufacturers Association
Polyurethane Foam Association
PRINTING United Alliance
RadTech International North America Inc
Society of Chemical Manufacturers & Affiliates
Specialty Equipment Market Association (SEMA)
Spray Polyurethane Foam Alliance
Steel Founders' Society of America
The Fertilizer Institute
The Hardwood Federation
The Styrene Information and Research Center (SIRC)
The Toy Association
Treated Wood Council
TRSA – The Linen, Uniform and Facility Services Association
U.S. Chamber of Commerce
USA Rice
Utility Water Act Group (UWAG)
Vinyl Institute
West Virginia Forestry Association
West Virginia Manufacturers Association