TOP TAKEAWAYS

New scientific review finds insufficient data to draw accurate conclusions about the association of PFAS with any specific disease.

CENTER FOR TRUTH IN SCIENCE

A new critical review of existing research on per- and polyfluoroalkyl substances (PFAS) found that most PFAS studies to-date include insufficient data to draw accurate conclusions about the association of PFAS with any specific disease.

A central recommendation from the authors is the need for additional specific research to properly calculate human-relevant dose to further link associations with human risk assessment and help set tolerable daily intake.

The critical review is featured in the latest issue of Environmental Research, a peer-reviewed environmental science and environmental health journal, and was performed by the Center of Environmental Food and Toxicological Technology at the University of Rovira i Virgili in Spain.

"This critical review highlights how a greater emphasis must be placed on developing workable and effective risk assessment methods for human health, including integrative translational toxicology to support regulatory processes and the development of relevant policy-related strategies for PFAS."
-Vikas Kumar, Ph.D., lead research scholar for the review at the Center of Environmental Food and Toxicological Technology at the University of Rovira i Virgili in Spain

This is the first review where highly referred articles on PFAS used for policymaking by several regulatory agencies were collected and evaluated based on the review guidelines developed by the U.S. National Toxicology Program's Office of Health Assessment and Translation review guidelines.

This new critical review provides key insight for improving methodological protocols for future PFAS experimental studies. The review was performed in accordance with PRISMA guidelines, the most rigorous set of internationally accepted criteria guiding the reporting of systematic reviews and meta-analyses.

"This scientific review performs a meticulous analysis of what is known and unknown surrounding PFAS chemicals," said. "It is my hope that this review provides a framework for researchers going forward and for how we, as a scientific community, can perform the most useful analysis of a compound's effects on the human body."
-Joseph Annotti, president and CEO and board member of the Center for Truth in Science

WHY IT MATTERS

- The findings come at a critical time, as the U.S. Environmental Protection Agency (EPA) moves to implement its PFAS Roadmap and states take PFAS regulation into their own hands.
- Rigorous, sound scientific studies must precede any expansive regulatory action on PFAS. This will lead to more fair and consistent policies that can help protect first responders and consumers and that allow innovation to happen, without raising unnecessary alarms.
- The findings reported in the paper get the global community closer to the conclusive science that is needed to make informed and responsible decisions. And the authors' recommendations provide a foundation for better decision making.
- This work will help individuals, families and health professionals to have more peace of mind.
- This review presents a clear road map and good guidance that can help industry to reduce their exposure to litigation.
- Consumers, especially parents, can have their concerns eased that past exposures have not yet been proven as harmful as some media reports have stated.

The findings of this critical review may surprise many outside of the scientific community. The researchers found that the most impactful studies on PFAS—those cited most often by regulators and legislators in the United States and worldwide for policy and rulemaking—lack sufficient evidence to draw accurate conclusions about the association of PFAS with any specific disease.

TOP TAKEAWAYS continued

Per- and polyfluoroalkyl substances (PFAS) are a group of man-made chemicals that includes PFOA, PFOS, GenX, and many others. PFAS have been manufactured and used in a variety of industries around the globe, including in the United States since the 1940s, and are found in more than 4,700 products including lifesaving tools for first responders, and a variety of household and consumer goods.

MORE KEY FINDINGS

Several limitations in the analyzed studies were observed, including co-exposure to multiple chemicals and limited measurement of primary and secondary outcomes related to specific toxicity. In general, more longitudinal epidemiology studies are required that utilize additional susceptible human endpoints.

Although recent studies have associated exposure to PFAS with adverse health outcomes, most are cross-sectional analyses. Therefore, data are insufficient to draw accurate conclusions about the association of PFAS with any specific disease.

Findings from all the studies provide a moderate to strong level of confidence for an association between PFAS exposure and various adverse outcomes. Two of the studies that were reviewed found an association between PFAS exposure and negative immune outcomes, but some inconsistency in those studies was observed.

In-silico, or computer modeling, performed by the research team demonstrated the following:

Recent lowering of TDI (tolerable daily intake) by the European Food Safety Authority (EFSA) based on immunotoxicity, if compared with the RfD (reference dose) set by U.S. EPA based on the animal study, remains lower than the concentration at which toxic effects were observed in infants.

In-silico models, sometimes referred to as computer models, have become a vital part of toxicology research, adding an additional category of analysis to standard in-vivo, in-vitro, and in-situ models. The in-silico approach models physiologic processes, taking advantage of advances in computational methods to help reduce the need for expensive and time-consuming experimental studies, as well as reduce the time and expense of replication.

Based on scaling, the dosing used in past animal studies to identify a toxic effect is quite appropriate for the EPA's setting of human exposure limits, but the animal dosing compared to the EFSA limit is now very high, raising a question about whether these animal studies should be considered valid for human risk assessment, or is there a need to conduct animal studies at lower doses.

To view the full report, visit Framework for risk assessment of PFAS utilizing experimental studies and in-silico models – Environmental Research, Volume 208, 2022.

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